CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

E

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

40th Session

Geneva, Switzerland, 17 – 22 July 2017

REPORT OF THE 38th SESSION OF
THE CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

Budapest, Hungary

8 – 12 May 2017

TABLE OF CONTENTS

SUMMARY AND STATUS OF WORK

Responsible Party	Purpose	Text / Topic	Code / Reference	Step	Para(s)
Members CCEXEC73 CAC40	Adoption	Methods of analysis for provisions in Codex standards	CODEX STAN 234-1999	-	28
Members CCEXEC73 CAC40	Adoption	Amendment to the Procedural Manual	Procedural Manual	-	36
CAC40	Revocation	Codex recommended methods in Codex standards	CODEX STAN 234-1999	-	28
CCFO	Information	Conversion factor phosphorous to phospholipids (draft Standard for fish oils)	-	-	9
CCPFV	Action / Information	Method for free fatty acids (annex on quick frozen French fries – Standard for quick frozen vegetables) Sampling plans (standards for ginseng and for quick frozen vegetables)	-	-	13, 14
CCASIA	Information / action	Method for acid value of laver proudct (and extraction method) Sampling plans (Standard for laver)	-	-	16, 17 and 18
CCNFSDU CCMAS39	Information / action	Methods for chromium, molybdenum and selenium, and trans fatty acids of infant formula And alternative methods to biological methods	-	-	19, 21, 28 and 40
CCAFRICA	Information	Methods for arsenic, lead and iron (Standard for unrefined shea butter)	-	-	22
CCSCH	Information / action	Sampling plans in the standards for cumin and thyme	-	-	24
All committees developing commodity standards	Information	Presentation of methods of analysis for endorsement	-	-	27
Secretariat / Committees	Publication Information / Use	Information documents: criteria for methods which use a "sum of components" and Practical examples for the selection of appropriate sampling plans	-	-	36 and 62
EWG (Chile and Mexico) CCMAS39	Development	Biological methods criteria	-	-	46

Responsible Party	Purpose	Text / Topic	Code / Reference	Step	Para(s)
CCEXEC73 CAC40 EWG (Brazil and Uruguay) CCMAS39	New work / review and update	Revision of CODEX STAN 234 / review and update of CODEX STAN 234	CODEX STAN 234-1999	1/2/3	25, 61
IDF/ISO/AOAC CCMAS39	Update	Review and update of methods of analysis for dairy products	CODEX STAN 234-1999	-	61
EWG (Germany) CCMAS39	Discussion	Revision of the *Guidelines on measurement uncertainty*	CAC/GL 54-2004	-	69
EWG (New Zealand) CCMAS39	Discussion	Revision of the *Guidelines on Sampling*	CAC/GL 50-2004	-	77
PWG (USA / Australia) CCMAS39	Endorsement	Methods of analysis and sampling for endorsement	CODEX STAN 234-1999	-	30, 40, 61

LIST OF ABBREVIATIONS

AOAC	AOAC International (formerly known as Association of Official Agricultural Chemists)
AOCS	American Oil Chemists' Society
CAC	Codex Alimentarius Commission
CCAFRICA	FAO/WHO Coordinating Committee for Africa
CCASIA	FAO/WHO Coordinating Committee for Asia
CCFO	Committee on Fats and Oils
CCMAS	Committee on Methods of Analysis and Sampling
CCNFSDU	Committee on Nutrition and Foods for Special Dietary Uses
CCPFV	Committee on Processed Fruits and Vegetables
CCSCH	Committee on Spices and Culinary Herbs
CRD	Conference room document
EU	European Union
EWG	Electronic working group
FDA	Food and Drug Administration (of the United States Department of Health and Human Services)
HPLC	High performance liquid chromatography
IAM	Interagency Meeting
ISO	International Organization for Standardization
NFCSO	National Food Chain Safety Office (Hungary)
MU	Measurement uncertainty
PWG	Physical working group
SDO	Standards development organisations

INTRODUCTION

1. The Codex Committee on Methods of Analysis and Sampling (CCMAS) held its 38th Session in Budapest, Hungary, from 8 to 12 May 2017, at the kind invitation of the Government of Hungary. The Session was chaired by Dr. Marót Hibbey, Veterinary officer, Ministry of Agriculture. Dr Ákos Jóźwiak, Vice director, National Food Chain Safety Office (NFCSO) and Dr Andrea Zentai, Food Safety Analyst (NFCSO), acted as the Vice-Chairpersons.

2. The Session was attended by 47 Member countries, 1 Member organization and 11 observer organizations. A list of participants is given in Appendix I.

OPENING OF THE SESSION

3. The Session was opened by Dr Lajos Bognár, Chief Veterinary Officer of Hungary and Deputy State Secretary of the Ministry of Agriculture who welcomed delegates to Hungary. Dr Márton Oravecz, President of the NFCSO also attended at the opening ceremony. Dr Bognár reminded the delegates of the importance of Codex in protecting public health and promoting fairness in trade. He highlighted the inter-dependency of Codex work and importance of food chain safety and wished the Committee successful deliberations.

Division of Competence[1]

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.

ADOPTION OF THE AGENDA (Agenda item 1)[2]

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

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER SUBSIDIARY BODIES (Agenda item 2)[3]

6. The Committee noted (i) the matters of interest arising from the Codex Alimentarius Commission and its subsidiary bodies; and (ii) several matters for action had been considered by the physical Working Group (PWG) on endorsement and would be considered under Agenda item 3.

7. In addition the Committee took the following decision.

Committee on Fats and Oils

Conversion factor for phosphorous to phospholipids

8. The Observer of AOCS informed the Committee that while it would be possible to establish a theoretical conversion factor, establishment of a practical single conversion factor was not possible.

9. The Committee agreed to inform CCFO that CCMAS was not in a position to recommend a single conversion factor.

ENDORSEMENT OF METHODS OF ANALYSIS PROVISIONS AND SAMPLING PLANS IN CODEX STANDARDS (Agenda item 3)[4]

10. The Committee considered the recommendations on methods of analysis and sampling plans proposed for endorsement and other related matters as presented in CRD2. The Committee agreed with some of the recommendations of the WG and made the following amendments or recommendations. All decisions are presented in Appendix II.

Committee on Processed Fruits and Vegetables

Methods for quick frozen vegetables – RM methods

11. In view of the replacement of CAC/RM34, 43 and 54 with AOAC 963.26, AOAC 932.12 and AOAC 971.33, respectively, the Committee agreed to request their revocation by CAC40.

---

[1] CRD1
[2] CX/MAS 17/38/1
[3] CX/MAS 17/38/2-Rev; Report of the pWG on endorsement of methods of analysis and sampling (CRD2); Comments from Philippines, Kenya, AOAC, IDF, ISO and Mexico (CRD 6), India (CRD 13), Republic of Korea (CRD 18).
[4] CX/MAS 17/38/3; CX/MAS 17/38/3 Add 1; Report of the PWG on endorsement of methods of analysis and sampling (CRD2); comments of Philippines, Kenya, AOAC, IDF, ISO, Mexico and Ghana (CRD 6), Senegal (CRD 14), Nigeria (CRD 15).

<u>Quick frozen French fried potatoes – method for free fatty acids</u>

12. The Committee noted that the methods for the determination of free fatty acids was for fats and oils and not for foods and that a method for fat extraction was necessary prior to the use of the suggested methods.

13. The Committee therefore agreed to request CCPFV to recommend a method for fat extraction.

<u>Sampling plans</u>

14. The Committee did not endorse the sampling plans for ginseng and for quick frozen vegetables since the values in the table did not correspond to those recommended in the *General Guidelines on Sampling* (CAC/GL 50-2004) and it was unclear whether the attributes sampling plan actually applied to attributes and not to characteristics that might be described as variable. The Committee noted that a similar question had already been posed to CCPFV with regard to the sampling plan for ginseng and that CCPFV had replied that if the resubmitted sampling plan was not appropriate, CCMAS should develop appropriate sampling plans. The Committee noted the offer of New Zealand (as chair of the EWG on revision of GL50) to develop a template to provide guidance to committees for development of sampling plans, and therefore agreed to defer decision on developing sampling plans at this time.

15. The Committee further noted that similar sampling plans had been endorsed in the past for processed fruits and vegetables and that CCMAS would need to address all sampling plans in a comprehensive way to avoid inconsistencies in *Recommended Methods of Analysis and Sampling* (CODEX STAN 234) and/or commodity standards.

FAO/WHO COORDINATING COMMITTEE FOR ASIA (CCASIA)

<u>Methods of analysis for laver products</u>

16. The Committee did not endorse the methods for acid value and agreed to request clarification from CCASIA whether the provision "acid value" applied to the laver product itself, or the extracted oil. If the method was for the extracted oil, it could be endorsed as Type I.

17. The Committee further noted that the extraction method in the Standard for laver products had been validated for instant noodles and not for laver, and that in this case, a classification as Type IV was recommended, and encouraged CCASIA to submit validation data to CCMAS to reconsider the proposed typing.

18. The Committee did not endorse the sampling plans since the values in the table did not correspond to those recommended in the *General Guidelines on Sampling* (CAC/GL 50-2004). It was noted that the sampling plans provided were attribute based. It was questioned whether a sampling plan by variables is more appropriate for certain provisions and requested CCASIA to reconsider the values in line with GL50. The Committee also agreed to inform CCASIA that it would be providing commodity committees with a template for developing sampling plans in case the Committee would like to await developing sampling plans until such time CCMAS would provide the aforesaid template.

COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY PURPOSES

<u>Chromium, molybdenum and selenium</u>

19. The Committee agreed to endorse the new methods for chromium, molybdenum and selenium as Type II and retained or retyped, where necessary, the older methods as Type III. The Committee further agreed to inform CCNFSDU of its concerns that the Type III methods may not all meet the requirements necessary for the determination of analytes at the minimum levels stated in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981) and that CCMAS could reconsider the endorsement of the Type III methods based on validation data to be submitted CCMAS at its next session.

<u>Total fatty acids</u>

20. The Committee endorsed the AOAC 2012.13|ISO 16958|IDF 231 for total fatty acids, noting that the provision was correct as stated in CODEX STAN 72.

<u>Trans fatty acids</u>

21. The Committee agreed to forward information on the methods identified by CCNFSDU on the matrices and levels for which they had been validated for their consideration (Appendix II, part 3).

FAO/WHO Coordinating Committee for Africa (CCAFRICA)

22. The Committee endorsed all methods submitted by CCAFRICA for the provisions in the proposed draft Standard for unrefined shea butter with the exception of the methods for arsenic, lead and iron as there were no provisions for these contaminants in the Standard.

Committee on Spices and Culinary Herbs (CCSCH)

Cumin and thyme: methods for insect damage, mammalian excreta and mould damage

23. The Committee noted the concern expressed by a delegation with regard to the endorsement of certain national methods (FDA method) rather than internationally validated methods. It was clarified that while internationally validated methods were desirable, the FDA methods had been agreed upon by CCSCH and were fit for purpose, and no other internationally validated methods had been identified or were available at this time.

Sampling plans

24. The Committee did not endorse the sampling plans since the values in the table did not correspond to those recommended in the *General Guidelines on Sampling* (CAC/GL 50-2004). It was unclear whether the sampling plan provided were being applied to attributes or variable characteristics and requested CCSCH to reconsider the values in line with GL50. The Committee also agreed to inform CCSCH that it would be providing commodity committees with a template for developing sampling plans in case the Committee would like to await developing sampling plans until such time CCMAS would provide the aforesaid template.

Other matters

Presentation of methods in CODEX STAN 234

25. The Committee clarified the presentation of multiple methods for a provision in CODEX STAN 234. When methods were identical and/or collaboratively developed, the references for these methods were separated by a vertical bar |, whereas when methods were technically identical, but were formatted or written differently, then the references for these methods were separated by a forward slash /. In the latter case, these methods could be typed as Type I as the methods were technically identical and would produce the identical analytical results. The Committee decided to ask the EWG on CODEX STAN 234 to consider defining the forward slash (/) and advise the Committee at the next meeting.

Process for timely information on endorsement of methods

26. The Committee noted the need for a procedure to ensure that information to assist in the endorsement work of the PWG is provided in a timely manner. The USA, as chair of the WG, informed the Committee that he was in consultation with the Codex Secretariat to address this matter. Ways were being explored to deliver methods for endorsement to SDOs earlier to allow feedback to the PWG co-chairs in advance so that a preparatory document could be circulated to all delegates prior to the session.

Presentation of methods of analysis by committees

27. The Committee agreed to remind committees that when methods are submitted to CCMAS for endorsement, these methods should indicate also the principle as well as proposed typing for the methods.

Conclusion

28. The Committee agreed to send:

- the methods of analysis, as endorsed, to CAC40 for adoption (Appendix II, Part 1),

- the methods for revocation to CAC40 (Appendix II, Part 2); and

- the information on the methods for trans fatty acids to CCNFSDU for their consideration (Appendix II, Part 3).

29. Uruguay expressed their reservation to the decision on the methods of analysis for quick frozen vegetables, as the methods of analysis presented for endorsement (Appendix I, CX/MAS 17/38/3) had been omitted from the Spanish version of the document. Uruguay was therefore not in a position to examine the methods prior to the session.

30. The Committee agreed to re-establish the PWG on methods of analysis and sampling, chaired by USA and co-chaired by Australia, working in English only, to meet immediately prior to the next session.

GUIDANCE ON THE CRITERIA APPROACH FOR METHODS WHICH USE A "SUM OF COMPONENTS" (Agenda item 4)[5]

31.   The United Kingdom, as Chair of the EWG, introduced the item. The Delegation reminded the Committee of the decision of CCMAS37 for the work to continue and that this session would take a decision on how to take this work forward[6].

32.   The Delegation indicated that overall the EWG agreed that the approaches available in developing criteria approaches for methods that use a sum of components were complex and need to be addressed on a case-by-case basis. In order to take the work forward the Delegation suggested that firstly Note 2 to the *Working Instructions for the Implementation of the Criteria Approach in Codex* of the Procedural Manual be revised to reinforce the complexity of the issues involved and secondly, Appendix 1 of CX/MAS 17/38/4 be converted into an Information Document format for publication on the Codex website so that the information and guidance developed were readily accessible to users wishing to develop numeric method performance criteria for methods that are a sum of components.

33.   The Committee recognized that there were numerous ways in which methods and limits that involve a sum of components could be converted into numeric method performance criteria and that approaches taken needed to be developed and decided on a case-by-case basis and would be influenced by several factors including but not limited to whether: (i) components are equally weighted, (ii) there is a known natural-abundance of the components, (iii) measured values for individual components are correlated or uncorrelated, etc. The Committee also noted that consideration of some of relevant information was under the remit of other committees

34.   The Committee thus agreed that it would not be appropriate to develop a criteria approach for methods which use a "sum of components" but rather (i) to amend Note 2 (*Working Instructions for the Implementation of the Criteria Approach in Codex*) to improve clarity on the implementation of the criteria approach when developing numeric method performance criteria for approaches that involve a "sum of components" and (ii) to provide information to Codex committees and CCMAS on a variety of (non-exhaustive) issues they may wish to consider when developing numeric method performance for approaches that involve sum of components as well as examples of such approaches and to place this information in an Information Document.

