

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
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World Health
Organization

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REP19/MAS

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

42nd Session

Geneva, Switzerland, 8 - 7 July 2019

**REPORT OF THE 40th SESSION OF
THE CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING**

Budapest, Hungary

27 - 31 May 2019

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SUMMARY AND STATUS OF WORK

Responsible Party	Purpose	Text / Topic	Code / Reference	Step	Para(s)
Members CCEXEC77 CAC42	Adoption / Revocation	Methods of analysis / performance criteria for provisions in Codex standards	CXS 234 - 1999	-	9 Appendix II, Parts 1 and 2
CAC42	Editorial amendments	Methods of analysis for provisions in Codex standards	CXS 234 - 1999	-	Para. 16 Appendix II, Part 3
Members CCEXEC77 CAC42	Adoption	Preamble and document structure for the <i>General Standard on Methods of Analysis and Sampling</i>	CXS 234 – 1999	5/8	61, Appendix III
		<i>Guidelines on Measurement Uncertainty</i>	CXG 54 – 2004	5	66, Appendix IV
CCNFSDU	Action	Methods performance criteria / method for vitamin K in follow up formula	CXS 72-1981 / CXS 156 - 1987	-	10 – 11
CCSCH	Action	Methods of analysis in various standards for spices and culinary herbs	CXS 234 – 1999	-	12 – 14
Codex Secretariat / CAC42 / CCEXEC77	Publication / information	Guidance on endorsement	-	-	51
EWG (USA / NZ) / PWG on endorsement CCMAS41	Review / update	Dairy workable package	CXS 234 - 1999	-	28i
EWG (The Netherlands) / PWG on endorsement CCMAS41	Review / update	Fats and oils workable package	CXS 234 – 1999	-	28ii
AACCI, AOAC, ISO / PWG on endorsement CCMAS41	Review / update	Cereals, pulses and legumes workable packages	CXS 234 - 1999	-	28iii
PWG (USA / Australia) CCMAS41	Endorsement	Methods of analysis and sampling and other related matters	CXS 234 – 1999	-	28iv
Switzerland CCMAS41	Drafting Discussion	Criteria to select Type II methods from multiple Type III methods	CXS 234 – 1999	-	38
Germany CCMAS41	Drafting Discussion	Information document: support the application of <i>Guidelines on Measurement Uncertainty</i>	-	-	66
EWG (NZ / USA) CCMAS41	Drafting Comments Discussion	Revision of the <i>Guidelines on Sampling</i>	CXG 50 - 2004	2/3	80

Responsible Party	Purpose	Text / Topic	Code / Reference	Step	Para(s)
All Committees	Information	Review and update of the General Standard for Methods of Analysis and Sampling / database	CXS 234 – 1999	-	92 i
CCFH / CCPR / CCRVDF	Information / consideration	CCMAS nodal committee for methods of analysis and sampling / links to methods of analysis / performance criteria	CXS 234 – 1999	-	92 ii, iii
CCCF / CCFA / CCFH	Consideration	Transfer of methods to CXS 234 / update / revoke	CXS 228, 239 and 231	-	92 iv, v
CCCF	Consideration Information	Identify methods of analysis / performance criteria for contaminants	CXS 193 - 1995 / CXS 234 – 1999	-	92 vi
Hungarian Secretariat CCMAS42	Information	Information document of provisions updated since CCMAS40 (new format)	CXS 234 - 1999	-	52

LIST OF ABBREVIATIONS

AACCI	The American Association of Cereal Chemists International
AOAC	AOAC International (formerly known as Association of Official Agricultural Chemists)
AOCS	American Oil Chemists' Society
CAC	Codex Alimentarius Commission
CCCF	Committee on Contaminants in Foods
CCFH	Committee on Food Hygiene
CCFICS	Committee on Import and Export Food Inspection and Certification Systems
CCFO	Committee on Fats and Oils
CCMAS	Committee on Methods of Analysis and Sampling
CCNFSDU	Committee on Nutrition and Foods for Special Dietary Uses
CCPR	Committee on Pesticide Residues
CCRVDF	Committee on Residues of Veterinary Drugs in Foods
CCSCH	Committee on Spices and Culinary Herbs
CRD	Conference room document
EU	European Union
EWG	Electronic working group
HPLC	High performance liquid chromatography
IAM	Interagency Meeting
IDF	International Dairy Federation
ISO	International Organization for Standardization
NFCSO	National Food Chain Safety Office (Hungary)
MC	Microbiological criterion
ML	Maximum level
MRL	Maximum residue limit
MU	Measurement uncertainty
PWG	Physical working group
ROK	Republic of Korea
SDO	Standards development organisations
UK	United Kingdom
USA	United States of America
USPC	United States Pharmacopeial Convention
WG	Working group

INTRODUCTION

1. The Codex Committee on Methods of Analysis and Sampling (CCMAS) held its 40th Session in Budapest, Hungary, from 27 to 31 May 2019, at the kind invitation of the Government of Hungary. The Session was chaired by Dr. Attila Nagy, director, National Food Chain Safety Office (NFCSO) and Dr Andrea Zentai, Food Safety Analyst (NFCSO), acted as the Vice-Chairperson. The Session was attended by 49 Member countries and 1 Member organization and 12 observer organizations. A list of participants is given in Appendix I.

OPENING OF THE SESSION

2. The Session was opened by Dr Márton Oravecz, President of the National Food Chain Safety Office who welcomed delegates to Hungary. Dr. Márton Oravecz, reminded the Committee of the importance of Codex standards considering global food trade and rapid development of food technologies, furthermore, the importance of accuracy and elaboration of data, and wished the Committee successful deliberations. Ms. Mary Kenny, Regional Office for Europe and Central Asia (REU) of the Food and Agriculture Organization of the United Nations (FAO) and Dr. Ledia Lazeri, Regional Office for Europe of World Health Organization (WHO) also addressed the Committee.

Division of Competence¹

3. CCMAS 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

4. CCMAS adopted the Provisional Agenda with the addition under Item 9, "Other Business and Future work" of CCMAS Nodal Committee for all analytical methods with Codex provisions (IAM).³

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER SUBSIDIARY BODIES (Agenda Item 2)⁴

5. CCMAS noted the matters were for information only.

Sampling plans related to histamine food safety in fish commodities

6. CCMAS welcomed the information that CCFH would take into consideration of the revision of CXG 50-2004 when they consider the sampling plans of histamine in fish commodity.
7. A delegation also pointed out that the challenge faced by CCFH on achieving a balance between consumer protection, feasibility and practicability was a risk management decision that should be taken by CCFH and not CCMAS.

Food integrity and food authenticity

8. A delegation drew the attention of the Committee to the Food Authenticity Network and offered to share further information with interested delegates.