35.   The Committee made a number of adjustments to Appendix 1 of CX/MAS 17/84/4 to improve the clarity and accuracy of the information provided. The EU and its member states asked whether the Information Document could be referenced in the proposed amendment to Note 2 in the Procedural Manual. The Codex Secretariat commented that this was not possible as information documents are not formally adopted by the Commission, but they could be made available on the Codex website for consultation.

Conclusion

36.   The Committee agreed:

- to forward the revised Note 2 to the *Working Instructions for the Implementation of the Criteria Approach in Codex* to the Commission for adoption and inclusion in the Procedural Manual (Appendix III); and

- to make the Information Document available on the Codex website (Appendix IV).

CRITERIA FOR ENDORSEMENT OF BIOLOGICAL METHODS USED TO DETECT CHEMICALS OF CONCERN (Agenda item 5)[7]

37.   The Delegations of Chile and France, co-chairs of the EWG, presented the report of the WG (CX/MAS 17/38/5) and explained the process followed by the WG and the key outcomes; which were a modified list of biological methods (Part I) and biological methods and their validation criteria (Part II).

38.   The chairs of the EWG recommended that the Committee consider the recommendations and agree on a way forward.

---

[5]   CX/MAS 17/38/4; comments from Philippines, Kenya, EU, Mexico and Ghana (CRD 7), Senegal (CRD 14), Nigeria (CRD 15), Ecuador (CRD 17; Information document proposal by UK (CRD20).

[6]   REP16/MAS, paras. 62-63

[7]   CX/MAS 17/38/5; comments from the EU and Mexico (CRD 8), Senegal (CRD 14), Ecuador (CRD 17).

Part I

39. The Committee noted that while many currently used microbiological methods to quantify vitamins may be replaced by HPLC methods, there were still some microbiological methods considered useful for the quantification of vitamin B12, folates and pantothenic acid in foods. A list of biological methods had been prepared by the EWG with proposals for possible new methods and proposals to either retype or remove the microbiological methods.

<u>**Conclusion**</u>

40. The Committee agreed to request CCNFSDU to consider the proposed methods and whether they wished to retain the currently used microbiological methods (Appendix V) The replies from CCNFSDU would be considered by the PWG on endorsement of methods of analysis (see Agenda item 3) at CCMAS39.

Part II

41. The Committee considered whether to proceed with the development of criteria for biological methods.

42. Delegations in favour of proceeding with the work were of the opinion that not all the *General Criteria for Selection of Methods of Analysis* were applicable to biological methods; and specific criteria were needed for the review in a consistent and scientific manner of the currently endorsed biological methods in CODEX STAN 234 and for any biological methods that might be introduced in future.

43. These delegations also explained that biological methods continued to be used in their countries and that chemical methods were not always available to replace these methods.

44. Delegations opposing to proceed with further work, expressed the opinion that the *General Criteria for Selection of Methods of Analysis* in the Procedural Manual were applicable also to biological methods and therefore additional criteria were not necessary; and if numerical criteria were needed, these could be considered on a case-by-case basis.

45. These delegations further expressed the view that priority should be given to the extensive work currently being undertaken on the review and update of CODEX STAN 234, especially since biological methods were increasingly being replaced by newer chemical methods and that it was unlikely that many new biological methods would be developed in future.

<u>**Conclusion**</u>

46. The Committee agreed to continue work on biological methods criteria and to establish an EWG chaired by Chile and Mexico, working in English and Spanish:

- to use the *General Criteria for the Selection of Methods of Analysis* laid down in the Procedural Manual and other related Procedural Manual referenced documents for the validation of methods of analysis to assess methods in which potency of a substance is measured by the response of living organisms or living systems,

- to determine which criteria would not apply and propose some other criteria that might be necessary for biological methods which are currently endorsed by Codex.

47. The Committee further agreed that the work should be discontinued if the EWG does not produce a concrete result for consideration by CCMAS39.

REVIEW AND UPDATE OF METHODS IN CODEX STAN 234-1999 (Agenda Item 6)[8]

48. Brazil, Chair of the EWG and the PWG on the review and update of methods of analysis and sampling in CODEX STAN 234, presented the item and highlighted the key points of discussion and recommendations of the PWG held prior to the session (points 1-5 of CRD4).

49. The Committee considered the report of the PWG as follows:

---

[8] CL 2017/4-MAS; CX/MAS 17/38/6; CX/MAS 17/38/6-Add.1 (Comments of Argentina, Canada, Japan, New Zealand and Switzerland); summary report of the PWG on the review and update of methods in CODEX STAN 234-1999 (CRD4); IDF (CRD5); Kenya, Peru, EU, Mexico, Ghana and Egypt (CRD9); Senegal (CRD14); Nigeria (CRD15); Ecuador (CRD17).

Codex general methods

50. The Committee agreed that at this stage there was no need for a definition nor a separate section to list Codex general methods in CODEX STAN 234. Update of such methods would be done on a case-by-case basis by the PWG on Endorsement as work on the review progresses (including those general methods related to additives and contaminants as described in *General Methods of Analysis for Food Additives* (CODEX STAN 239-2003) and *General Methods of Analysis for Contaminants* (CODEX STAN 228-2001), respectively).

Structure of CODEX STAN 234-1999

51. The Committee agreed that new work on the standard would address the preamble, scope, structure and other relevant information aimed at facilitating the reading of the methods listed in CODEX STAN 234.

52. The Committee noted that such information did not refer to intellectual property associated to the methods in CODEX STAN 234 (e.g. performance data that may not be available or may be proprietary), but rather to complementary information such as description of CAC/RMs when no internationally validated methods from SDOs had been identified to replace these methods or performance criteria of methods as endorsed by CCMAS.

53. The Committee agreed that this work would constitute new work for approval by CAC40.

Follow-up work on the review and update of CODEX STAN 234-1999

54. The Committee agreed that it would continue to work on the workable packages for the review and update of CODEX STAN 234-1999 as described in CX/MAS 17/38/6. The workable packages will be prepared by the EWG on the review and updated of CODEX STAN 234-1999 and will be sent to the Codex Secretariat in order to be considered by the PWG on endorsement and CCMAS. Depending on the complexity of the issues associated to the workable package a circular letter (CL) could be issued by the Codex Secretariat to seek specific comments from Codex members and observer organizations.

55. The Committee recognized that the above approach would not preclude the Codex Secretariat from already proceeding with the editorial update of CODEX STAN 234 and/or commodity standards in those cases where (i) inconsistencies had been identified between the methods endorsed in CODEX STAN 234-1999 and the methods listed in the commodity standards for the same provision(s) and (ii) the inclusion of CAC/RMs that have been confirmed by CCMAS in the absence of other international references. This work will be done in close collaboration with the Chair of the EWG on the review and update of CODEX STAN 234-1999 and submitted to CCMAS for information and to CAC for adoption as editorial amendments.

56. The Committee further acknowledged that some work could already be advanced in parallel with work on the workable package by addressing methods of analysis for groups of products. This could alleviate the work envisaged on some of the workable packages and could also lead to enhance cooperation with SDOs in the review and update of the methods for other food groups.

57. The Committee agreed that the above work (including consideration of Codex general methods) may imply confirmation, removal, retyping or reassignment of the method to a specific food or group of foods.

58. The Observer of IDF in partnership with ISO and AOAC expressed their willingness to consider all the dairy-related methods as one pack and provide CCMAS with updated references for consideration by CCMAS39.

59. The Observer from AOCS referred to the discussion held at the IAM meeting (Agenda item 10) in regard to the review and update of methods of analysis and sampling plans in CODEX STAN 234-1999. The Observer conveyed the views of the SDOs that updating method references in CODEX STAN 234 should be the responsibility of each SDO to ensure that references and harmonization information are correct though this work will likely take several years. The Committee further agreed (i) to continue to work on the workable packages as well as to pilot an update of all methods related to dairy products with the assistance of IDF, ISO and AOAC and (ii) that the Codex Secretariat will closely work with the Chair of the EWG on the review and update of CODEX STAN 234 on those editorial amendments identified in paragraph 55 that can be presented for information to CCMAS39 and editorial amendments to CAC41.

Future work on database for Codex methods of analysis and sampling plans

60. The Committee noted the importance of having a searchable database with information specific to CCMAS to manage the regular review process and a general interface with information on methods of analysis and sampling adopted by CAC for Codex members and observers available on the Codex website. In the meanwhile, CCMAS can work with an informative document to track the review process.

Conclusion

61. The Committee agreed:

- To start new work on a new format for CODEX STAN 234-1999 subject to approval of CAC40 (Appendix VI).

- To continue work on the review and update of methods of analysis and sampling plans in CODEX STAN 234-1999 through the workable packages.

- To establish an EWG, chaired by Brazil and Uruguay, working in English, to carry out the work indicated in the bullet points above.

- To proceed with the review and update of methods of analysis for dairy products in CODEX STAN 234-1999 by IDF, ISO and AOAC.

INFORMATION DOCUMENT ON PRACTICAL EXAMPLES ON THE SELECTION OF APPROPRIATE SAMPLING PLANS (Agenda item 7)[9]

62. The Delegation of Germany, chair of the eWG on the development of practical examples for the selection of appropriate sampling plans, presented the paper (CX/MAS 17/38/7) and sought approval of the Committee to publish the information document. The Committee agreed on the content of the information document (Appendix VII), which will be made available on the Codex website.

PROPOSAL TO AMEND THE GUIDELINES ON MEASUREMENT UNCERTAINTY (CAC/GL 54-2004) (Agenda item 8)[10]

63. Germany, Chair of the EWG on the review of CAC/GL54, introduced the item and recalled that CCMAS37 agreed to establish an EWG to (i) identify areas for improvements and amendments to CAC/GL 54, (ii) recommend procedures if necessary for determining uncertainty of measurement results including sub-sampling, sample processing and analysis and (iii) avoid overlapping with the *Guidelines on Estimation of Uncertainty of Results* (CAC/GL 59-2006) and to proceed with work based on CRD26 presented at CCMAS37.

64. The Delegation informed the Committee on the output of the work of the EWG in order to keep CAC/GL 54 as simple as possible as follows: (i) the explanatory notes have been relieved from redundancies and are now integrated into the main texts, (ii) a new chapter with recommended procedures for determining uncertainty of measurement results has been introduced based on the document contained in CRD26, (iii) the examples have been revised to be in line with the cited standards and international guidelines, and (iv) the tables of the anticipated measurement uncertainties is now harmonized with the Procedural Manual, Section II, Chapter 1.3. Apart from these changes, all the aspects of general importance of measurement of uncertainty (MU) of CAC/GL 54 were maintained. The proposed revised CAC/GL54 with the changes indicated in points (i) – (iv) are presented in Appendix I to CX/MAS 17/38/8.

65. The Delegation also explained that the proposed introductory text in the proposed revised CAC/GL 54 was necessary to clarify why MU is important in its influence on sampling plans (i.e. on the procedure of lot assessment) and its role in conformity assessment of a particular analytical test sample. Therefore, the proposed revised CAC/GL 54 explains the influence of MU on sampling plans and the corresponding decisions of lot compliance and contain a reference to the concerning ISO standards on sampling.

66. The Delegation further clarified that MU deals with laboratory samples and not with the homogeneity of the lot (i.e. CAC/GL 54 do not address sampling uncertainties). MU of laboratory samples can however influence the sampling plans and the subsequent lot acceptance and conformity assessment of the product with the specification in the standards.

67. The Committee noted that CAC/GL54, as all Codex standards and related texts, are primarily targeted to Codex member countries and as such to any stakeholder in government (e.g. laboratories dealing with MU in the particular case of CAC/GL 54).

---

[9] CX/MAS 17/38/7; comments from Kenya, Mexico (CRD 10); Senegal (CRD14); Ecuador (CRD).

[10] CX/MAS 17/38/8; comments from Kenya, Peru, EU, IDF, Mexico and Ghana (CRD 11), Senegal (CRD 14), Nigeria (CRD 15), Ecuador (CRD 17).

68. The Committee noted that the proposed revision to CAC/GL 54 would envisage new work for CCMAS and that a clear outline of what the work would entail should be given in a project document for consideration by CCMAS39. Besides, the recommended procedures for estimating MU (new addition) would be better developed as an information document and that it would address examples of procedures for estimating MU. The Committee reasserted that such examples were of illustrative nature and by no means were limited to nor restricted to those to be described in the information document. The Committee also noted that the new work should focus on measurement uncertainty and not deal with sampling uncertainty.

Conclusion

69. The Committee agreed to establish an EWG chaired by Germany and working in English only with the following TOR:

- Preparation of a project document that indicates which amendments and improvements should be identified and used in GL54.

- Revision of GL54 considering the identified areas of improvement and technical and other amendments taking into account the need to simplify the content.

- Elaboration of an information document with examples of procedures for estimating measurement uncertainty.

70. The Committee further agreed that the above work will be developed on the basis of the document presented in Appendix I to CX/MAS 17/38/8.

PROPOSAL TO AMEND THE GENERAL GUIDELINES ON SAMPLING (CAC/GL 50-2004) (Agenda item 9)[11]

71. The Delegation of New Zealand, chair of the EWG, introduced the paper (CX/MAS 17/38/9) and explained that there was wide support in the EWG to undertake new work on simplifying/updating CAC/GL 50-2004.

72. The Delegation highlighted some of the general and technical areas of improvements that could be considered in the revision. Some of the improvements will be developed to assist understanding of the principles of sampling, i.e. (i) an initial section discussing the principles of acceptance sampling and how it works, and how to determine a sampling plan for a particular application; (ii) sampling of materials sold in bulk, and (iii) especially about the use of the terms 'consumers' risk' and 'producers' risk'.

73. The Delegation further pointed out that there might be a need for assistance from outside technical experts in undertaking the work.

74. The Delegation recommended that the Committee consider the review paper and agree on a method to achieve the work, in particular its prioritisation and the means of undertaking the first priority work, whereafter a project document could be prepared.

Discussion

75. The following views were expressed:

- The current CAC/GL50 was very theoretical and needed simplification and therefore the future revision should avoid inclusion of additional theoretical information;

- The review document was a good starting point to update CAC/GL 50, but work proposed was considerable and prioritization was necessary as was the need for assistance from external experts;

- The revision of CAC/GL 50 would be extensive and it was premature to embark on the new work. An outline of the possible revised CAC/GL50 would assist in taking a decision on new work.

76. The Codex Secretariat emphasized that the revision should aim at providing a simple and understandable guidance and avoid the overuse of statistical information; that consideration should be given to cross-referencing existing guidance on sampling developed by other internationally recognized standards organisations and the use of examples within the revised document should be avoided to the extent possible.

Conclusion

77. The Committee noted that it was not in a position to request approval at this stage, and agreed to re-establish an EWG chaired by NZ, working in English, to:

- prepare a project document with a clear scope of the work to be undertaken; and

---

[11] CX/MAS 17/38/9; Comments from Kenya, Peru, EU and Ghana (CRD 12), Senegal (CRD 14), Nigeria (CRD 15), Ecuador (CRD 17); draft Project document prepared by NZ (CRD19).

- an outline of a new CAC/GL 50; and

- prioritization of technical and other improvements; and

- timeframes for the different phases of the work.

REPORT OF AN INTER-AGENCY MEETING ON METHODS OF ANALYSIS (Agenda item 10)[12]

78. The Observer of the American Oil Chemists' Society (AOCS), as chair of the Interagency Meeting (IAM), introduced the report of the IAM and highlighted the various issues discussed in the IAM with respect to the work of CCMAS and other related matters.

79. The Committee noted that several of the issues raised in CRD 16 had been considered under the relevant agenda items.

80. The Committee also noted that a revised version of the proposed ISO Technical Specification for the Assessment of Qualitative Methods will be circulated by ISO/TC 34/SC16 for comment shortly and the guidance document on the validation of non-targeted methods of analysis for detecting adulteration by USP/FCC are under review for publication in late 2017.

81. In relation to timely and extensive review of methods of analysis for endorsement by CCMAS, the Committee noted that IAM agreed to provide feedback to the PWG on endorsement of methods of analysis and sampling where documents are available at least 4 weeks prior to meeting of the PWG.

82. The Committee thanked the members of IAM for their contribution to the work of the Committee.

OTHER BUSINESS AND FUTURE WORK (Agenda item 11)

83. 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)

84. The Committee was informed that the 39th Session would take place in Budapest, Hungary, within the next 18 to 24 months, the final arrangements being subject to confirmation by the host country and the Codex Secretariat.

---

[12] Report of the 29th IAM (CRD16).

LIST OF PARTICIPANTS – LISTE DES PARTICIPANTS – LISTA DE PARTICIPANTES

CHAIRPERSON - PRESIDENT – PRESIDENTE

Dr Marót Hibbey
Feed Safety Rapporteur
Food Chain Control
Ministry of Agriculture
Kossuth Lajos tér 11
Budapest
Hungary
Email: marot.hibbey@fm.gov.hu

CHAIR´S ASSISTANT – ASSISTANT AU PRESIDENT – ASSISTENTE AL PRESIDENTE

Dr Ákos Jóźwiak
Vice-director
System Management and Supervision Directorate
National Food Chain Safety Office
Kis Rókus utca 15/B
Budapest
Hungary
Email: jozwiaka@nebih.gov.hu

Dr Andrea Zentai
Food Safety Analyst
System Management and Supervision Directorate
National Food Chain Safety Office
Kis Rókus utca 15/B
Budapest
Hungary
Email: zentaia@nebih.gov.hu

ALGERIA - ALGÉRIE - ARGELIA

Mr Ali Achoui
Conseiller
Ambassade d'Algérie en Hongrie
21 Glugetti 4 T 27-1121 Budapest
Hongrie
Hungary
Email: aliachoui@yahoo.fr

AUSTRALIA - AUSTRALIE

Mr Richard Coghlan
Laboratory Services Manager
National Measurement Institute
PO Box 138
North Ryde
Australia
Email: richard.coghlan@measurement.gov.au

Ms Karina Budd
Director, Residues Chemistry and Laboratory
Performance
Department of Agriculture and Water Resources
GPO Box 858
Canberra City
Australia
Email: karina.budd@agriculture.gov.au

Mr Neil Shepherd
Sector Manager, Life Sciences
National Association of Testing Authorities, Australia
1st Floor 2-6 Railway Parade Camberwell
Victoria
Australia
Email: neil.shepherd@nata.com.au

AUSTRIA - AUTRICHE

Mr Thomas W. Kuhn
Austrian Agency for Health and Food Safety
Spargelfeldstrasse 191
Vienna
Austria
Email: thomas.kuhn@ages.at

BELGIUM - BELGIQUE - BÉLGICA

Mr Rudi Vermeylen
Expert
Laboratories Administration
Belgian Federal Agency for the Safety of the food chain
Kruidtuinlaan, 55
1000 Brussels
Belgium
Email: rudi.vermeylen@favv.be

BRAZIL - BRÉSIL - BRASIL

Mrs Ligia Schreiner
Regulation National Health Surveillance Specialist
Brazilian Health Surveillance Agency - ANVISA
SIA Trecho 5 Àrea Especial 57, Bloco D, 2 andar
Brasília
Brazil
Email: ligia.schreiner@anvisa.gov.br

Ms Carla Ivone Carraro
Brazil
Email: carla.carraro@brf-br.com

Mr Nilton Silva
Analyst and researcher in health and technology
Fundação Ezequiel Dias
Rua Conde Pereira Carneiro, 80, Gameleira
Belo Horizonte
Brazil
Email: niltoncs@gmail.com

Mrs Carolina Vieira
Expert on Regulation and Health Surveillance
Brazilian Health Surveillance Agency - ANVISA
SIA Trecho 5 Àrea Especial 57, Bloco D, 2 andar
Brasília
Brazil
Email: carolina.vieira@anvisa.gov.br

Ms Lina Yamachita Oliveras
Brazil
Email: lina.yamachita@gmail.com

BULGARIA - BULGARIE

Dr Ivelin V. Rizov
State expert
Directorate for Policies of the Agricultural Food Chain
Ministry of Agriculture and Food
Blvd Histo Botev, 55
Sofia
Bulgaria
Email: ivrizov@mzh.government.bg

CANADA - CANADÁ

Ms Barbara Lee
Director
Bureau of Chemical Safety
Health Canada
Room C237 251 Sir Frederick Banting Driveway
Tunney's Pasture Postal locator 2202C
Ottawa
Canada
Email: barbara.lee@hc-sc.gc.ca

Dr Thea Rawn
Research Scientist
Bureau of Chemical Safety
Health Canada
Room C319 251 Sir Frederick Banting Driveway
Tunney's Pasture, P.L. 2203C
Ottawa
Canada
Email: thea.rawn@hc-sc.gc.ca

Dr Sheryl Tittlemier
Program Manager
Grain Research Laboratory
Canadian Grain Commission
Grain Research Laboratory, Canadian Grain
Commission 1404 -303 Main St. Winnipeg, MB
Winnipeg
Canada
Email: sheryl.tittlemier@grainscanada.gc.ca

Mr Jeffrey Van De Riet
National Manager
Food Safety Science Services
Canadian Food Inspection Agency
1992 Agency Drive
Dartmouth
Canada
Email: jeffrey.vanderiet@inspection.gc.ca

CHILE - CHILI

Mrs Soraya Sandoval Riquelme
Jefe de Sección de Metrología Ambiental y de
Alimentos
Instituto de Salud Pública (ISP)
Ministerio de Salud
Marathon 1000. Ñuñoa.
Santiago
Chile
Email: soraya@ispch.cl

CHINA - CHINE

Ms Jun Bei
Assistant Researcher
Chinese Academic of Inspection and Quarantine
(CAIQ)
Room A1109,No.9,Madian East Road, Haidian District
Beijing
China
Email: beidiorange@163.com

Mrs Chenguang Cao
Director
Department of Science, Technology & Standards,
CFDA
Rm913, building 2,26, Xuanwumenxi St.Xicheng District
Beijing
China
Email: caocg1763@139.com

Dr Stephen Wai-Cheung Chung
Section Chemist (Food Research Laboratory)
Centre for Food Safety, Food and Environmental
Hygiene Department, HKSAR Government
4/F, Public Health Laboratory Centre 382 Nam Cheong
Street, Shek Kip Mei, Kowloan
Hongkong
China
Email: swcchung@fehd.gov.hk

Ms Xiaomei Cui
Engineer
Zhejiang Entry-Exit Inspection and Quarantine Bureau
NO.126 Fuchun Road, Hangzhou,
Zhejiang
China
Email: cuixm@ziq.gov.cn

Mr Xianjin Meng
Officer
General Administration of Quality Supervision,
Inspection and Quarantine of the PRC
9# Madian East Road, Haidian District
Beijing
China
Email: mengxj@aqsiq.gov.cn

Mr Haibo Wang
Principal Staff Member
China Food and Drug Administration
26 Xuanwumen Xidajie, Beijing, P.R. China
Beijing
China
Email: wanghb@cfda.gov.cn

COLOMBIA - COLOMBIE

Eng Myriam Rivera
Food Engineer
Instituto nacional de Vigilancia de Medicamentos y
Alimentos - INVIMA
Carrera 10 No. 64 - 28
Bogotá
Colombia
Email: mriverar@invima.gov.co

ECUADOR - ÉQUATEUR

Ms Maria Gonzalez
Head
Ministry of Foreign Affairs
Ecuador
Email: mcgonzalez@mmrree.gob.ec

Ms Daniela Jimenez
Officer
Ministry of Foreign Affairs
Ecuador
Email: t-djimenez@mmrree.gob.ec

EGYPT - ÉGYPTE - EGIPTO

Eng Mariam Barsoum
Food Standards Specialist
Food Standards
Egyptian organization for standardization and quality
16 Tadreeb AlMudarebeen St. AlAmeriah
Cairo
Egypt
Email: eos_mariam@yahoo.com

Ms Ola Ragab Hassan Khalifa Elnemer
Chemist, Department Manager
General Organization of Export and Import Control
Cairo
Egypt
Email: ola_elnemer@yahoo.com

Eng Ahmed Eltoukhy
Specialist
Technical Department
Chamber of food Industries (CFI)
1195 Nile Corniche, Boulaq, Cairo Governorate
Cairo
Egypt
Email: aeltoukhy@egycfi.org.eg

EQUATORIAL GUINEA - GUINÉE ÉQUATORIALE - GUINEA ECUATORIAL

Mr Patricio Ndiba Macute
Director Adjunto
Ministerio de Agricultura
Malabo
Equatorial Guinea
Email: salvadorbolekia@yahoo.es

ESTONIA - ESTONIE

Dr Mari Reinik
Head of Tartu Laboratory
Health Board, Tartu Laboratory
Põllu 1a
Tartu
Estonia
Email: Mari.Reinik@terviseamet.ee

EUROPEAN UNION - UNION EUROPÉENNE - UNIÓN EUROPEA

Prof Ana Gago-Martinez
Director
European Union Reference Laboratory for Marine Biotoxins
European Union
Agencia Española de Seguridad Alimentaria y Nutrición
CITEXVI, Fonte das Abelleiras s-n
Vigo
Spain
Email: anagago@uvigo.es

Ms Barbara Moretti
Administrator
Dg Sante
European Commission
Rue Froissart 101
Brussels
Belgium
Email: barbara.moretti@ec.europa.eu

Mr Franz Ulberth
Head of Unit - Standards for Food Bioscience
JRC D 5
Geel
Belgium
Email: Franz.ULBERTH@ec.europa.eu

FRANCE - FRANCIA

Mr Jean-Luc Deborde
SCL (DGCCRF and DGDDI)
Laboratoire SCL de Strasbourg 13, chemin du Routoir
Illkirch
France
Email: jean-luc.deborde@scl.finances.gouv.fr

GERMANY - ALLEMAGNE - ALEMANIA

Dr Gerd Fricke
Head of Department
Federal Office of Consumer Protection and Food Safety
Mauerstr. 39-42
Berlin
Germany
Email: gerd.fricke@bvl.bund.de

Dr Katrin Franks
Scientific Officer
Federal Office of Consumer Protection and Food Safety
Mauerstr. 39-42
Berlin
Germany
Email: katrin.franks@bvl.bund.de

Dr Petra Gowik
Head of Department
Federal Office of Consumer Protection and Food Safety
Diedersdorfer Weg 1
Berlin
Germany
el: +49 30 18445 8000
Email: petra.gowik@bvl.bund.de

Mr Stephan Walch
Executive Director
State Institute for Chemical and Veterinary Analysis (CVUA)
Weißenburger Str. 3
Karlsruhe
Germany
Email: stephan.walch@cvuaka.bwl.de

Dr Claus Wiezorek
Advisor for Federal Office of Consumer Protection and Food Safety
Mauerstr. 39-42
Berlin
Germany
Email: wiezorek.claus@orange.fr

GHANA

Dr Paul Ayiku Agyemang
Research Manager
Quality Control Company Ltd
Ghana Cocoa Board
P. O. Box M 54
Accra
Ghana
Email: pagyengo467@yahoo.com

Mrs Eunice Adjoa Harrison
Chief Revenue Officer
Operations (Laboratory)
Customs Division Of Ghana Revenue Authority
Ghana Revenue Authority Customs Division P. O. Box
9046 Kia
Accra
Ghana
Email: eahodasi@yahoo.com

Mr Eric Sebastian Koko
Principal Revenue Officer
Operations (Laboratory)
Customs Division of Ghana Revenue Authority
Ghana Revenue Authority Customs Division P. O. Box
9046 Kia
Accra
Ghana
Email: eriquekoko@gmail.com

Mrs Marian Ayikuokor Komey
Principal Regulatory Officer
Food Safety
Food and Drugs Authority
P. O. Box Ct 2783
Accra
Ghana
Email: riankom2@yahoo.com

HUNGARY - HONGRIE - HUNGRÍA

Dr Tamás János Szigeti
Business Development Manager
Knowledge Center
WESSLING Hungary Ltd.
Fóti street 56.
Budapest
Hungary
Email: szigeti.tamas@wessling.hu

Ms Enikő Dorogházi
Food safety coordinator
Directorate for Food Safety Risk Assessment
National Food Chain Safety Office
Kitaibel P. u. 4.
Budapest
Hungary
Email: doroghazie@nebih.gov.hu

Ms Marianna Dömölki
Head of Unit
Ministry of Agriculture
Kossuth tér 11.
Budapest
Hungary
Email: marianna.domolki@fm.gov.hu

Dr Tekla Engelhardt
risk assessor
System Management and Supervision Directorate
National Food Chain Safety Office
Email: EngelhardtT@nebih.gov.hu

Mrs Zsuzsa Farkas
Analyst
System Management and Supervision Directorate
National Food Chain Safety Office
Kis Rókus utca 15/B
Budapest
Hungary
Email: farkaszs@nebih.gov.hu