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

9. CCMAS considered the recommendations on methods of analysis proposed for endorsement and other related matters as presented in CRD2. CCMAS agreed with some of the recommendations of the PWG that met prior to the plenary session and made the following amendments or recommendations. All decisions are presented in Appendix II.

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

Methods of analysis for provisions in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CXS 72-1981)

10. CCMAS agreed to:

¹ CRD1

² CX/MAS 19/40/1

³ CRD4

⁴ CX/MAS 19/40/2

⁵ CX/MAS 19/40/3; CX/MAS 19/40/3-Add.1; CX/MAS 19/40/3-Add.2; CX/MAS 19/40/3-Add.3; CRD2 (Report of the PWG on endorsement); CRD5 (AOAC, ISO and IDF); CRD6 (AOAC/IDF/ISO and IDF/ISO); CRD14 (EU); CRD15 (Uruguay); CRD16 (Kenya); CRD17 (AACC-AOAC); CRD18 (Ghana); CRD19 (ISO); CRD23 (Argentina)

- also endorse the AOAC 2011.14 / ISO 15151 | IDF 229 as a Type III method for calcium, copper, iron, magnesium, manganese, phosphorous, potassium, sodium and zinc, but that the methods should be referred to CCNFSDU for their concurrence before submission to CAC for adoption;
- recommend that CCNFSDU:
 - consider establishing numerical method performance criteria for calcium, copper, iron, magnesium, manganese, phosphorous, potassium, sodium and zinc, and identify appropriate methods that meet the criteria; and
 - consider whether the methods for Vitamin K in follow-up formula currently in CXS 234 (AOAC 999.15 / EN 14148) should be replaced by the methods just endorsed as a Type II methods for infant formula (i.e. AOAC 2015.09 / ISO 21446).

11. CCMAS noted that there were questions about the applicability of ISO 8070 | IDF 119 to infant formula and whether typing as Type III or Type IV was appropriate and that the PWG had retained the methods as Type III, but should be reviewed either during the establishment of method performance criteria by CCNFSDU or at CCMAS41. Similarly questions on other methods for minerals (e.g. AOAC 985.35) arose and the same approach would be followed as for ISO 8070 | IDF 119.

Committee on Spices and Culinary Herbs (CCSCH)

Methods of analysis in standards for dried or dehydrated garlic, dried oregano, dried root, rhizomes and bulbs – dried or dehydrated ginger, dried basil, dried floral parts – dried cloves, and saffron

12. CCMAS did not endorse the methods of analysis submitted by CCSCH, and noted that several methods were submitted for endorsement as Type I methods, even though the methods were not identical. CCMAS agreed on the selections of methods of analysis proposed by the PWG as possible examples for consideration by CCSCH in their reconsideration of methods of analysis. These recommendations were similar to those previously endorsed for other standards developed by CCSCH.
13. CCMAS agreed that CCSCH should note:
- The provisions such as total ash and acid insoluble ash, and volatile oils (plus other chemical characteristic provisions) were listed as “on dry basis” in the standard(s) and therefore this must be captured in the provision in CXS 234 and requires a calculation from a determination of moisture prior to ashing or volatile oil determinations. These steps must be captured in CXS 234.
 - It was important to establish and utilize consistent provisions and terminology when possible. For example: either ‘mammalian excreta’ or “excreta mammalian” should be selected. It was noted that mammalian excreta was used in previous CCSCH tables and endorsed by CCMAS.
 - Similarly, “extraneous matter” and “extraneous vegetable matter” seems to be used interchangeably and requires clarification.
 - In the draft standard(s) the specification for mammalian excreta is established on a w/w basis (mg/kg), while in the methods it referred to units of particle/w (particle/10g) for AOAC 993.27.
 - References to methods, including formatting and hyperlinks need to be consistent to ensure that the correct methods are being referenced.
14. The Committee encouraged delegations to CCMAS to liaise with their counterparts to CCSCH on methods of analysis, India as the lead country on spices and culinary herbs in both Codex and ISO to better coordinate work on methods of analysis for these products, and that equally the Codex Secretariat should ensure that guidance is given to CCSCH on how to present methods of analysis for endorsement taking into account the guidance provided in the Procedural Manual.

Committee on Fats and Oils (CCFO)

Methods of analysis for acid value and free fatty acids for virgin palm oil and crude palm kernel oil

15. CCMAS noted the explanation provided by the Observer from AOCS that the three methods ISO 660 / AOCS Cd 3d-63 / AOCS Ca 5a-40 could be used to calculate both acid value and free fatty acids. Each of the methods used an alkali titrant and indicators that change colour as the pH changes. He reported that AOCS 5a-40 used an indicator that comes closest to neutral pH and the same applied to ISO 660. The Observer further noted that while the methods might not fully meet the definition for “identical”, from the chemical point of view, they could be considered identical and would provide the same result. Based on this explanation, CCMAS agreed to endorse the three methods for both acid value and free fatty acids.

Dairy Workable Package

16. CCMAS agreed with the recommendations as proposed by the PWG. CCMAS noted that for several provisions in milk and milk product commodities that require calculation using for example, total solids content, fat content, protein content, dry matter content, the addition of methods for these determinations would be considered editorial in nature in order to avoid giving the impression that the methods for the provisions had been reviewed for their fitness for purpose. These methods were contained in the table for further review and update in the next round of review of the dairy workable package.
17. Concerns were raised on the inclusion of ISO 5537 | IDF 26 as the methodology required for determination of moisture was sophisticated, was limited to do analysis in powders, and that other methods were available for such determinations for which validation data were available. To address this concern, CCMAS agreed to request that the further review of methods for moisture should be applicable to all milk and milk products. Further consideration would be given to ISO 5537 | IDF 26 method in the next round of the review of the dairy workable package and the table listing those methods requiring review was amended accordingly.
18. Discussion was also held on the appropriateness to retype the methods for determination of lead in certain commodities as Type IV, noting that these methods were not fit for purpose. It was proposed that the methods should be retained as Type II while it was further reviewed during the next round of review of the dairy workable package or that CCCF should be requested to establish methods performance criteria. However, it was noted that retaining the methods as Type II would give the impression that the methods were fully validated and not give tentative results. Retyping the methods to Type IV would signal to the analyst that the results were tentative. Further consideration would be given to these methods in the next round of the review of the dairy workable package.
19. CCMAS agreed to the recommendation to retype the methods for lead as Type IV, that further consideration of these methods would be given in the review of the dairy workable package and to keep CCCF informed of this discussion in relation to decision taken on CXS 228 (see Agenda item 9).
20. CCMAS noted the concern that the method for milk fat purity, ISO 17678 | IDF 202, was not fit for purpose and not applicable to all milk products. The Observer from IDF informed the Committee that while the method included some restrictions, it was still fit for purpose and that further consideration of the method could be done in the next round of discussions on the review of the remaining dairy package.
21. CCMAS further agreed to add the methods for peroxide value in milkfat products, milkfat purity in milkfat products and butter and dairy spreads to the table on future review.
22. A recommendation was made for the endorsement of an ELISA method for the detection of melamine in milk and milk products. CCMAS noted that melamine in milk and milk products methods would be considered in a future review and encouraged the submission of validated methods and appropriate performance data for consideration at CCMAS41.