Ms Andrea Fodor
Food Safety Coordinator
Food and Feed Safety Directorate
National Food Chain Safety Office
Mester utca 81.
Budapest
Hungary
Email: fodora@nebih.gov.hu

Mr Gábor Kelemen
Executive counsellor
Department of Food Processing
Ministry of Agriculture
Kossuth L. tér 11.
Budapest
Hungary
Email: gabor.kelemen@fm.gov.hu

Ms Csilla Kurucz
Sector Manager
Hungarian Standards Institution (MSZT)
Horváth M. tér 1.
Budapest
Hungary
Email: cs.kurucz@mszt.hu

Dr Attila Nagy
Vice director
Food and Feed Safety Directorate
National Food Chain Safety Office
Mester utca 81.
Budapest
Hungary
Email: nagyattila@nebih.gov.hu

Ms Erika Országh
Planning officer
NÉBIH
Keleti Károly utca 24.
Budapest
Hungary
Email: orszaghe@nebih.gov.hu

Ms Agnes Szegedyne Fricz
professional advisor
Department of Food Processing
Ministry of Agriculture
Kossuth Lajos tér 11.
Budapest
Hungary
Email: agnes.fricz@fm.gov.hu

INDIA - INDE

Mr Shailender Kumar
Assistant Director
QA
Food Safety and Standards Authority of India
FDA Bhawan Kotla Road
Email: shailender.kumar@gov.in

INDONESIA - INDONÉSIE

Mrs Fajarina Budiantari
Head of Division for Testing Laboratory Accreditation
Centre for Laboratory and Inspection Body
Accreditation
National Standardization Agency of Indonesia
Menara Thamrin Building, 11th Floor Jl. M.H. Thamrin
Jakarta
Indonesia
Email: rina@bsn.go.id

Ms Niza Nemara
Head of Food Division
National Quality Control Laboratory of Drug and Food
National Agency for Drug and Food Control
Jl. Percetakan Negara No. 23
Jakarta
Indonesia
Tel: +6221 4245075
Email: nnemara@yahoo.com

Mr Adinugroho Kristiawan Santosa
Director
Saraswanti Indo Genetech
Jl. Rasamala No. 20 Taman Yasmin
Bogor
Indonesia
Email: adinugroho@saraswanti.com

Ms Eny Tulak
Deputy Director for Cooperation on Standardization
Directorate Standardization and Quality Control
Ministry of Trade
Jl. Raya Bogor KM. 26, Ciracas Jakarta Timur
Jakarta
Indonesia
Email: ks.ditstandalitu@gmail.com

Mrs Novianti Wulandari
Assistant Deputy Director for National Cooperation on
Standardization
Directorate Standardization and Quality Control
Ministry of Trade
Jl. Raya Bogor Km. 26, Ciracas Jakarta Timur
Jakarta
Indonesia
Email: ks.ditstandalitu@gmail.com

IRELAND - IRLANDE - IRLANDA

Ms Ita Kinahan
State Chemist
State Laboratory
Department of Public Expenditure and Reform
The State Laboratory Backweston Campus Celbridge
Co. Kildare
Ireland
Tel: +353 1 5057001
Email: Ita.Kinahan@statelab.ie

JAPAN - JAPON - JAPÓN

Dr Hidetaka Kobayashi
Deputy Director
Agricultural Chemicals Office, Plant Products Safety
Division
Ministry of Agriculture, Forestry and Fisheries
1-2-1 Kasumigaseki Chiyoda-ku
Tokyo
Japan
Email: hidetaka_kobayash400@maff.go.jp

Mr Daisuke Fujii
Assistant Director
Inspection and Safety Division, Department of
Environmental Health and Food Safety
Ministry of Health, Labour and Welfare
1-2-2, Kasumigaseki, Chiyoda-ku
Tokyo
Japan
Email: codexj@mhlw.go.jp

Mr Yuichi Itoi
Section Chief
Office of Import Food Safety, Inspection and Safety
Division, Department of Environmental Health and
Ministry of Health, Labour and Welfare
1-2-2 Kasumigaseki, Chiyoda-ku
Tokyo
Japan
Email: codexj@mhlw.go.jp

Mr Masayuki Oda
Associate Director
Plant Products Safety Division, Food Safety and
Consumer Affairs Bureau
Ministry of Agriculture, Forestry and Fisheries
1-2-1 Kasumigaseki, Chiyoda-ku
Tokyo
Japan
Email: masayuki_oda280@maff.go.jp

Dr Takahiro Watanabe
Section Chief
Division of Foods
National Institute of Health Sciences
1-18-1, Kamiyoga, Setagaya-ku
Tokyo
Japan
Email: tawata@nihs.go.jp

Ms Mao Yanagisawa
Technical Official
Department of environmental Health and Food Safety
Ministry of Health, Labour and Welfare
1-2-2, Kasumigaseki, Chiyoda-ku
Tokyo
Japan
Email: yanagisawa-mao@mhlw.go.jp

MALI - MALÍ

Mr Almoustapha Fofana
Directeur Général
Ministère de l'Energie et de l'Eau
Laboratoire National des Eaux sise à Magnabougou
Wèrèda, rue: 126 BPE : E4161
Bamako
Mali
Email: lneaux@yahoo.fr

MALTA - MALTE

Ms Adrienn Nagy
Assistant
General Secretariat
Council of the European Union
Rue de la Loi 175
Brussel
Belgium
Email: adrienn.nagy@consilium.europa.eu

Mr Alexander Rogge
Political Administrator
Veterinary and Plant Health Questions, Food Chain and
Forestry Unit. Directorate Fisheries, Food and
Directorate General Agriculture, Fisheries, Social
Affairs and Health
JL-40-50-DH38 Rue de la Loi / Wetstraat 175
Brussels

Belgium
Email: alexander.rogge@consilium.europa.eu

MEXICO - MEXIQUE - MÉXICO

Mr César Omar Gálvez González
Comisión de Control Analítico y Ampliación de
Cobertura (CCAYAC)
Comisión Federal para la Protección contra Riesgos
Sanitarios (COFEPRIS)
Calzada de Tlalpan 4492 Col. Toriello Guerra
Delegación Tlalpan Ciudad de México
Distrito Federal
México
Email: cgalvez@cofepris.gob.mx

MOROCCO - MAROC - MARRUECOS

Mr Said Zantar
Coordinateur de l'unité de recherche sur les techniques
nucléaire, l'environnement et la qualité
Agriculture
Institut National de Recherche Agricole
78 Boulevard sidi Mohammed Ben Abdellah
Tangier
Morocco
Email: zantar_said@hotmail.com

Mr El Hassane Zerouali
Head of Laboratory
Agriculture
Etablissement Autonomme de Contrôle et de
Coordination Des Exportation
Qualipole Alimentation-Madagh Berkane
Berkane
Morocco
Email: hassane_zerouali@yahoo.fr

NETHERLANDS - PAYS-BAS - PAÍSES BAJOS

Mr Henk Van Der Schee
Senior Scientist
Dutch Food and Consumer Product Safety Authority
(NVWA)
PO Box 43006
Utrecht
Netherlands
Email: h.a.vanderschee@nvwa.nl

Mr Yannick Weesepoel
Scientist
RIKILT
PO Box 230
Wageningen
Netherlands
Email: yannick.weesepoel@wur.nl

NEW ZEALAND - NOUVELLE-ZÉLANDE - NUEVA ZELANDIA

Ms Susan Morris
Principal Adviser
Ministry for Primary Industries
25 The Terrace
Wellington
New Zealand
Email: susan.morris@mpi.govt.nz

Mr Roger Kissling
Fonterra
New Zealand
Email: Roger.Kissling@fonterra.com

NIGERIA - NIGÉRIA

Mr Augustus Olawale Olugbenga Babarinde
Deputy Director
Laboratory Services
National Agency for Food and Drug Administration and Control
NAFDAC, Wuse Zone 7,
Abuja
Nigeria
Email: waleron@yahoo.com

Dr Charles Uchenna Nwachukwu
Deputy Director
Laboratory Services
National Agency for Food and Drug Administration and Control
NAFDAC, Wuse Zone 7
Abuja
Nigeria
Email: nwachukwucharles50@gmail.com

NORWAY - NORVÈGE - NORUEGA

Dr Stig Valdersnes
Researcher
National Institute of Nutrition and Seafood Research
Postboks 2029 Nordnes
Bergen
Norway
Email: stig.valdersnes@nifes.no

POLAND - POLOGNE - POLONIA

Ms Martyna Mielewczyk
Laboratory Assistant
Agricultural and Food Quality Inspection
11/13 Reymonta Str.
Poznań
Poland
Email: mmielewczyk@ijhars.gov.pl

REPUBLIC OF KOREA - RÉPUBLIQUE DE CORÉE - REPÚBLICA DE COREA

Ms Guiim Moon
Senior Researcher
Food Safety Risk Assessment Division
National Institute of Food and Drug Safety Evaluation
Republic of Korea
Email: luna@korea.kr

Dr Young-min Choi
Research Scientist
National Institute of Agricultural Sciences
Ministry of Agriculture, Food, and Rural Affairs
166, Nongsaengmyeong-ro
wanjugun
Republic of Korea
Email: ychoi2@korea.kr

Dr Kyu-jai Han
Principal Research Scientist
Korea Food Research Institute
1201-62, Anayangpangro-ro Bundang-gu
Seongnam-si
Republic of Korea
Email: hankj@kfri.re.kr

Mr Dae-jung Kim
Scientific Officer
National Agricultural Products Quality Management Service(NAQS)
Ministry of Agriculture, Food, and Rural Affairs
141, Yongjeon-ro, Gimcheon-si,
Gyeongsangbuk-do
Republic of Korea
Email: dj9475@korea.kr

Ms Chae-hyung Kim
Codex Researcher
Food Standard Division
Ministry of Food and Drug safety
Republic of Korea
Email: wonya8282@korea.kr

Mr Hyo-sub Lee
Scientific Officer
National Institute of Agricultural Sciences
Ministry of Agriculture, Food, and Rural Affairs
166, Nongsaengmyeong-ro, Iseo-myeon,
Wanju-gun, Jeollabuk-do
Republic of Korea
Email: lhs8255@korea.kr

Dr Sung-won Park
Senior Scientific Officer
Animal and Plant Quarantiner Agency
Ministry of Agriculture, Food, and Rural Affairs
177, Hyeoksin 8-ro
Gimcheon-si, Gyeongsangbuk-do
Republic of Korea
Email: pasawa@korea.kr

Mrs Eun Ryong Park
Scientific Officer
Residues and Contaminants Standard Division
Food Standard Planning Office
Email: jisein@korea.kr

Dr Youshin Shim
Principal Researcher
Korea Food Rearsch Institute
1201-62, Anyangpangyi-ro, Bundang-gu, Seongnam-si,
Gyeonggi-do,
Republic of Korea
Email: ysshim@kfri.re.kr

**RUSSIAN FEDERATION -
FÉDÉRATION DE RUSSIE -
FEDERACIÓN DE RUSIA**

Mr Konstantin Eller
Head of laboratory
Laboratory of metabolic and proteomic analysis
Federal Research Centre of nutrition, biotechnology
and food safety
Ustinsky proezd 2/14
Moscow
Russian Federation
Email: eller@ion.ru

**SAUDI ARABIA - ARABIE SAOUDITE –
ARABIA SAUDITA**

Mr Naseer Alnakhli
Email: CODEX.CP@sfda.gov.sa

Mr Ahmad Alromaihi
Email: CODEX.CP@sfda.gov.sa

SENEGAL - SÉNÉGAL

Mr Bacary Diatta
Responsable De Laboratoire
Ministère Du Commerce
Laboratoire National De Contrôle et d'Analyses
Dakar
Sénégal
Email: Bakaryadiatta@hotmail.com

Mrs Astou Ndiaye
Chef De Section Chimie
Ministère Commerce
Laboratoire National d'Analyses et de Contrôle
Rue Parchappe Dakar
Dakar
Sénégal
Email: maguidadou@yahoo.fr

SERBIA

Ms Milica Rankov-Šicar
Executive Director of Samples booking and Analysis
Supervision Dpt.
Samples booking and Analysis Supervision Dpt.
SP Laboratorija
Industrijska 3
Bečej
Serbia
Email: milica.rankov-sicar@victoriagroup.rs

Ms Marija Vujić-Stefanović
Deputy C.E.O of Gen. and Phys-Chem Analysis
Dpt of Genetical and Physical-Chemical Analysis
SP Laboratorija
Industrijska 3
Bečej
Serbia
Email: marija.vujic-stefanovic@victoriagroup.rs

SINGAPORE - SINGAPOUR - SINGAPUR

Dr King Tiong, Paul Chiew
Group Director, Laboratories Group
Agri-Food & Veterinary Authority of Singapore
10 Perahu Road Singapore 718837
Singapore
Email: paul_chiew@ava.gov.sg

Dr Ping Shen
Deputy Director
Drug Residues Section, VPHL Chemistry Department,
Laboratories Group
Agri-Food & Veterinary Authority of Singapore
10 Perahu Road Singapore 718837
Singapore
Email: shen_ping@ava.gov.sg

SLOVAKIA - SLOVAQUIE - ESLOVAQUIA

Ms Iveta Vojsova
Head
Department of Chemistry and Toxicology
State Veterinary and Food Institute Dolny Kubin
Veterinary and Food Institute Botanicka 15
Bratislava
Slovakia
Tel: +421 917 313 572; +421 2 38108
Email: yvojsova@svuba.sk

SOUTH AFRICA - AFRIQUE DU SUD - SUDÁFRICA

Mr Ephraim Moruke
Laboratory Manager
Department of Agriculture, Forestry and Fisheries
Private Bag X343
Pretoria
South Africa
Email: EphraimMor@daff.gov.za

SPAIN - ESPAGNE - ESPAÑA

Mr Pedro A. Burdaspal
Head
Spanish Consumer Affairs, Food Safety and Nutrition
Agency
Email: pburdaspal@msssi.es

SWITZERLAND - SUISSE - SUIZA

Dr Gérard Gremaud
Scientific Officer
Food and Nutrition
Federal Food Safety and Veterinary Office FSVO
Bern
Switzerland
Email: gerard.gremaud@blv.admin.ch

Dr Erik Konings
Expert
Method Management Group - Quality and Safety
Department
Nestlé Research Center
Switzerland
Email: erik.konings@rdls.nestle.com

THAILAND - THAÏLANDE - TAILANDIA

Ms Chanchai Jaengsawang
Advisor
Department of Medical Sciences
Taiwan Road,
Nonthaburi
Thailand
Email: chanchai84@outlook.com

Ms Rungrassamee Mahakhaphong
Standard Officer
Office of Commodity and System Standards
National Bureau of Agricultural Commodity and Food
Standards
National Bureau of Agricultural Commodity and Food
Standards, 50 Phaholyothin Road, Ladyao Chatuchak
Bangkok
Thailand
Tel: +662 561 2277
Email: mahakhaphong@gmail.com

Mr Prawit Srisa-ard
Veterinarian, Expert Level
Department of Livestock Development
Ministry of Agriculture and Cooperatives
280 Soi ladprao 47 Sapansong Vangthonglang
Bangkok
Thailand
Email: pavit.srisa@gmail.com

Mrs Supanoi Subsinserm
Food Technologist, Senior Professional Level
Department of Fisheries
Ministry of Agriculture and Cooperatives
50 Kaset-Klang, Chatuchak
Bangkok
Thailand
Email: supanois@dof.mail.go.th

Mr Somchai Wongsamoot
Veterinarian, Expert Level
Department of Livestock Development
Ministry of Agriculture and Cooperatives
Bureau of Quality Control of Livestock Products 91
Moo. 4, Tiwanon Rd., Bangkadee, Muang
Pathumthani
Thailand
Email: somchai_6@yahoo.com

TURKEY - TURQUIE - TURQUÍA

Mr Ahmet Gungor
Food Engineer
Food Codex Department
Ministry of Food, Agriculture and Livestock
Eskisehir Yolu 9.km Lodumlu
Ankara
Turkey
Email: agungor1977@mynet.com

Mr Hasan Kartal
Food Engineer
Food Establishments and Codex Department
Ministry of Food Agriculture and Livestock
Eskisehir Yolu 9. Km Lodumlu
Ankara
Turkey
Email: hasan.kartal@tarim.gov.tr

**UNITED KINGDOM - ROYAUME-UNI -
REINO UNIDO**

Mr Duncan Arthur
Association of Public Analysts (APA)
Email: DuncanArthur@PublicAnalystServices.co.uk

Dr Andrew Damant
Food Standards Agency (FSA)
Email: andrew.damant@foodstandards.gsi.gov.uk

Mrs Selvarani Elahi
Deputy Government Chemist
Laboratory of the Government Chemist
Queens Road Teddington Middlesex
United Kingdom
Email: selvarani.elahi@lgcgroup.com

Ms Chelvi Leonard
Food Standards Agency (FSA)
Email: chelvi.leonard@foodstandards.gsi.gov.uk

**UNITED STATES OF AMERICA -
ÉTATS-UNIS D'AMÉRIQUE -
ESTADOSUNIDOS DE AMÉRICA**

Dr Gregory Noonan
Director
Division of Bioanalytical Chemistry
Food and Drug Administration
5100 Paint Branch Parkway, HFS 706
College Park, MD
United States of America
Email: Gregory.Noonan@fda.hhs.gov

Mrs Doreen Chen-moulec
International Issues Analyst
Food Safety and Inspection Service; Office of CODEX
U.S. Department of Agriculture
1400 Independence Ave
Washington, DC
United States of America
Email: Doreen.Chen-Moulec@fsis.usda.gov

Dr Patrick Gray
Chemist
US Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD
United States of America
Email: Partick.Gray@fda.hhs.gov

Dr Timothy Norden
Chief Scientist, Technology and Science Division
Grain Inspection, Packers and Stockyards
Administration (GIPSA)
U. S. Department of Agriculture
10383 Ambassador Dr.
Kansas City, MO
United States of America
Email: Timothy.D.Norden@usda.gov

URUGUAY

Mrs Laura Flores
Dirección de Calidad
Laboratorio Tecnológico del Uruguay
Avda Italia 6201
Montevideo

Uruguay
Email: lflores@latu.org.uy

VIET NAM

Mrs Thanh Nha Bui
Specialist
Bureau of Accreditation
Bureau of Accreditation
8 Hoang Quoc Viet street
Hanoi
Viet Nam
Email: nha.tn2009@gmail.com

Mr Thanh Van Hoang
director
Livestock Product Department
Ministry of Agriculture and Rural Development
2 Ngoc Ha street
Hanoi
Viet Nam
Email: hgthanhvanbv@gmail.com

Mr Huu Dung Nguyen
Secretary
Vietnam Association of Testing Laboratories
Floor 4, 130 Nguyen Duc Canh Street. Hoang Mai
District.
Hanoi
Viet Nam
Email: director@vinacert.vn

Mr Xuan Binh Nguyen
Officer
Ministry of Agriculture and Rural Development
Vietnam Association Of Testing Laboratories
163 Dien Bien Phu Street, Binh Thanh District.
Ho Chi Minh City
Viet Nam
Email: info@vinalab.org.vn

Mrs Thi Thap Nguyen
Specialist
VINALAB
163 Điện Biên Phủ Street, Binh Thanh District,
Ho Chi Minh City
Viet Nam
Email: info@vinalab.org.vn

Mr Van Quynh Nguyen
Official
Government office
16 Le Hong Phong
Hanoi
Viet Nam
Email: nguyenvanquynh@chinhphu.vn

Mr Van Vinh Phuong
Specialist
Livestock Product Department
Ministry of Agriculture and Rural Development
2 Ngoc Ha street
Hanoi
Viet Nam
Email: phuongvanvinhccn@gmail.com

Mrs Thi Luu Tran
Officer
Ministry of Agriculture and Rural Development
VINALAB
4th Floor, 130 Nguyen Duc Canh Street, Hoang Mai
District.
Hanoi
Viet Nam
Email: info@vinalab.org.vn

Mrs Thi Thuy Thu Truong
Director
Center for food safety application
Vietnam Food Administration
135 Nui truc street
Hanoi
Viet Nam
Email: Thuythu_vfa@yahoo.com

**NON GOVERNAMENTAL ORGANIZATION -
ORGANISATION NON GOUVERNEMENTALE -
ORGANIZACIÓN NO GUBERNAMENTAL**

AACC INTERNATIONAL

Dr Anne Bridges
Technical Director
AACC International
3340 Pilot Knob Road
St Paul
United States of America
Email: annebridges001@earthlink.net

AOAC INTERNATIONAL (AOAC)

Mr Darryl Sullivan
Secretary
AOAC INTERNATIONAL
2275 Research Blvd, Suite 300
Rockville
United States of America
Email: darryl.sullivan@covance.com

Dr John Szpylka
Scientific Affairs Director, Chemistry N.A.
Mérieux NutriSciences
AOAC International
3600 Eagle Nest Drive
Crete, IL
United States of America
Email: john.szpylka@mxns.com

Mr Wayne Wargo
Principal Res Scientist
AR&D and Food Safety
Abbott Nutrition
3300 Stelzer Road, D104110/RP4-2
Columbus
United States of America
Email: wayne.wargo@abbott.com

AMERICAN OIL CHEMISTS' SOCIETY (AOCS)

Dr Richard Cantrill
Email: richard.cantrill@aocs.org

**ASSOCIATION OF EUROPEAN COELIAC
SOCIETIES (AOECS)**

Mrs Hertha Deutsch
Codex and Regulatory Affairs
AOECS
Anton-Baumgartner-Strasse 44/C5/2302
Vienna
Austria
Email: hertha.deutsch@gmx.at

Mrs Tunde Koltai
member
Association of European Coeliac Societies
Palanta utca 11
Budapest
Hungary
Email: tunde.koltai@gmail.com

EURACHEM

Dr Marina Patriarca
Eurachem Vice Chair
Istituto superiore di sanità
Viale Regina Elena 299
Rome
Italy
Email: secretariat@eurachem.org

INTERNATIONAL DAIRY FEDERATION (IDF/FIL)

Dr Jaap Evers
IDF Leader – Global Standards
International Dairy Federation
Private Bag 11029, Palmerston North 4442 Dairy Farm
Road,
Palmerston North
New Zealand
Email: jaap.evers@fonterra.com

INTERNATIONAL FRUIT AND VEGETABLE JUICE ASSOCIATION (IFU)

Dr David Hammond
IFU (International Fruit & Vegetable Juice Association)
23, Boulevard des Capucines
Paris
France
Email: davidfruitjuice@aol.com

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO)

Mrs Sandrine Espeillac
Secretary of ISO-TC 34
AFNOR
Email: sandrine.espeillac@afnor.org

NORDIC COMMITTEE ON FOOD ANALYSIS (NMKL)

Mrs Nina Skall Nielsen
Senior Research Scientist
National Food Institute
Technical University of Denmark
Søltoft Plads
Kgs. Lyngby
Denmark
Email: nsni@food.dtu.dk

UNITED STATES PHARMACOPEIAL CONVENTION (USP)

Mrs Kristie Laurvick
Acting Director, Science - Foods
Food Standards
U. S. Pharmacopeial Convention
12601 Twinbrook Parkway
Rockville MD
United States of America
Email: kxb@usp.org

Ms Gina Clapper
Sr. Scientific Liaison
Food Standards
U. S. Pharmacopeia
12601 Twinbrook Parkway
Rockville MD
United States of America
Email: gina.clapper@usp.org

FAO

Mrs Eleonora Dupouy
Food Safety and Consumer Protection Officer
Food and Agriculture Organization
Benczur u. 34.
Budapest
Hungary
Email: eleonora.dupouy@fao.org

CODEX SECRETARIAT

Ms Verna Carolissen-Mackay
Food Standards Officer
Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization of U.N.
Viale delle Terme di Caracalla
00153 Rome
Italy
Email: verna.carolissen@fao.org

Ms Gracia Brisco
Food Standards Officer
Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization of U.N.
Viale delle Terme di Caracalla
00153 Rome
Italy
Email: gracia.brisco@fao.org

Ms Myoengsin Choi
Food Standards Officer
Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization of U.N.
Viale delle Terme di Caracalla
00153 Rome
Italy
Email: myoengsin.choi@fao.org

Ms Rain Yamamoto
Food Standards Officer
Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization of U.N.
Viale delle Terme di Caracalla
00153 Rome
Italy
Email: rain.yamamoto@fao.org

PART 1. METHODS OF ANALYSIS FOR ADOPTION BY THE 40TH CODEX ALIMENTARIUS COMMISSION

A. Committee on Processed Fruits And Vegetables

B. Coordinating Committee For Asia

C. Committee on Nutrition And Foods For Special Dietary Uses

D. Coordinating Committee For Africa

E. Committee on Spices And Culinary Herbs

F. Committee on Fats And Oils

PART 2. METHODS OF ANALYSIS FOR REVOCATION BY THE 40TH CODEX ALIMENTARIUS COMMISSION

PART 3. METHODS OF ANALYSIS ON TRANS FATTY ACIDS FOR CCNFSDU

PART 1. METHODS OF ANALYSIS FOR ADOPTION BY THE 40TH CODEX ALIMENTARIUS COMMISSION

A. COMMITTEE ON PROCESSED FRUITS AND VEGETABLES

Methods of analysis for quick frozen vegetables

Product	Provision	Method	Principle	Type
Quick frozen fruits and vegetables	Thawing procedure	Method CAC/RM 32 to be placed in CODEX STAN 234	Thawing	I
Quick frozen fruits and vegetables: Vegetables	Cooking procedure	Method CAC/RM 33 to be placed in CODEX STAN 234	Cooking	I
Quick frozen fruits and vegetables (non-glazed)	Net weight	AOAC 963.26	Weighing	I
Quick frozen peas	Solids, alcohol insoluble	Method CAC/RM 35 to be placed in CODEX STAN 234	Gravimetry	I
Quick frozen green and wax beans	Tough strings	Method CAC/RM 39 to be placed in CODEX STAN 234	Stretching	I
Quick frozen fruits and vegetables: Berries, Whole kernel corn and Corn-on-the-cob	Soluble solids, total	AOAC 932.12	Refractometry	I
Quick frozen fruits and vegetables: Berries, leek and carrot	Mineral impurities	AOAC 971.33	Gravimetry	I
Quick frozen fruits and vegetables: Peaches and berries	Drained fruit/drained berries	AOAC 953.15	Draining	I
Quick frozen spinach	Dry matter, Sodium chloride-free	Method described in CODEX STAN 77-1981 is to be moved to CODEX STAN 234	Weighing	I
Quick frozen French fried potatoes	Moisture	AOAC 984.25	Gravimetry (convection oven)	I

B. COORDINATING COMMITTEE FOR ASIA

Methods of analysis for laver products

Provision	Method	Principle	Type
Moisture content	AOAC 925.45B	Gravimetry, drying at atmospheric pressure	IV

Method of analysis for Tempe

Provisions	Method	Principle	Type
Lipid Content	AOAC 963.15	Gravimetry (Soxhlet Extraction)	I

C. COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Methods of analysis for infant formula

Provisions	Method	Principle	Type
Vitamin C	AOAC 2012.22	ISO/DIS 20635	HPLC-UV	II
Chromium (Section B of CODEX STAN 72-1981 only)	AOAC 2011.19	ISO 20649	IDF 235	ICP-MS	II
	EN 14082	Graphite furnace atomic absorption after dry ashing	III
Molybdenum (Section B of CODEX STAN 72-1981 only)	AOAC 2011.19	ISO 20649	IDF 235	ICP-MS	II
	EN 14083	Graphite furnace AAS after pressure digestion	III
Selenium	AOAC 2011.19	ISO 20649	IDF 235	ICP-MS	II
	EN 14627	Hydride generation atomic absorption spectrometry (HGAAS)	III
Vitamin B12	AOAC 986.23	Turbidimetric	III
	AOAC 2011.10	ISO 20634	HPLC	II
Myo-Inositol	AOAC 2011.18	ISO 20637	LC-pulsed amperometry	II
Vitamin E	AOAC 2012.10	ISO 20633	HPLC	II
Total fatty acids	AOAC 996.06	Gas chromatography	III
	AOAC 2012.13	ISO16958	IDF231	Gas chromatography	II

D. COORDINATING COMMITTEE FOR AFRICA

Methods of analysis for unrefined shea butter

Provision	Method	Principle	Type
Moisture content	ISO 662	Gravimetry	I
Free fatty acid content: acid value and acidity	ISO 660 AOCS Cd 3d-63	Titrimetry	I
Relative density	AOCS Cc 10c-95/ ISO 6883	Pycnometry	I
Saponification value	ISO 3657 / AOCS Cd 3d-25	Titrimetry	I
Iodine value	AOAC 993.20 / ISO 3961 / AOCS Cd 1d-92/ NMKL 39	WijsTitrimetry	I
Peroxide value	AOCS Cd 8b-90/ ISO 3960 / NMKL 158	Titrimetry	I
Unsaponifiable matter	ISO 3596 / AOCS Ca 6a-40	Gravimetry	I
Insoluble impurities content	ISO 663 / AOCS Ca 3a-46	Gravimetry	I
Melting point	ISO 6321 AOCS Cc 3b-92	Open ended capillary tube	I