Cereals, pulses and legumes workable package

23. CCMAS agreed to refer the proposal for methods of analysis for gluten free as presented in CX/MAS 19/40/3 Add.2 to CCNFSDU for their consideration.
24. The Observer from AO ECS supported that consideration and discussion should take place in CCNFSDU and highlighted the importance not to change the commodity "gluten-free foods". Additional to special gluten-free dietary products, the claim "gluten-free" was also permitted for foods for normal consumption in the *Standard for foods for special dietary use for persons intolerant to gluten* (CXS 118-1979) (section 4.3) and in several national food legislations. The gluten-free market was increasing rapidly in the world trade, therefore it was essential for avoiding health problems of coeliacs and trade barriers to use the same and most reliable method for gluten determination.
25. CCMAS also noted a comment that CCNFSDU should consider a general reference to CXS 234 in section 5 on methods of analysis in *Standard for foods for special dietary use for persons intolerant to gluten* (CXS 118-1979), in accordance with the Procedural Manual.
26. CCMAS further agreed that the methods for "gluten free" would not be considered in the continued review of the methods of analysis in the cereals, pulses and legumes workable package.

Fats and Oils Workable Package

27. CCMAS noted that the review of the workable package on fats and oils would continue and that the table of methods presented in CX/MAS 19/40/3 Add.3 would serve as basis for this further consideration.

Conclusion

28. CCMAS agreed:
- i. To establish an EWG chaired by USA and co-chaired by New Zealand working in English to continue with the review of the dairy workable package and to work in close coordination with the relevant SDOs.
 - ii. To establish an EWG chaired by the Netherlands working in English, to review the fats and oils workable package, using CX/MAS 19/40/3 Add.3 as the basis for the review, and to work in close coordination with the relevant SDOs.
 - iii. The AACCI with assistance from AOAC and ISO would continue working on the cereals, pulses and legumes working packages and present reports (or preliminary reports) for consideration by the next session.
 - iv. To establish the PWG on endorsement, chaired by USA and co-chaired by Australia, working in English, to meet immediately prior to the next session to consider all methods of analysis and sampling submitted for endorsement by Codex Committees, including the proposals on the workable packages: dairy, fats and oils, and cereals, pulses and legumes.

GUIDANCE ON ENDORSEMENT (Agenda Item 4)⁶

29. The United States of America, as Chair of the EWG, introduced the item and recalled the background to the work, outlined the process followed by the EWG and informed the Committee that a draft Guidance was presented in Appendix I of CX/MAS 19/40/4. The proposed Guidance used the Procedural Manual as a framework, and intended to capture and clarify the current CCMAS process and provide guidance on the outcome of definitions/decisions based on past CCMAS practices. However, key outstanding questions needed to be addressed in order to finalise the Guidance.

30. The Committee agreed to consider the outstanding questions identified by the EWG.

Definition of identical

31. CCMAS noted that there was still confusion on how available validation data influences whether two methods could be defined as identical and that clarity around the use of validation data was necessary. CCMAS agreed that while equivalent validation data (i.e. same matrices had been used during validation) for two identical methods was preferable, the lack of such equivalent data did not in itself prevent the methods from being identical.
32. CCMAS noted that the proposed definition was too restrictive and not practical, and if the current definition were used, many methods with a long history of use in trade would be removed from CXS 234 which could have ramifications for international trade.
33. CCMAS agreed that a more flexible nuanced definition should be developed (See para 50).

Type III method when no Type II exists / designation of multiple Type III methods

34. CCMAS noted that the Procedural Manual stipulates that Type II methods should be selected from Type III methods which would imply that a method cannot be endorsed directly as a Type II because it must first be adopted as a Type III before it can be "selected from Type III methods".
35. CCMAS agreed that it was not the intention of the Procedural Manual that methods must be adopted as Type III methods before they can be considered for endorsement as Type II. CCMAS noted that the Committee had been endorsing methods directly as Type II, since the definitions of method Type were developed.
36. CCMAS also discussed the statement in the draft Guidance Document "*Type III methods cannot exist without a Type II method*". Some delegates had supported this idea, while others had expressed concern that a method which meets the definition for Type III might still not be suitable as the Type II reference method, perhaps due to equipment supply issues or environmental concerns.
37. CCMAS agreed that the statement "*Type III methods cannot exist without a Type II method*" should remain in the document and that if a method was not yet appropriate as a Type II, then it could be endorsed as a Type IV, until all concerns about the method were addressed.

⁶ CX/MAS 19/40/4; CRD8 (ROK); CRD12 (Thailand); CRD14 (EU); CRD16 (Kenya); CRD18 (Ghana); CRD27 (revised comprehensive guidance for the process of submission, consideration and endorsement of methods for inclusion in CXS 234)

38. CCMAS noted that when there are multiple Type III methods it was unclear what criteria were used to determine which method should be endorsed as Type II. The Committee also noted that it was unclear how often and in what situations, the selection of a Type II method from multiple Type III methods occurs. In view of this, CCMAS agreed that Switzerland would prepare a discussion paper to investigate the extent of the problem with multiple Type III methods in CXS 234 and consider the need and feasibility to establish criteria to assist with the selection of a Type II method from multiple Type III methods.

Methods without specification in a Codex standard

39. The Committee noted that the “*General Criteria for the Selection of Methods of Analysis*” in the Procedural Manual was not specific to “provision” but was more wide ranging in stating “*All proposed methods of analysis must have direct pertinence to the Codex standard to which they are directed*”, however, in past discussions in the Committee, CCMAS had focused on the idea that there must be a provision in a standard in order to have a method listed in CXS 234. If a strict application of “provision” were applied, it could result in methods of analysis being removed from CXS 234 as they could not be linked to specific provisions in commodity standards.
40. The Secretariat clarified that the Procedural Manual did refer to identifying methods for provisions (see section *Relations between Commodity Committees and General Subject Committee*), but at no point did it refer to specific numerical provisions. She also noted that the Committee should proceed with caution especially in the review of methods coming from committees adjourned *sine die* as there might have been a rationale for the decisions at the time and simple removal of methods from CXS 234 could have implications for trade, and that it was necessary to first research and understand the background of the decisions. In future, it might be easier to link the proposals for methods with particular provisions (numerical or not) in standards.
41. The Committee agreed to apply the more wide-ranging statement from the Procedural Manual that methods must have a *direct pertinence* to the Codex standard to which they are directed; and that it should not be necessary to have a numerical provision to endorse a method noting that there were situations where a specific numerical provision might not be in a standard as was the case for determining authenticity of fruit juices.