E. COMMITTEE ON SPICES AND CULINARY HERBS

Methods of analysis for cumin

Provision	Method	Principle	Type
Moisture	ISO 939	Distillation	I
Total ash	ISO 928	Gravimetry	I
Acid-insoluble ash	ISO 930	Gravimetry	I
Volatile oils	ISO 6571	Distillation / Volumetric	I
Extraneous vegetable matter	ISO 927	Visual examination / Gravimetry	I
Foreign matter	ISO 927	Visual examination / Gravimetry	I
Insect damage	Method V-8 Spices, Condiments, Flavors and Crude Drugs (Macroanalytical Procedure Manual, FDA Technical Bulletin Number 5) http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm084394.htm#v-32	Visual examination	IV
Mammalian excreta	Macroanalytical procedure manual USFDA technical bulletin V.39 B (for whole)	Visual examination	IV
Mammalian excreta	AOAC 993.27 (for ground)	Enzymatic Detection method	IV
Mould damage	Method V-8 Spices, Condiments, Flavors and Crude Drugs (Macroanalytical Procedure Manual, FDA Technical Bulletin Number 5) http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm084394.htm#v-32	Visual examination	IV

Methods of analysis for thyme

Provision	Method	Principle	Type
Moisture	ISO 939	Distillation	I
Total ash	ISO 928	Gravimetry	I
Acid-insoluble ash	ISO 930	Gravimetry	I
Volatile oils	ISO 6571	Distillation / Volumetric	I
Extraneous vegetable matter	ISO 927	Visual examination / Gravimetry	I
Foreign matter	ISO 927	Visual examination / Gravimetry	I
Insect damage	Method V-8 Spices, Condiments, Flavors and Crude Drugs (Macroanalytical Procedure Manual, FDA Technical Bulletin Number 5) http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm084394.htm#v-32	Visual examination	IV
Mammalian excreta	Macroanalytical procedure manual USFDA technical bulletin V.39 B (for whole)	Visual examination	IV
	AOAC 993.27 (for ground)	Enzymatic Detection method	IV
Mould damage	Method V-8 Spices, Condiments, Flavors and Crude Drugs (Macroanalytical Procedure Manual, FDA Technical Bulletin Number 5) http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm084394.htm#v-32	Visual examination	IV

Methods of analysis for black, white and green pepper

Provision	Method	Principle	Type
Bulk density	ISO 959-1 Annex B (black) ISO 959-2 Annex A (white)	Gravimetry	IV
Light berries	ISO 959-1 Annex A (black)	Flotation	IV
Extraneous vegetable matter	ISO 927	Visual examination / Gravimetry	I
Foreign matter	ISO 927	Visual examination / Gravimetry	I
Black berries	Physical separation and weighing ISO 959-2	Visual examination	IV
Broken berries	Physical separation and weighing ISO 959-2	Visual examination	IV
Mouldy berries	Macroanalytical procedure manual USFDA technical bulletin V.39 B	Visual examination	IV
Insect damage	Macroanalytical procedure manual USFDA technical bulletin V.39 B	Visual examination	IV
Pinheads or broken berries	Physical separation and weighing ISO959-1	Visual examination	IV
Mammalian excreta	Macroanalytical procedure manual USFDA technical bulletin V.39 B (For Pepper Whole)	Visual examination(For whole pepper)	IV
Mammalian excreta	AOAC 993.27 (for ground pepper)	Enzymatic Detection method (For ground pepper)	I
Moisture content	ISO 939	Distillation	I
Total ash	ISO 928	Gravimetry	I
Non-volatile ether extract	ISO 1108	Soxhlet extraction	I
Volatile oils	ISO 6571	Distillation	I

Provision	Method	Principle	Type
Piperine content	ISO 5564	Spectrophotometry	I
Acid- Insoluble ash	ISO 930	Gravimetry	I
Crude Fibre	ISO 5498	Gravimetry	I

F. COMMITTEE ON FATS AND OILS

Methods of analysis for fish oils

Provisions	Method	Principle	Type
P-Anisidine value	EuropeanPharmacopeia 2.5.36 / AOCS Cd 18-90 / ISO 6885	Spectrophotometry	I
Phospholipids	USP-FCC10 2S (Krill oil): Phosopholipids, Nuclear Magnetic Resonance, Appendix IIC	NMR Spectroscopy	IV
Triglycerides	USP 40-NF35 (Omega-3 Acid Triglycerides): Content of oligomers and partial glyceride;	HPLC-RI	III
	European Pharmacopoeia 1352 (Omega3 acid triglycerides): Oligomers and partial glycerides	HPLC-RI	III
	AOCS Cd 11d-96	HPLC-ELSD	III

PART 2. METHODS OF ANALYSIS FOR REVOCATION BY THE 40TH CODEX ALIMENTARIUS COMMISSION

Methods of analysis for quick frozen vegetables

CAC/RM 34 (Determination of net weight in quick frozen fruits and vegetables (non-glazed))

CAC/RM 43 (Determination of soluble solids, quick frozen fruits and vegetables; berries; total in whole kernel corn and Corn- on-the-cob)

CAC/RM 54 (Determination of mineral impurities in quick frozen fruits and vegetables: Berries, leek and carrot)

PART 3. METHODS OF ANALYSIS ON TRANS FATTY ACIDS FOR COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Additional Information: Determination of TFA in Collaborative Studies for each method/matrix[1]

Product	Method		
	ISO 16958/IDF 231/ AOAC 2012.13 (g/100g of product)	AOCS Ce 1h-05 and AOAC 996.06	AOCS Ce 1j-07 and Ce 2b-11/Ce 2c-11 (g/100g of sample)
Dairy and ruminant products/fats	**TFA Range: 0.17–5.06 g/100 g (n=5)**: • Cheese (extracted fat), 5.06 g/100 g • Butter, 4.24 g/100 g • Cream, 1.62 g/100 g • Milk powder, 1.03 g/100 g • Liquid milk, 0.17 g/100 g	Not validated	**TFA Range: 0.32–7.27% of total fatty acids (n=5)**: • Cheese powder, 7.27% • Anhydrous milk fat, 5.11% • Butter, 2.49% • Evaporated milk, 0.33% • Yogurt, 0.32%
Adult nutritionals	**TFA Range: 0.006–0.010 g/100 g (n=3)**: • High protein RTF, 0.009 g/100 g • High fat RTF, 0.010 g/100 g • Milk-based powder, 0.006 g/100 g	Not validated	Not validated
Infant formula	**TFA Range: 0.010–0.073 g/100 g (n=4)**: • Milk-based powder, 0.073 g/100 g • Milk-based RTF, 0.027 g/100 g • Milk-based powder, 0.012 g/100 g • Soy-based powder, 0.010 g/100 g	Samples unknown	**TFA Range: 0.15% of total fatty acids (n=1)** • DHA/EPA-fortified infant formula, 0.15%
Samples containing vegetable oils	Not validated	**TFA Range: 0.06–45.01% of total fatty acids (n=10)**: • Vegetable shortening, 45.01% • Canola oil, 26.27% and 26.55% • Margarine, 11.62% • Hydrogenated lard, 1.00% • Lard, 0.90% • Sunflower oil, 0.17% • Coconut oil, 0.10% and 0.11% • Cocoa butter, 0.06%	Not validated
Samples containing marine oils or other oils with long chain polyunsaturated fatty acids	Not validated	Not validated	**TFA Range: 0.00–0.68% of total fatty acids (n=2)**: • Encapsulated DHA/EPA, 0.68% • DHA/EPA-fortified orange juice, 0.00%

---

[1] Tyburczy et al., Anal. Bioanal. Chem. (2013), 405, 5759

| Samples with unknown fat sources | | Not validated | **TFA Range: 0.00–0.68% of total fatty acids (n=14):**
• Tallow, 7.14%
• Chocolate-cake mix, 0.90%
• Whole-egg powder, 0.43%
• Frozen cheese pizza, 0.37%
• Extruded dog food, 0.31%
• Creamy ranch-dressing, 0.24%
• Potato chips, 0.22%
• Peanut butter, 0.06%
• Oatmeal cookie, 0.05%
• Canned cat food, 0.05%
• Full-fat soy flour flakes, 0.02%
• Dry cereal fortified with flax, 0.00%
• Horse feed, 0.00%
• Gamebird feed, 0.00% |

AMENDMENTS TO THE PROCEDURAL MANUAL

(For adoption by CAC)

(note: the amendments are in <u>bold underlined</u> font)

Principles for the Establishment of Codex Methods of Analysis

Section II: Elaboration of Codex standards and related text

Principles for the Establishment of Codex Methods 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. **There are numerous ways in which methods and limits that involve a sum of components can be converted into method performance criteria but this should be undertaken with care on a case-by-case basis.**

INFORMATION DOCUMENT ON

CRITERIA APPROACHES FOR METHODS WHICH USE A 'SUM OF COMPONENTS'

(For publication on Codex website)

INTRODUCTION

1.   The Procedural Manual of the Codex Alimentarius Commission provides extensive instructions detailing how a Codex Committee may propose an appropriate method of analysis for determining the analyte and/or develop a set of criteria to which a method used for the determination must comply. In either case the specified maximum / minimum level, any other normative level or the concentration range of interest has to be stated.

2.   When a Codex Committee decides that a set of criteria should be developed, in some cases the Committee may find it easier to recommend a specific method and request the Committee on Methods of Analysis and Sampling (CCMAS) to "convert" that method into appropriate criteria. The Criteria will then be considered by CCMAS for endorsement and will, after the endorsement, form part of the standard. Methods are evaluated on the characteristics of:

- Selectivity

- Accuracy

- Precision

- Limit of detection

- Sensitivity

- Practicability

- Applicability.

3.   It also allows for the establishment of other criteria as required and offers some guidance on choosing between different methods.

4.   The Procedural Manual allows for the "Criteria Approach" as an alternative to the endorsement of a specific method (ibid). The Criteria Approach enables the establishment of a set of criteria (numeric values) which must be met by a method in order for the method to be applicable (i.e. "fit for purpose") to a specific standard. The Criteria Approach is applicable to fully validated Type II and III methods, except for methods such as PCR and ELISA; it is not applicable to Type I methods. The Criteria Approach currently requires information on Applicability, Minimum Applicable Range, Limit of Detection and Quantitation, Precision (with requirements for reproducibility relative standard deviation), Recovery and Trueness.

5.   Two approaches for establishing criteria are described in the Procedural Manual. The first utilizes the specified limit (maximum or minimum limit) to establish numeric criteria for the characteristics mentioned above and the second involves the conversion of a specific method to establish numeric criteria. Although the method should be validated and appropriate for the analyte and commodity, there is not a specific requirement that the method be endorsed prior to being "converted" to criteria.

6.   The Guidelines for Establishing Numeric Values for Criteria in the Procedural Manual were developed considering only single analyte determinations and not determinations that involve a sum of components. That is, methods where the concentration of a specific analyte is measured and that determination is assessed against a specification. As such, the approach detailed in the Procedural Manual can be inappropriate for determinations that involve a sum of components i.e. where multiple analytes are determined and summed and the sum is assessed against a specification.

7.   This Information Document provides information to Codex Committees and the CCMAS on a variety of (non-exhaustive) issues they may wish to consider when developing numeric method performance criteria for approaches that involve a summation of components.

BACKGROUND

8.   There are numerous ways in which methods and limits that involve a sum of components can be converted into numeric method performance criteria. Two example approaches are shown in Annex A but these are not the only approaches available. Approaches taken need to be developed and decided on a case-by-case basis and will be influenced by a number of factors including whether, for example:

- the components are equally or unequally weighted;

- there is a known natural-abundance of the components (e.g. Fumonisins B1 and B2 are determined together where the typical ratio of B1:B2 in naturally contaminated samples is 5:2 but the (maximum limit) ML is a total value of B1+B2);

- measured values for individual components are correlated or uncorrelated. The presence of correlation (for example due to multiple components measured on the same instrument at the same time) can have a substantial effect on the precision of the resulting summed values compared to the precision available when components are measured independently;

- the MLs or methods involving the use of toxic equivalents (TEQs) or toxic equivalent factors (TEFs); or,

- the specification contains multiple MLs for both a single analyte and a sum of components.

9.   It is unsurprising that there is currently no single mechanism for converting maximum limits that involve a sum of components into method performance criteria as it is complex. With the assessment of future methods and method developers taking into consideration a 'sum of components' approach, Codex may find future compliance less problematic. Further, as analytical technology capability improves the identification and lower quantitation of multi-components of a provision in a commodity may become feasible when historically this was not the case. Alternatively, individual components may be specified as a 'marker' for the 'total components' e.g. benzo[a]pyrene for polynuclear aromatic hydrocarbons in drinking-water. So some options in the 'sum of components' criteria applied by Codex, plus reviews by Codex Committees in cases where there is a 'sum of components' standard specification, may have to occur together to achieve the best outcome.

TOXIC EQUIVALENT FACTORS

10.   For certain commodities or analytes there are specifications where the individual concentrations of multiple analytes are determined by a single method, the concentrations are converted to a "toxic equivalent" using a toxic equivalency factor (TEF) and the specification is a limit based on the sum of equivalents. One example of this approach is the determination of the saxitoxin group in the *Standard for Live and Raw Bivalve Molluscs* (CODEX STAN 292-2008). The specification is for the concentration of saxitoxin equivalents which is determined from 12 saxitoxin congeners each multiplied by a TEF and summed. TEFs are also used in other determinations, such as dioxins and dioxin-like PCBs. The current Criteria Approach in the Procedural Manual was not developed considering specifications which use TEF or a sum of toxic equivalents.

RECOMMENDATIONS

1.   It is important to note that when developing a Criteria Approach, it is the competent authority (Government, Codex Committee) that is responsible for specifying the range of concentrations for each analyte. Consideration of the ratio of components, toxicity, and properties of matrices (commodities) are outside of the terms of reference of CCMAS, but rather fall under the responsibilities of Codex Commodity Committees or individual Governments.

2.   There are numerous ways in which methods and limits that involve a sum of components can be converted into method performance criteria but this should be undertaken with care and also on a case-by-case basis. CCMAS is available to advise Codex Committees if they wish to develop numeric method performance criteria for methods or limits that involve a summation of components.

3.   If methods of analysis that employ a summation of components have been collaboratively trialled on a 'sum of components' basis then these can be converted directly into criteria.

11.   For MLs that involve use of TEQs/TEFs or other toxicological potencies it is recommended that the MLs themselves are not converted to method performance criteria. In such instances the second approach detailed within the Procedural Manual (i.e. the conversion of a specific method to establish numeric criteria) may be appropriate where numeric criteria may be developed on using untransformed method performance data (i.e. raw data that has not been converted into TEQs) assuming the method has been suitably validated. This was the approach taken when an amendment was made to the *Standard for Live and Raw Bivalve Molluscs* (CODEX STAN 292-2008) where un-weighted numerical performance criteria (i.e. TEFs not applied) were established from the various approved methods.