Section 3.2 iiii. “It is not the role of CCMAS delegates to research the methods and determine if the method is fit for purpose, since this is the role of SDOs”

42. The Committee agreed that SDOs should provide information on methods to assist CCMAS to take the necessary decisions. The Committee further noted that the way information was provided in CRD5 was appropriate and should be used as a template for the future provision of information by SDOs. It was further noted that all documents should be made available at least 2 months prior to a session to allow sufficient time for consideration and consultation.

Changing Type I methods to Type IV

43. The Committee agreed that for current methods in CXS 234 it would not be practical to convert these methods to Type IV as it would have implications for trade. An observer noted that many of these methods were developed many years ago and providing validation data for such old methods would be problematic, and it would be difficult to get collaborative tests for these old methods. He noted that SDOs generally develop methods because trade organisations require such methods to be useful for international trade.
44. A delegation pointed out that concerns on retyping to Type IV were not warranted as Type IV methods could also be used for dispute settlement, if they were agreed by concerned parties. However, another delegation pointed out that if Type I methods were converted to Type IV in cases where there was no validation data then there would be no method to turn to in the case of a dispute.
45. Some other delegations pointed out that the PM did not address this issue adequately and that more reflection was needed on how to address this in the Procedural Manual. They further pointed out that they had validation data which could be submitted for review.
46. The Committee agreed that at this stage it would consider this matter on a case by case basis when considering the workable packages, recalling the decision taken at CCMAS39 that “*a general rule to extend or not extend the typing was not appropriate because the decision would depend on matrices involved as well as the analytical procedure. The typing determination should therefore be based on a case-by-case basis.*” (REP18/MAS, para 26)
47. It would also be up to SDOs to provide information and that weight should be given to their view.

Submission of methods of analysis to CCMAS when there is an active Codex Committees

48. CCMAS noted that when there are active Codex committees, methods of analysis should ideally be submitted to CCMAS by such active committees either through the “matters referred” or “methods for endorsement” items. However, if proposals were made directly to CCMAS, a recommendation should be made to the active committee for their agreement before submitting such methods to the Commission for adoption unless the changes were of editorial nature. The Committee was also reminded of a decision taken at CCMAS37 (REP16/MAS appendix IV) on an internal CCMAS process for methods of analysis updating and in this process it was agreed that active committees should be consulted.

Guidance on endorsement and template for information

49. CCMAS considered a revised guidance document (CRD27) and template for submission of information (CRD28) based on the agreements taken on the outstanding questions above.
50. In addition to editorial corrections, CCMAS agreed to further amend the definition for “identical” to explain that in cases where a standard contains multiple approaches to the determination but which are not separately identified, comparison with a second method with more prescriptive details will be carried out on a case by case basis to determine if the two methods may be considered identical. CCMAS also agreed to the removal of the term and definition of “mutually exclusive”, noting that by capturing the necessary information in the commodity description (e.g. Cottage Cheese (for samples containing lactose up to 5%)) the methods are no longer listed in the same row, thus making a “mutually exclusive” identifier unnecessary.

Conclusion

51. CCMAS agreed:
- i. to publish the guidance on endorsement including the template for submission of information as an Information Document for internal use by CCMAS (Appendix V); and
 - ii. the document would be a living document that could be revised if issues arose during the use of the guidance on endorsement.

REVISION OF THE CODEX GENERAL STANDARD FOR METHODS OF ANALYSIS AND SAMPLING (CXS 234-1999): PREAMBLE AND STRUCTURE (Agenda Item 5)⁷

52. Brazil, as Chair of the EWG, and also on behalf of Uruguay as co-Chair, introduced the item and summarized the key points of discussion and revisions made to the preamble and structure in the PWG held prior to the plenary based on written comments submitted to this Session and discussions in the PWG, for example.
- The Preamble states that all Codex methods can be used for any purpose (including trade disputes when relevant parties agree).
 - The definitions are limited to those strictly necessary for the purposes of CXS 234 and cross-references to relevant Codex texts are used for other definitions such as for types of methods of analysis for consistency.
 - The term “attribute” is a broader term to define provisions in Codex standards associated to a methods of analysis.
 - The revised structure of CXS 234 lists all methods of analysis in the same table and uses hyperlinks to display those Codex methods (CX/RM) that should be described in the CXS 234 and method performance criteria (MPC) associated to a provision in a Codex standard.
 - The searchable database on methods of analysis and sampling will be developed by the Codex Secretariat and be available on the Codex website. The database will generate a printable version of CXS 234 and the information document (INF/DOC). The latter would be updated by the Host Country Secretariat and be made available at each session of CCMAS for consultation in particular when considering matters related to CXS 234 such as endorsement of methods of analysis and sampling.
53. The EWG Chair invited CCMAS to consider the preamble and structure as revised by the PWG and presented in CRD3. CCMAS concurred with this proposal and made the following additional comments and decisions:

Introduction

54. CCMAS agreed with the introduction as proposed by the PWG.

⁷ CL 2019/15-MAS; CX/MAS 19/40/5; CX/MAS 19/40/5-Add.1 (Canada, Ecuador, Egypt, Norway, Peru and Switzerland); CRD9 (New Zealand, EU, Mexico, Thailand, ROK); CRD13 (India); CRD16 (Kenya); CRD18 (Ghana)

Part I: Preamble

55. CCMAS agreed with the scope and definitions as proposed by the PWG.

Part II: Structure of CXS 234

56. CCMAS agreed with the structure of CXS 234 as proposed by the PWG.
57. CCMAS agreed and made some revisions to Section I to improve the clarity and accuracy of the text. No changes were made to Sections II and III.
58. In particular for Section I, CCMAS agreed to delete the reference to the situation of separate lines under the commodity column where two or more methods were required to cover the full range of values as mutually exclusive methods were no longer considered in CXS 234. In addition, the square brackets around the description of the methods (e.g. identical methods) were removed in view of the agreed definitions for methods as described in the guidance document for endorsement of methods of analysis (see Agenda Item 4).

Explanatory examples

59. CCMAS agreed to delete the examples on situations covered under Sections I – III as not necessary.

Other matters

60. CCMAS noted the offer of the USA to develop a prototype database using the dairy workable package as a basis for the next session. This would aid the Committee in visualising the future database and its features.

Conclusion

61. CCMAS agreed to forward the Preamble and structure of CXS 234 to CAC42 for adoption at Step 5/8 (Appendix III).

REVISION OF THE GUIDELINES ON MEASUREMENT UNCERTAINTY (CXG 54-2004) (Agenda Item 6)⁸

62. Germany, as Chair of the EWG, introduced the item and summarized the main discussions and outcomes of the EWG. The EWG Chair informed CCMAS that she had revised the guidelines based on the written comments submitted to this session which was further considered by an in-session WG which discussed issues around (i) whether provisions for conformity assessment should be part of the revised CXG 54 or developed as a separate document; (ii) whether the examples on acceptance sampling and figure 1 should remain in the revised CXG 54; (iii) whether an adapted version of CXG 59, chapter 4 should be included in the revised CXG 59; (iii) any other general / specific comments on the revision of CXG 54. She invited CCMAS to consider the recommendations and revised CXG 54 from the in-session WG as presented in CRD26.
63. CCMAS agreed to consider the revised CXG 54 as presented in CRD26 and made the following comments and decisions:
- The scope of this work included (i) use of measurement uncertainty in the interpretation of measurement results, (ii) the relationship between the measurement uncertainty and (given) sampling plans, (iii) only focusing on laboratory samples including sub-sampling, (iv) making CXG 54 as simple as possible.
 - The revised CXG 54 does not cover conformity assessment and the development of a separate document was welcomed but postponed due to priority of other ongoing work in CCMAS.
 - The examples were transferred into the information document as more appropriate.
 - The figure was retained with clarifications on the explanation of each situation illustrated in the figure to show how, in principle MU could be used in the interpretation of the measurement result.
 - The table of multiplication factors (adapted version of CXG 59, chapter 4) was replaced with a more appropriate Excel formula.
 - The source of information and the list of references were deleted as not appropriate for Codex documents. References to documents developed by international organizations such as ISO, EURACHEM, etc. relevant to the provisions in the revised CXG 54 were kept in the text as necessary.

⁸ CX/MAS 19/40/6; CX/MAS 19/40/6 Add.1 (Australia, Canada, Ecuador, Egypt, Jamaica, Morocco, New Zealand, Norway, Peru and BIPM); CRD10 (Mexico, Thailand, ROK); CRD14 (EU); CRD16 (Kenya); CRD18 (Ghana); CRD22 (Germany); CRD25 (Presentation of report of EWG on the revision of CXG 54); CRD26 (Report of in-session WG on the revision on the CXG 54)

64. In addition, CCMAS made a number of revisions throughout the text for better accuracy and clarity and for consistency with provisions in relevant Codex texts (including the Procedural Manual) as well as those of international organizations serving as references to the revised CXG 54.
65. CCMAS noted that the information document was intended to give some examples on the procedures for estimating MU and to provide the user with some references on the general topics. The information document was not considered at this time as it had to take into account changes made in the revision of CXG 54 at this session. The document would be presented to CCMAS41 for consideration.

Conclusion

66. CCMAS agreed:
- i. to forward the revised *Guidelines on Measurement Uncertainty* (CXG 54-2004) to CAC 42 for adoption at Step 5 (Appendix IV); and
 - ii. that Germany would develop the information document taking into account the decisions of this session and provide a draft for consideration by CCMAS41.

REVISION OF THE GUIDELINES ON SAMPLING (CXG 50-2004) (Agenda Item 7)⁹

67. New Zealand, as Chair of the EWG, introduced the item and summarized the key points of the discussions at CCMAS that led to the new work on the revision of the *Guidelines on Sampling* (CXG 50 – 2004). The EWG Chair further explained the work process followed by the EWG in (i) the revision of CXG 50 to provide a simplified and understandable guidance on the design and selection of sampling plans and (ii) the development of a supplementary document to provide a sampling plan tool with application links to facilitate the use of the revised guideline. The sampling plan app links were accessible online as an electronic book (e-book) and was intended to demonstrate how an e-book could be used to provide sampling plan apps along with information to support their use (e.g. explanation of the different sampling plans, how to interpret the OC curves, etc.). She noted that a workshop on the sampling plan apps would provide further details on content and use of the e-book and the presentation would be made available on the Codex website.
68. The EWG Chair also provided a mid-term report on the work progress in relation to the prioritization of work on the revision of CXG 50 as agreed by CCMAS39¹⁰ as well as the remaining work to be done for consideration by CCMAS41. In concluding, she drew the attention of CCMAS to the recommendations of the EWG in particular the three key questions that would allow further progress on the revision of CXG 50 in the EWG.
69. CCMAS considered the recommendations put forward by the EWG as follows:
- Revision of CXG 50*
70. CCMAS supported continuation of work on the revision of CXG 50 in accordance with the prioritization of work agreed by CCMAS39.
71. CCMAS noted that the revised CXG 50 would provide guidance to developing / choosing appropriate sampling plans for use by all CAC subsidiary bodies (including CCMAS), Codex members and other relevant stakeholders, and as such the guidance in CXG 50 was not limited to addressing sampling plans for commodity committees / standards.
- Development of a supplement document (e-book with sampling plan apps)*
72. CCMAS agreed with the further development of the supplementary document providing sampling plan apps based on the presentation provided by New Zealand on the content and use of the e-book.
73. CCMAS noted that New Zealand and the Codex Secretariat would discuss how to house the e-book on the Codex website once completed and how the e-book could be easily accessible to Codex members and committees and other relevant stakeholders as a separate supplement document to facilitate the understanding and use of the revised CXG 50.
74. New Zealand explained that regular maintenance of the e-book (or some of the apps in the e-book) was not foreseen to be necessary and that possible updates that might be needed in future could be done in consultation with CCMAS and the Codex Secretariat. New Zealand further clarified that they were developing the apps for use by Codex and once completed could be transferred to the Codex Secretariat for housing and there would be no limitation to access and use of these apps by Codex committees, members and observers.

⁹ CL 2019/17-MAS; CX/MAS 19/40/7; CX/MAS 19/40/7-Add.1 (Canada, Ecuador, Egypt, Japan, Norway, Peru, Uruguay and USA); CRD11 (Chile, Mexico, Nigeria, ROK); CRD14 (EU); CRD16 (Kenya); CRD20 (EWG); CRD24 (El Salvador)

¹⁰ REP18/MAS, Appendix VI

75. The Codex Secretariat thanked New Zealand for this undertaking and explained that innovative e-technologies were under discussion in other committees such as CCFICS and CCFL and the use of web-based technologies might become a more common practice in future within Codex. The Secretariat further noted that copyright issues did not seem to be a problem based on the explanation of New Zealand but that this and other issues around housing the e-book on the Codex website, including access to the apps, would be further discussed with New Zealand and the relevant FAO department(s). She also noted that apps were examples in support of the use of the revised CXG 50 and as such should be agreed by CCMAS but would not be formally adopted by CAC and would remain a separate document available for use by Codex committees, members and other stakeholders in addition to any other apps countries might consider more appropriate to suit their needs. Further consideration of this matter could be given at CCMAS41 when the Committee would have an opportunity to consider both the revised CXG and the supplement document (e-book) with a view to their possible finalization.