12.   For provisions that contain MLs for both single components and also a sum of components, a combination of approaches may be appropriate. For example, using approaches laid down within the Procedural Manual for the single components and a sum of components approach for MLs that involve a summation of components.

ANNEX A - EXAMPLE APPROACHES

APPROACH 1: THE ML IS A SUM OF COMPONENTS THAT ARE EQUALLY WEIGHTED

For multi-analyte analyses where all components are weighted equal, n is the number of components/analytes. The criteria for multi-analyte (and single analyte, n=1) would then be as given in Table 1.

Table 1: Guidelines for establishing numeric criteria if the ML is a sum of components that are equally weighted.

Applicability:			The method has to be applicable for the specified provision, specified commodity and the specified level(s) (maximum and/or minimum) (ML). The minimum applicable range of the method depends on the specified level (ML) to be assessed, and can either be expressed in terms of the reproducibility standard deviation (s_R) or in terms of LOD and LOQ.
Minimum Applicable **Range for <u>the individual components</u>[1]:**			For ML/n ≥ 0.1 mg/kg, [ML/n - 3 s_R, ML + 3 s_R] For ML/n < 0.1 mg/kg, [ML/n - 2 s_R, ML + 2 s_R] NB: the upper level is above the ML for the individual components.
Limit of Detection (LOD) for <u>the individual components</u>:			For ML/n ≥ 0.1 mg/kg, LOD ≤ ML/n · 1/10 For ML/n < 0.1 mg/kg, LOD ≤ ML/n · 1/5
Limit of Quantification (LOQ) for <u>the individual components</u>:			For ML/n ≥ 0.1 mg/kg, LOQ ≤ ML/n · 1/5 For ML/n < 0.1 mg/kg, LOQ ≤ ML/n · 2/5
Precision for <u>the individual components</u>:	For ML/n ≥ 0.1 mg/kg, HorRat value ≤ 2 For ML/n < 0.1 mg/kg, the RSD$_R$ < [44%]. RSD$_R$ = relative standard deviation of reproducibility.		
Recovery (R) <u>for the individual components</u>:	**Concentration**	**Ratio**	**Unit**	**Recovery (%)**
	100	1	100% (100 g/100g)	98-102
	≥10	10^{-1}	≥10% (10 g/100g)	98-102
	≥1	10^{-2}	≥1% (1 g/100g)	97-103
	≥0.1	10^{-3}	≥0.1% (1 mg/g)	95-103
	0.01	10^{-4}	100 mg/kg	90-107
	0.001	10^{-5}	10 mg/kg	80-110

---

[1] For multi-analyte analyses where all components are weighted equal, n=number of components/analytes.

0.0001	10^{-6}	1 mg/kg	80-110
0.00001	10^{-7}	100 µg/kg	80-110
0.000001	10^{-8}	10 µg/kg	60-115
0.0000001	10^{-9}	1 µg/kg	40-120

Trueness:	Other guidelines are available for expected recovery ranges in specific areas of analysis. In cases where recoveries have been shown to be a function of the matrix other specified requirements may be applied. For the evaluation of trueness preferably certified reference material should be used.

Worked Example

Substance X, consisting of 4 analytes, x_1, x_2, x_3 and x_4, in matrix Y.

The ML (i.e. $x_1 + x_2 + x_3 + x_4$) = 20 µg/kg,

As there are 4 analytes, $n = 4$,

ML/n = 20/4 µg/kg = 5 µg/kg

Using the NMKL Excel spreadsheet, the following are established:

Minimum Applicable	0.003* - 0.029** mg/kg = 3 - 29 µg/kg
Range for <u>the individual components</u>:	*corresponding to ML/n = 5 µg/kg
	**corresponding to ML = 20 µg/kg
Limit of Detection (LOD) for <u>the individual components</u>:	1 µg/kg
Limit of Quantification (LOQ) for <u>the individual components</u>:	2 µg/kg
Precision for <u>the individual components</u>:	RSD$_R$ ≤ 44%
Recovery for the individual components (R):	40-120%

Issues for consideration

1. It is important to note that throughout this approach the actual ML (for compliance purposes) remains unchanged.

2. The concept of minimum applicable range is clear and can be applied for testing compliance with a specification. However, it might be misinterpreted in cases of food contaminants where the analytical results are used for assessment of exposure to the substances analysed and consumers' risk (e.g. mycotoxins, dioxins PCBs, etc.). For this purpose, the results of measurements of low concentrations at or above the technically achievable LOQ are important. Especially for the most toxic analytes of the sum to be determined.

3. Using this approach the LOD and LOQ criteria may be too strict; especially when "n" is large (e.g. $n >> 5$). In such instances the developers of numeric method performance criteria need to consider the manner in which it considers methods that involve the summation of multiple components (e.g. sterols and PAHs) but where there is only ever likely to be a few components actually present. In such instances the calculated LOD/LOQ may be far too strict for practical purposes and an alternative approach may be more appropriate. For example, in such instances it may be appropriate for n to equal the number of analytes of 'interest' rather

than the total number of components. Alternatively, it may be appropriate to leave the individual minimum applicable range, the LODs and LOQs if already stipulated without taking into account the number of congeners or components of the sum.

APPROACH 2: THE ML IS A SUM OF COMPONENTS WHERE THERE IS A KNOWN NATURAL ABUNDANCE/RATIO OF COMPONENTS.

For multi-analyte analyses where there is a known natural abundance/ratio of components, f is the ratio factor. The criteria for multi-analyte (and single analyte, $f=1$) would then be as given in Table 2.

Table 2: Guidelines for establishing numeric criteria if the ML is a sum of components where there is a known natural abundance/ratio of components.

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

Precision for <u>the individual components</u>:	For ML $\cdot$ $f \geq 0.1$ mg/kg, HorRat value $\leq$ 2			
	For ML $\cdot$ $f < 0.1$ mg/kg, the RSD$_R$ < [44%]			
	RSD$_R$ = relative standard deviation of reproducibility.			
Recovery (R) for <u>the individual components</u>:	**Concentration**	**Ratio**	**Unit**	**Recovery (%)**
	100	1	100% (100 g/100g)	98-102
	≥10	10^{-1}	≥10% (10 g/100g)	98-102
	≥1	10^{-2}	≥1% (1 g/100g)	97-103
	≥0.1	10^{-3}	≥0.1% (1 mg/g)	95-103
	0.01	10^{-4}	100 mg/kg	90-107
	0.001	10^{-5}	10 mg/kg	80-110

	0.0001	10^{-6}	1 mg/kg	80-110
	0.00001	10^{-7}	100 µg/kg	80-110
	0.000001	10^{-8}	10 µg/kg	60-115
	0.0000001	10^{-9}	1 µg/kg	40-120
Trueness:	Other guidelines are available for expected recovery ranges in specific areas of analysis. In cases where recoveries have been shown to be a function of the matrix other specified requirements may be applied. For the evaluation of trueness preferably certified reference material should be used.			

Worked Example

Substance X, consisting of 2 analytes, x_1 and, x_2, in matrix Y. It is known that analytes x_1 and x_2 are typically found in a ratio of 5:3 in naturally-contaminated samples.

The ML = 5000 µg/kg,

As the 2 analytes are normally found in the ratio of 5:3

f_1 = 5/8 = 0.625 and,

f_2 = 3/8 = 0.375

For analyte x_1

ML · f_1 = 5000 · 0.625 µg/kg = 3125 µg/kg and,

For analyte x_2

ML · f_2 = 5000 · 0.375 µg/kg = 1875 µg/kg

Using the NMKL Excel spreadsheet[2] the following are established:

Analyte x_1

Minimum Applicable Range for <u>Analyte x_1</u>:	1.862* - 6.883** mg/kg = 1860 - 6880 µg/kg *corresponding to ML · f = 3125 µg/kg **corresponding to ML = 5000 µg/kg
Limit of Detection (LOD) for <u>Analyte x_1</u>:	313 µg/kg
Limit of Quantification (LOQ) for <u>Analyte x_1</u>:	625 µg/kg
Precision for <u>Analyte x_1</u>:	RSD_R ≤ 27%
Recovery (R) for <u>Analyte x_1</u>:	80-110%

Analyte x_2

Minimum Applicable Range for <u>Analyte x_2</u>:	1.056* - 6.883** mg/kg = 1060 - 6880 µg/kg *corresponding to ML · f = 1875 µg/kg **corresponding to ML = 5000 µg/kg
Limit of Detection (LOD) for <u>Analyte x_2</u>:	188 µg/kg
Limit of Quantification (LOQ) for <u>Analyte x_2</u>:	375 µg/kg
Precision for <u>Analyte x_2</u>:	RSD_R ≤ 29%
Recovery (R) for <u>Analyte x_2</u>:	80-110%

Issues for consideration

It is important to note that throughout the above process the actual ML (for compliance purposes) remains unchanged.

---

[2] www.nmkl.org under "How to get method criteria based on ML"

METHODS OF ANALYSIS FOR CONSIDERATION BY THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

VITAMIN B3: NICOTINAMIDE

Commodity	Provision	Method	Principle	Type	Propose to remove or change	Possible method proposed
Special foods	Nicotinamide for milk-based foods	AOAC 944.13	Microbioassay	II	Yes (III)	HPLC method like EN 15652 (Type II)

VITAMIN B3: NIACIN

Commodity	Provision	Method	Principle	Type	Propose to remove or change	Possible method proposed
Infant formula	Niacin	AOAC 985.34 (niacin (preformed) and nicotinamide)	Microbioassay And turbidimetry	III	No	HPLC method like EN 15652 (Type II)

VITAMIN B5: PANTOTHENIC ACID

Commodity	Provision	Method	Principle	Type	Propose to remove or change	Possible method proposed
Follow-up formula	Pantothenic acid	AOAC 992.07 Measures total pantothenate : free pantothenic acid + bounded forms	Microbioassay	II	II or III	AOAC 2012.16/ISO 20639 UHPLC MS/MS (Type I or II)

VITAMIN B6: PYRIDOXINE

Commodity	Provision	Method	Principle	Type	Propose to remove or change	Possible method proposed
Infant formula	Vitamin B6	AOAC 985.32	Microbioassay	III	---	HPLC-Fluorescence like AOAC 2004.07 or EN 14164 (Type II)
Infant formula	Vitamin B6	CEN 14166 (Aggregates free and bound pyridoxal, pyridoxine and pyridoxine and measures as pyridoxine)	Microbioassay	III	----	HPLC – Fluorescence like AOAC 2004.07 or EN 14164 (Type II)

Commodity	Provision	Method	Principle	Type	Propose to remove or change	Possible method proposed
Special foods	Vitamin B6	AOAC 961.15	Microbioassay	II	type III	HPLC-Fluorescence like AOAC 2004.07 or EN 14164 (Type II) and EN 14663 (includes glycosylated forms) (Free and bound hosphorylated and glycosylated forms measured as the individual forms pyridoxal, pyridoxine and pyridoxamine), HPLC fluorometric method, (Type III)

VITAMIN B12: COBALAMIN

Commodity	Provision	Method	Principle	Type	Propose to remove or change	Possible method proposed
Special foods	Vitamin B12	AOAC 952.20	Microbioassay	II	Type III	HPLC-UV AOAC 2011.10 / ISO 20634 (Type II)
Infant Milk formula	Vitamin B12	AOAC 986.23	Bioassay-Turbidimetric	II	Type III	HPLC UV AOAC 2011.10 / ISO 20634 (Type II)

VITAMIN D: ERGOCALCIFEROL (D2) & cholecalciferol (D3), OTHERS

Commodity	Provision	Method	Principle	Type	Propose to remove or Change	Possible method proposed
Special foods	Vitamin D	AOAC 936.14	Rat bioassay	IV	----	HPLC method like EN 12821(Type II)

PROJECT DOCUMENT FOR NEW WORK ON THE NEW FORMAT TO CODEX STAN 234-1999

RECOMMENDED METHODS OF ANALYSIS AND SAMPLING

1. Purpose and scope of the proposed standard

The purpose of the proposed new work is to amend the Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999) to the normal format for a standard, including a preamble and other relevant information, scope and use of the Standard.

2. Relevance and timeliness

The methods of analysis listed in Codex standards are primarily intended as methods for the verification of provisions in Codex standards. In this context, it is critical to keep updating the methods of analysis in a single document or a single database, which would allow a simplified and effective search for method as well as a permanent and dynamic revision system. The CCMAS supported CODEX STAN 234 as a single reference for methods of analysis and proposed that CODEX STAN 234 be amended to the normal format for a standard, i.e. to include a preamble and other relevant information as to the scope and use of the Standard. The *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995) or the *General Standard for Food Additives* (CODEX STAN 192-1995) could be used as examples for the amendment.

3. The main aspects to be covered

A number of changes will be considered such as the inclusion of a preamble, scope and other relevant information to the use of the standard as well as establishing a new structure with a format that allows cross references with commodities standards.

4. An assessment against the *Criteria for the Establishment of Work Priorities*

General Criterion: Consumer protection from the view of health, food safety, ensuring fair practices in food trade and taking into account the identified needs of developing countries.

The proposed work falls under the general criterion for establishment of work priorities, because the use of the Code will strengthen protection of consumers by ensuring food safety. This work also seeks to promote fair practices in food trade taking into account the identified needs of developing countries.

The proposed work is directed primarily to provide a trusted source of information regarding methods of analysis in a single document or a single database, which would allow the verification of provisions in Codex standards.

Criteria applicable to general subjects:

a) Diversification of national legislations and apparent resultant or potential impediments to international trade:

It is covered by the preceding paragraph.

b) Scope of work and establishment of priorities between the various sections of work:

See above section on purpose and scope.

c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies):

No other similar work has been undertaken by other international organizations.

d) Amenability of the subject of the proposal to standardisation:

It is amenable to standardization since the CODEX STAN 234-1999 is already adopted, and the revisions will be simply to streamline information and make it readily available. Thus, there should be no problem with standardization.

e) Consideration of the global magnitude of the problem or issue:

It is covered by the preceding paragraph.

5. Relevance to Codex strategic objectives

The proposed work falls under 3 Codex Strategic Goals:

Strategic goal 1. Establish international food standards that address current and emerging food issues: the standard intents to verify the provisions in Codex standards.

Strategic goal 2. Ensure the application of risk analysis principles in the development of Codex standards: this work will help in risk management activities, providing a single source of methods of analysis in case of dispute and for inspection and control program.

Strategic goal 4. Implement effective and efficient work management system and practices: making readily available a single trusted source of Methods of Analysis.

6. Information on the relation between the proposal and other existing Codex documents

This standard will build on the Procedure Manual and the CODEX STAN 234-1999 Recommended Methods of Analysis and Sampling

7. Identification of any requirement for and availability of expert scientific advice

Additional scientific advice is not necessary at this moment.