Question 1 on whether it is practical to achieve a perfectly balanced producer/consumer risk, based on statistical theory will rarely ever be practically achieved, as there is not a single producer for a commodity, or a single consumer (importing country), or single testing authority who are importing and testing at the boarder all the producer product?

76. CCMAS noted the following comments made:

- Practicability must be considered when developing and implementing sampling plans. In the development of sampling procedures the producers' risk and consumers' risk have to be taken into account on a pragmatic basis as opposed to ensure a "perfectly balanced producer/consumer risk based on a statistical theory". For the control of safety standards the sampling plan should ensure a minimization of the consumers' risk combined with an acceptable producers' risk. For the control of quality standards the sampling plan should ensure a fair balance of the consumers' risk and producers' risk on a pragmatic basis.
- "Balanced" may not refer to equal distribution of the risk to both producers and consumers. Risk to the producer is often financial risk, while the risk to consumer might be health related. In this instance the outcomes need to be evaluated in order to "balance" risk and not simply have it "equally distributed". Additionally, sampling and testing plans cannot "test safety into food", so additional process control procedures are critical and the presence or absence of such controls should be considered when developing sampling plans.
- Sampling plans should be based on statistical principles but should remain flexible to adjust to real situations.
- Coordination between Codex and ISO is necessary to ensure guidance is consistent.

77. CCMAS agreed on the appropriateness of statistical principles in the development of sampling plans while keeping a pragmatic approach to ensure a fair balance of consumers' and producers' risks as opposed to an equal balance of consumers' and producers' risks which would not be applicable in real situations.

Question 2 - Are Codex sampling plans intended for use in international trade disputes?

78. CCMAS noted that Codex sampling plans were intended to be used for lot assessment in all situations namely for routine (normal) inspection or for disputes.

Question 3 - When using Codex sampling plans, what are the situations that are covered or not covered?

79. CCMAS noted that the revised CXG 50 would cover those situations identified in the prioritization² of work and the project document¹¹ on new work for the revision of CXG 50.

Conclusion

80. CCMAS agreed to re-establish the EWG chaired by New Zealand and co-chaired by the USA, working in English, to continue with the revision of CXG 50 and the further development of the supplement document (e-book with sampling plan apps) taking into account written comments submitted at this session and the comments and recommendations made in the paragraphs above with a view to advancing the revised CXG 50 in the Step Procedure at its next session.
81. CCMAS further agreed that the document should be submitted to the Codex Secretariat well in advance the next session, e.g. 3 months before CCMAS41, in order to ensure sufficient time for translation and circulation for comments.

¹¹ REP18/MAS, Appendix V

REPORT OF AN INTER-AGENCY MEETING ON METHODS OF ANALYSIS (Agenda Item 8)¹²

82. The Observer of the United States Pharmacopeial Convention (USPC), as Chair of the InterAgency Meeting (IAM), introduced the report of IAM and highlighted the various issues discussed in the IAM with respect to the work of CCMAS and other related matters.
83. CCMAS noted that several of the issues raised in point 8 of CRD21 had been considered under the relevant agenda items.
84. The Observer in particular highlighted the contribution of a small team of IAM members to the preparation of a preliminary document used by the EWG on guidance on endorsement and also drew the attention of CCMAS to the activities of IAM member meetings and encouraged delegates to participate in these events.
85. CCMAS thanked the members of IAM for their contribution to the work of the Committee.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 9)¹³CCMAS as a nodal committee for methods of analysis

86. The Observer from AOAC on behalf of IAM introduced the proposal for CCMAS to become a nodal committee for methods of analysis. The Observer recalled the decision that CXS 234 would be a single reference for methods of analysis under the remit of Codex and that the new format would allow competent authorities to have access to a database and a simplified and effective search for fit for purpose methods. He noted that it would be appropriate to consider that this future database also include those methods of analysis that were currently outside the remit of CCMAS which would be beneficial to competent authorities and other stakeholders and proposed that CCMAS consider the recommendations in CRD4.
87. The Codex Secretariat noted that while a single source of methods of analysis, including for those for microbiological safety, pesticide and veterinary drug residues would be useful, this would imply changes to the Procedural Manual and also the concurrence of the affected Committees to such a proposal. The Secretariat further noted that changes to the Procedural Manual might not be warranted due to the limited work on methods of analysis in CCFH, and the policy decisions taken by CCPR and CCRVDF to not identify methods of analysis for pesticide residues and veterinary drugs in foods, but to provide guidance on methods performance criteria for use by governments to identify suitable methods of analysis for checking compliance with established MRLs. She clarified that for example in CCFH a method of analysis formed part of a microbiological criterion in accordance with the *Principles and Guidelines for the Establishment of Microbiological Criteria Applicable to Foods* (CXG 21-1997) and that CCFH had a limited number of MC established and it was unlikely that there would be many more in future as MC were only established when there was an absolute need based on risk assessment.
88. However, there was no procedural impediment to providing a link in CXS 234 to methods of analysis or guidelines on methods performance criteria established by CCFH, CCPR and CCRVDF if so required.
89. CCMAS noted that contaminants and food additives were within the remit of CCMAS (with the exception of specifications for food additives) and that CCCF was already conferring with CCMAS on methods performance criteria, but that CCFA had extensive work on establishing MLs for food additives and had not shown an interest to consider methods of analysis for determining compliance with these MLs.
90. CCMAS recalled its earlier decision that CXS 234 would be the single reference for methods under its remit and that methods from the *General Methods of Analysis for Contaminants* (CXS 228 – 2001), *General Methods for the Detection of Irradiated Foods* (CXS 231 – 2001) and the *General Methods of Analysis for Food Additives* (CXS 239 – 2003) should be transferred to CXS 234. It was further noted that some of the methods for heavy metals were outdated and that it would be appropriate for the CCCF to consider the development of method performance criteria for these contaminants for compliance with the MLs in the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995).
91. CCMAS therefore agreed that the relevant committees should be invited to consider whether the methods in those standards were still relevant and if so, should be transferred to CXS 234 and the standards revoked.

Conclusion

92. CCMAS agreed to not proceed further with the proposal at this stage and to:

¹² CRD21 (Report of IAM)

¹³ CRD4 (proposal by IAM)

- i. Inform all Codex committees of the current work of CCMAS regarding the review and update of CXS 234 and the development of a database for methods of analysis and sampling endorsed by CCMAS and adopted by CAC.
- ii. Inform CCFH, CCPR, and CCRVDF of the discussion in the Committee on the proposal for CCMAS to be a nodal committee for all methods of analysis and sampling and to request their view on this proposal.
- iii. Request CCFH, CCPR and CCRVDF to share information/links to their analytical methods and/or method criteria for future inclusion in CXS 234. This in order to achieve a single source of information for all analytical methods in Codex.
- iv. Remind the CCCF and CCFA of the decision that CXS 234 is the single reference for methods of analysis and request these committees to consider the appropriateness of the methods identified in CXS 228 and CXS 239 so that the methods could be transferred to CXS 234; or to identify more updated methods or methods performance criteria for endorsement by CCMAS and inclusion in CXS 234 in order to revoke CXS 228 and CXS 239.
- v. Remind CCFH of the decision that CXS 234 is the single reference for methods of analysis and request CCFH to consider the appropriateness of the methods identified in CXS 231 so that the methods could be transferred to CX 234; or to identify more updated methods or methods performance criteria for inclusion in CXS 234; in order to revoke CXS 231. The request was on the understanding that the responsibility for the methods of analysis remains with CCFH.
- vi. Encourage CCCF to identify methods of analysis or methods performance criteria for the contaminants for which MLs have been established in GSCTFF and for which no methods or method performance criteria have been identified to date.

DATE AND PLACE OF NEXT SESSION (Agenda Item 10)

93. CCMAS was informed that the 41st Session would take place in Budapest, Hungary, within the next 12 months, the final arrangements being subject to confirmation by the host country and the Codex Secretariat.

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Appendix II**PART 1. METHODS OF ANALYSIS FOR ADOPTION BY CAC42**

- 1.1 CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
- 1.2 CODEX COMMITTEE ON FATS OILS
- 1.3 MILK AND MILK PRODUCTS

PART 2. METHODS OF ANALYSIS FOR REVOCATION BY CAC42

- 2.1 CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
- 2.2 MILK AND MILK PRODUCTS

PART 3. AMENDMENTS TO METHODS OF ANALYSIS FOR ADOPTION BY CAC42

- 3.1 MILK AND MILK PRODUCTS

PART 4. METHODS FOR MILK AND MILK PRODUCTS CONSIDERED AND RETAINED UNCHANGED IN CXS 234: FOR INFORMATION**PART 5. METHODS OF ANALYSIS REFERRED TO CCNFSDU****PART 6. METHODS OF ANALYSIS REFERRED TO CCSCH**

PART 1**METHODS OF ANALYSIS FOR ADOPTION BY CAC42**(For inclusion in CXS 234 – 1999: changes indicated in **bold** or underlined font)**1.1 . CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES**

Commodity	Provision	Method	Principle	Type
Infant Formula	Calcium	AOAC 2015.06 / ISO 21424 IDF 243	ICP-MS	II
		ISO 8070 IDF 119	Flame atomic absorption spectrophotometry	III
		AOAC 985.35	Flame atomic absorption spectrophotometry	III
Infant Formula	Copper	AOAC 2015.06 / ISO 21424 IDF 243	ICP-MS	II
		AOAC 985.35	Flame atomic absorption spectrophotometry	III
Infant Formula	Iron	AOAC 2015.06 / ISO 21424 IDF 243	ICP-MS	II
		AOAC 985.35	Flame atomic absorption spectrophotometry	III
Infant Formula	Magnesium	AOAC 2015.06 / ISO 21424 IDF 243	ICP-MS	II
		ISO 8070 IDF 119	Flame atomic absorption spectrophotometry	III
		AOAC 985.35	Flame atomic absorption spectrophotometry	III
Infant Formula	Manganese	AOAC 2015.06 / ISO 21424 IDF 243	ICP-MS	II
		AOAC 985.35	Flame atomic absorption spectrophotometry	III

Commodity	Provision	Method	Principle	Type
Infant Formula	Phosphorus	AOAC 2015.06 / ISO 21424 IDF 243	ICP-MS	II
		AOAC 986.24	Spectrophotometry (molybdovanadate)	III
Infant Formula	Potassium	AOAC 2015.06 / ISO 21424 IDF 243	ICP-MS	II
		ISO 8070 IDF 119	Flame atomic absorption spectrophotometry	III
Infant Formula	Sodium	AOAC 2015.06 / ISO 21424 IDF 243	ICP-MS	II
Infant Formula	Sodium	ISO 8070 IDF 119	Flame atomic absorption spectrophotometry	III
Infant Formula	Zinc	AOAC 2015.06 / ISO 21424 IDF 243	ICP-MS	II
Infant Formula	Zinc	AOAC 985.35	Flame atomic absorption spectrophotometry	III
Infant Formula	Vitamin K	AOAC 2015.09 / ISO 21446	HPLC-FLD	II
Infant Formula	Folic acid	AOAC 2011.06	LC-MS/MS	II
Infant Formula	Folic acid	AOAC 992.05 / EN 14131	Microbioassay	III

1.2 CODEX COMMITTEE ON FATS OILS

Methods of analysis for acid value and free fatty acids for virgin palm oil and crude palm kernel oil

Commodity	Provision	Method	Principle	Type
<u>Named Vegetable Oils</u>	<u>Acidity: acid value</u>	ISO 660 / AOCS Cd 3d-63 / <u>AOCS Ca 5a-40</u>	<u>Titrimetry</u>	I
<u>Named Vegetable Oils</u>	<u>Free fatty acids</u>	ISO 660 / <u>AOCS Cd 3d-63</u> / <u>AOCS Ca 5a-40</u>	<u>Titrimetry</u>	I

1.3 MILK AND MILK PRODUCTS

Commodity	Provision	Method	Principle	Type
Milk and Milk Products				
<u>Blend of sweetened condensed skimmed milk and vegetable fat (for products sweetened with sucrose only)</u>	<u>Milk solids-not fat¹⁵ (MSNF)</u>	<u>ISO 6734 IDF 15 and ISO 1737 IDF 13 and ISO 2911 IDF 35</u>	<u>Calculation from total solids content, fat content and sucrose content</u> <u>Gravimetry, drying at 102 °C and Gravimetry (Röse-Gottlieb) and Polarimetry</u>	<u>IV</u>
<u>Blend of sweetened condensed skimmed milk and vegetable fat (for products sweetened with sucrose only)</u>	<u>Milk protein in MSNF¹⁵</u>	<u>ISO 6734 IDF 15 and ISO 1737 IDF 13 and ISO 2911 IDF 35 and ISO 8968-1 IDF 20-1</u>	<u>Calculation from total solids content, fat content, sucrose content and protein content</u> <u>Gravimetry, drying at 102 °C and Gravimetry (Röse-Gottlieb) and Polarimetry and Titrimetry (Kjeldahl)</u>	<u>IV</u>
<u>Blend of sweetened condensed skimmed milk and vegetable fat (for products sweetened with sucrose only)</u>	<u>Milk protein in MSNF¹⁵</u>	<u>ISO 6734 IDF 15 and ISO 1737 IDF 13 and ISO 2911 IDF 35 and AOAC 991.20</u>	<u>Calculation from total solids content, fat content, sucrose content and protein content</u> <u>Gravimetry, drying at 102 °C and Gravimetry (Röse-Gottlieb) and Polarimetry</u> <u>Titrimetry (Kjeldahl)</u>	<u>IV</u>
<u>Reduced fat blend of sweetened condensed skimmed milk and vegetable fat (for products sweetened with sucrose only)</u>	<u>Milk solids-not fat¹⁵ (MSNF)</u>	<u>ISO 6734 IDF 15 and ISO 1737 IDF 13 and ISO 2911 IDF 35</u>	<u>Calculation from total solids content, fat content and sucrose content</u> <u>Gravimetry, drying at 102 °C and Gravimetry (Röse-Gottlieb) and Polarimetry</u>	<u>IV</u>