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for

There is no need for additional technical input from external bodies.

9. Proposed timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the timeframe for developing a standard should normally not exceed five years

Work to start in 2018 with adoption at Step 5 and final adoption in 2020.

INFORMATION DOCUMENT ON PRACTICAL EXAMPLES OF SAMPLING PLANS

(For publication on Codex website)

This Information Document provides help in choosing appropriate sampling plans. These sampling plans are examples and should not be regarded as prescriptive. Each example is one option for the particular situation. Commodity committees may find alternative plans that are more appropriate.

Therefore, they do not present fixed values but give reference to correspondent passages of the standards.

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.

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.

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 versus measure / 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.

Table 1: Code of 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 2: Example sampling plans

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	**Consumer:** CAC/GL 50 section 3.1, see specifically ISO 2859-2:1985 Sampling: 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. 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. Decision: For given limiting quality (LQ) and number of samples *n*, a lot is compliant if the number of items with visible defects is less than the Rejection number Re (Tables A, D4). **Producer:** ISO 2859-2:1985: Sampling: see "Consumer" Decision: 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 Ac (Table A).	**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 Sampling: 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. 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. 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.

| | | | | 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.
Switching rules:
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). When tightened inspection is being carried out, normal inspection shall be re-instated when five consecutive lots have been considered acceptable on original inspection.
The outline of the switching rules is shown in Figure 1.
Decision:
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 is less than not the Rejection number Re (Tables 1 and 2 e.g. for single sampling).
Producer:
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
Sampling: see "Consumer"
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). |
| | | | NMKL procedure no 12. (Annex - Section 4):

Figure 1: Levels of inspection and the switching between those.

⬚ Tighten Inspection | |

No rejections in 5 consecutive lots	↺		↻	2 rejections in 5 consecutive lots
		Normal Inspection		
Start here ⇒				
No rejection in 10 lots	↺		↻	1 rejection
		Reduced Inspection		

| MI-Q | Fat content in Milkproducts | Variables Plan Prerequisites:
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 σ_μ no more than 1/10 of the sample standard deviation s or process standard deviation σ.
In the case that the measurement error is significant, the sampling number n should be increased by
$n^* = n(1+\gamma^2)$ where
$\gamma = \sigma_\mu/\sigma$ ISO 3951-1:2013, Annex O) | **Consumer and Producer:**
ISO 3951-1:2013: Sampling procedures for inspection by variables – Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL
Sampling:
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.
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.
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 2859-2:2010 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).
Summary table 1 directs users to the paragraphs and tables concerning any situation with which they may be confronted.
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.
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), the procedure for obtaining and implementing a plan is as follows. |

		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	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. 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. c) Take a random sample of size n, measure the characteristic x in each item and then calculate 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 x is outside the specification limit(s). 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) the procedure for obtaining and implementing a plan is as follows. a) From Table A.1 the sample-size code letter is obtained. b) 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. c) Take a random sample of this size, measure the characteristic under inspection for all items of the sample and calculate the mean value. 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). Decision: 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). If single upper or lower specification limits (U or L) are given, calculate the quality statistic $Q_U=(U-x)/s$ or $Q_L=(x-L)/s$ where x the sample mean and s, the sample standard deviation. The lot is acceptable if $Q_U \geq k$ or $Q_L \geq k$ respectively. For the "σ" method, s must be replaced by σ
FO-Q	water content in butter	Variables Plan Prerequisites: see example MI-Q	**Consumer and Producer:** see MI-Q Sampling: see example MI-Q Decision: 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. See also example MI-Q

F-Q	Net weight in prepackaged fish	Special Plan	**Consumer and Producer:** OIML R 87 (Edition 2004)[b]: Quantity of product in prepackages <u>Sampling:</u> see Table 1: Sampling plans for prepackages <u>Decision:</u> 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: 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: 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. 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. 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). 3. No package contains an actual quantity less than the nominal quantity minus twice the tolerable deficiency.
M-Q	Nonmeat Protein in Meat products	Variables Plan Prerequisites: see example MI-Q	**Consumer and Producer:** see MI-Q <u>Sampling:</u> see example MI-Q <u>Decision:</u> 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. See also example MI-Q
MW-Q	Sodium content of prepackaged Mineral Water	Variables Plan Prerequisites: see example MI-Q	**Consumer and Producer:** see MI-Q <u>Sampling:</u> see example MI-Q <u>Decision:</u> 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. See also example MI-Q
C-Q	Moisture in rice grains	Variables Plan on Bulk Material Sampling uncertainty implemented	**Consumer and Producer:** 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 Sampling: see example C-C 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 $\bar{x} = m_L + \gamma D$
FV-FH	*E. coli* in Frozen vegetables and fruits	Three-class attributes Plan	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 Sampling: See Table 28: Sampling plans and recommended microbiological limits for vegetables, fruits, nuts, and yeast Decision: The lot is accepted if not more than 2 items of 5 samples show the presence of *E. coli* with a concentration between 100 and 1000 CFU/g. The lot is rejected in the opposite case.
M-FH	*Staphylococcus aureus* in fresh or frozen poultry meat	Three-class attributes Plan	**Consumer and Producer:** 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 Sampling: see Table 22: Sampling plans and recommended microbiological limits for poultry and poultry products Decision: The lot is accepted if not more than 1 item of 5 samples shows the presence of *Staphylococcus aureus* with a concentration between 1000 and 10.000 CFU/g. The lot is rejected in the opposite case.
F-FH	*Listeria monocytogenes* in smoked fish – ready-to-eat	Two-class attributes Plan	**Consumer and Producer:** CAC/GL 50-2004 section 3.2 and NMKL Procedure No 12, Annex – section 3 (tables 3 and 4), see specifically CODEX STAN 311-2013 *Standard for smoked fish, smoke-flavoured fish and smoke-dried fish*, section 6.4. Sampling:See CAC/GL 61-2007 Guidelines on the application of general principles of food hygiene to the control of listeria monocytogenes in foods - Annex II Table 1 and 2 Decision: See CAC/GL 61-2007 Guidelines on the application of general principles of food hygiene to the control of listeria monocytogenes in foods - Annex III
MI-FH	*Staph. aureus* in Cheese, 'hard' and 'semi-soft' types	Two-class attributes Plan	**Consumer and Producer:** CAC/GL 50 section 3.2, see specifically: ICMSF (1986)[a)]: Chapter 15 Sampling plans for milk and milk products Sampling: see Table 24: Sampling plans and recommended microbiological limits for dried milk and cheese Decision:

			The lot is accepted if no item out of 5 samples show the presence of *Staph. aureus* in 1g, where the concentration is higher than 10.000 CFU/g. The lot is rejected in the opposite case.
MW-FH	Microorganisms in Natural Mineral Water	Two-class attributes Plan	**Consumer and Producer:** CAC/RCP 33-1985: *Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters* (see also ICMSF (1986)[a)]: Chapter 25: Sampling plans for natural mineral waters, other bottled waters, process waters, and ice.) Sampling and Decision: Annex I: Microbiological Criteria, Table: Microbiological Criteria, Point of application: at source, during production and end product. 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.
FV-P	Pesticides Residues in Apples for Compliance with MRL	Variables Plan sampling uncertainty not applicable	**Consumer and Producer:** CAC/GL33-1999: *Recommended Methods Of Sampling For The Determination Of Pesticide Residues For Compliance With MRLS* Sampling: 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. 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. Decision: 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.
FO-P	Pesticides Residues in vegetable oils	Variables Plan sampling uncertainty not applicable	**Consumer and Producer:** CAC/GL33-1999: *Recommended Methods Of Sampling For The Determination Of Pesticide Residues For Compliance With MRLS* Sampling: 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. 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. <u>Decision:</u> see FV-P
MI-P	Pesticides Residues in Cheeses, including processed cheeses units 0.3 kg or greater	Variables Plan sampling uncertainty not applicable	**Consumer and Producer:** CAC/GL33-1999: *Recommended Methods Of Sampling For The Determination Of Pesticide Residues For Compliance With MRLS* <u>Sampling:</u> 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. 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. <u>Decision:</u> see FV-P
M-P	Fat soluble Pesticides Residues in cattle carcass for Compliance with MRL	Variables Plan Sampling uncertainty not applicable	**Consumer and Producer:** CAC/GL33-1999: *Recommended Methods Of Sampling For The Determination Of Pesticide Residues For Compliance With MRLS* <u>Sampling:</u> 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. 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. <u>Decision:</u> see FV-P

C-P	Pesticides Residues in rice grains		**Consumer and Producer:** CAC/GL33-1999: *Recommended Methods Of Sampling For The Determination Of Pesticide Residues For Compliance With MRLS* <u>Sampling</u>: 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. 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. <u>Decision</u>: see FV-P
FV-C1	Aflatoxin in ready-to-eat Treenuts	Variables Plan on Bulk Material Sampling, sample preparation, and analytical variances used to compute operating characteristic curves	**Consumer and Producer:** CODEX STAN 193-1995: General Standard For Contaminants And Toxins In Food And Feed <u>Sampling</u>: 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 sublot should not exceed 25 tonnes. The minimum lot weight should be 500 kg. Representative sampling should be carried out from the same lot. In the case of *static lots* 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. In the case of *dynamic lots*, 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. 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. <u>Decision</u>: 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.

FV-C2	Total Aflatoxins in Peanuts intended for further Processing	Variables Plan on Bulk Material Sampling, sample preparation, and analytical variances used to compute operating characteristic curves	**Consumer and Producer:** CODEX STAN 193-1995: *General Standard For Contaminants And Toxins In Food And Feed* <ins>Sampling:</ins> 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). For the sampling procedure see example FV-C1. 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. <ins>Decision:</ins> If the aflatoxin test result is less than or equal to 15 µg/kg total aflatoxin in the test sample, the lot is accepted.
FO-C	Erucic acid in vegetable Oil (bulk)		**Consumer and Producer:** 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 <ins>Sampling:</ins> see example C-C <ins>Decision:</ins> see example C-C for a given maximum limit m_L, the lot is accepted if the sample grand average of these results $\bar{x}$ is lower than an upper acceptance value $\bar{x} = m_L + \gamma\, D$.
F-C	Dioxins and dioxin like PCB´s in Fish (individual packages or units)	Variables Plan Sampling uncertainty implemented	**Consumer and Producer:** ISO 3951-1:2013: Sampling procedures for inspection by variables – Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL <ins>Sampling:</ins> Since the Dioxin content usually is not process controlled, 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), the procedure for obtaining and implementing a plan is as follows. 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.

			b) For a single specification limit U (the ML for Dioxins and dioxin like PCB's), enter Table B.1, B.2 or B.3 as appropriate with this code letter and the (usually low) AQL, and obtain the sample size n and the acceptability constant k. 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). Decision: calculate the quality statistic $Q_U=(U-\bar{x})/s$ The lot is acceptable if $Q_U \geq k$
MI-C	Aflatoxin M1 in Milk (bulk)		**Consumer and Producer:** 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 CODEX STAN 193-1995: *General Standard For Contaminants And Toxins In Food And Feed* Sampling: see example C-C Decision: see example C-C for the given maximum limit m_L=0.5 µg/kg (CODEX STAN 193-1995: *General Standard for Contaminants and Toxins in Food and Feed*), the lot is accepted if the sample grand average of these results $\bar{x}$ is lower than an upper acceptance value $\bar{x} = m_L + \gamma D$.
M-C	benzo(a)pyrene in meat	Variables Plan Sampling uncertainty implemented	**Consumer and Producer:** ISO 3951-1:2013: Sampling procedures for inspection by variables – Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL Sampling: see Mi-Q 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. 3. 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), The procedure for obtaining and implementing a plan is as follows. 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. b) 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.

			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, the lot can be judged unacceptable without even calculating s if $\bar{x}$ exceeds the specification limit. 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) the procedure for obtaining and implementing a plan is as follows. 4. 5. a) From Table A.1 the sample-size code letter is obtained. 6. 7. b) 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. 8. c) Take a random sample of this size, measure the characteristic under inspection for all items of the sample and calculate the mean value. 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). <u>Decision:</u> calculate the quality statistic $Q_U=(U-\bar{x})/s$ The lot is acceptable if $Q_U \geq k$ For the "σ" method, s must be replaced by σ
MW-C	Arsenic in Natural Mineral Water	Variables Plan on Bulk Material Sampling uncertainty implemented	**Consumer and Producer:** 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 CODEX STAN 193-1995: *General Standard For Contaminants And Toxins In Food And Feed* <u>Sampling:</u> see example C-C <u>Decision:</u> see example C-C for the given maximum limit m_L=0.01 mg/kg (CODEX STAN 193-1995: *General Standard for Contaminants and Toxins in Food and Feed*), the lot is accepted if the sample grand average of these results $\bar{x}$ is lower than an upper acceptance value $\bar{x} = m_L + \gamma\, D$.
C-C	Cadmium content in wheat	Variables Plan on Bulk Material Sampling uncertainty implemented	**Consumer and Producer:** 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 <u>Sampling:</u> sampling from a commodity is classified into two different procedural types: • 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. 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. 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 α 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). For imprecise standard deviations, one measurement per test sample should be performed (ISO 10725:2000, 6.3.2.2). 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. <u>Decision:</u> 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). Taking into account the discrimination interval $D = (K_\alpha + K_\beta) \sigma_E$ (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 α of wrongly accepting a nonconforming lot. 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 $\bar{y} = m_A + \gamma D$ with the constant for obtaining the acceptance value $\gamma = K_\alpha/ (K_\alpha + K_\beta)$.
FO-R	Residues of Veterinary Drugs in Fat	Variables Plan sampling uncertainty not applicable	**Consumer and Producer:** 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 Sampling: See example F-R, The minimum quantity required for laboratory samples is 500 g (Table A II Group 031). Decision: see example F-R
F-R	Residues of Veterinary Drugs in Packaged Fish	Variables Plan Sampling uncertainty not applicable	**Consumer and Producer:** 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* Sampling: 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. 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: $n = \ln(1\text{-}p) / \ln(1\text{-}i)$ Where p is the probability to detect a non-compliant residue (e.g. 0.95), it is the supposed incidence of non-compliant residues (e.g. 0.10) in the lot. 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. 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). Decision: 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.

Mi-R	Residues of Veterinary Drugs in Raw Milk	Variables Plan on Bulk Material Sampling uncertainty not applicable	**Consumer and Producer:** 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* Sampling: See example F-R, The minimum quantity required for laboratory samples is 500 mL (Table B I Group 033). Decision: See example F-R
M-R	Residues of Veterinary Drugs in Meat/Meat products	Variables Plan sampling uncertainty not applicable	Consumer and Producer: 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* Sampling: See example F-R, The minimum quantity required for laboratory samples is 500 g (Table A I Group 030). Decision: See example F-R

[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)