Commodity	Provision	Method	Principle	Type
Milk and Milk Products				
<u>Reduced fat blend of sweetened condensed skimmed milk and vegetable fat (for products sweetened with sucrose only)</u>	<u>Milk protein in MSNF¹⁵</u>	<u>ISO 6734 IDF 15 and ISO 1737 IDF 13 and ISO 2911 IDF 35 and ISO 8968-1 IDF 20-1</u>	<u>Calculation from total solids content, fat content, sucrose content and protein content</u> <u>Gravimetry, drying at 102 °C and Gravimetry (Röse-Gottlieb) and Polarimetry and Titrimetry (Kjeldahl)</u>	<u>IV</u>
<u>Reduced fat blend of sweetened condensed skimmed milk and vegetable fat (for products sweetened with sucrose only)</u>	<u>Milk protein in MSNF²</u>	<u>ISO 6734 IDF 15 and ISO 1737 IDF 13 and ISO 2911 IDF 35 and AOAC 991.20</u>	<u>Calculation from total solids content, fat content, sugar content and protein content</u> <u>Gravimetry, drying at 102 °C and Gravimetry (Röse-Gottlieb) and Polarimetry and Titrimetry (Kjeldahl)</u>	<u>IV</u>
<u>Sweetened condensed milks (for products sweetened with sucrose only)</u>	<u>Milk protein in MSNF¹⁵</u>	<u>ISO 6734 IDF 15 and ISO 1737 IDF 13 and ISO 2911 IDF 35 and ISO 8968-1 IDF 20-1</u>	<u>Calculation from total solids content, fat content, sucrose and protein content</u> <u>Gravimetry, drying at 102 °C and Polarimetry</u> <u>Gravimetry (Röse-Gottlieb)</u> <u>Titrimetry (Kjeldahl)</u>	<u>I</u>
<u>Cottage cheese (for samples containing lactose over 5% or with non-dairy ingredients)</u>	<u>Milkfat in dry matter</u>	<u>ISO 5534 IDF4 and ISO 8262-3 IDF 124-3</u>	<u>Calculation from dry matter content and fat content</u> <u>Gravimetry, drying at 102°C and Gravimetry (Weibull-Berntrop)</u>	<u>I</u>

Commodity	Provision	Method	Principle	Type
Milk and Milk Products				
<u>Cottage cheese (for samples containing lactose up to 5%)</u>	<u>Milkfat in dry matter</u>	<u>ISO 5534 IDF4 and ISO 1735 IDF 5</u>	<u>Calculation from dry matter content and fat content</u> <u>Gravimetry, drying at 102°C and Gravimetry (Schmid-Bondzynski-Ratzlaff)</u>	I
<u>Cottage cheese (for samples containing lactose up to 5%)</u>	<u>Milkfat</u>	<u>ISO 1735 IDF 5</u>	<u>Gravimetry ((Schmid-Bondzynski-Ratzlaff))</u>	I
<u>Cottage cheese (for samples containing lactose over 5% or with non-dairy ingredients)</u>	<u>Milkfat</u>	<u>ISO 8262-3 IDF 124-3</u>	<u>Gravimetry (Weibull-Berntrop)</u>	I
Evaporated milks	Milk solids ¹⁵	ISO 6731 IDF 21	Gravimetry, drying at 102 °C	I
Fermented milks - Yoghurt and yoghurt products	<u>Quantification of <i>Lactobacillus delbrueckii</i> subsp <i>bulgaricus</i> & <i>Streptococcus thermophilus</i></u>	ISO 7889 IDF 117	Colony count at 37°C	I
Fermented milks - Yoghurt and yoghurt products	<u>Identification of <i>Lactobacillus delbrueckii</i> subsp <i>bulgaricus</i> & <i>Streptococcus thermophilus</i></u>	ISO 9232 IDF 146	Test for strain identification	I
Edible casein products	Lead	NMKL 139 (Codex general method) AOAC 999.11	Atomic absorption spectrophotometry	IV
Edible casein products	Lead	NMKL 161 / AOAC 999.10	Atomic absorption spectrophotometry	IV
Butter	Lead	AOAC 972.25 (Codex general method)	Atomic absorption spectrophotometry	IV
Creams, Whipped Creams and Fermented Creams	Milk solids-not-fat (MSNF)	ISO 3727-2 IDF 80-2	Gravimetry	I
<u>Edible casein products</u>	<u>Copper</u>	<u>AOAC 2015.06 / ISO 21424 IDF 243</u>	<u>ICP-MS</u>	II
Edible casein products	Copper	AOAC 985.35	Atomic absorption spectrophotometry	III

Commodity	Provision	Method	Principle	Type
Milk and Milk Products				
Fermented milks	Milkfat	ISO 1211 IDF 1	Gravimetry (Röse-Gottlieb)	I
<u>Milkfat Products</u>	<u>Copper</u>	<u>ISO 5738 IDF 76</u>	<u>Photometry, diethyldithiocarbamate</u>	<u>II</u>
<u>Milkfat Products</u>	<u>Copper</u>	<u>AOAC 960.40</u>	<u>Photometry, diethyldithiocarbamate</u>	<u>IV</u>
Note 15: milk total solids and milk solids-not-fat (MSNF) content include water or crystallization of lactose				
Note 16: water content excluding the crystallized water bound to lactose (generally known as “moisture content”)				
Note 17: moisture content excluding water of crystallization of lactose				

PART 2.

METHODS OF ANALYSIS FOR REVOCATION BY CAC42

2.1 CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Commodity	Provision	Method	Principle	Proposed Type
Infant Formula	Calcium	AOAC 984.27	ICP emission spectroscopy	III
Infant Formula	Copper	AOAC 984.27	ICP emission spectroscopy	III
Infant Formula	Iron	AOAC 984.27	ICP emission spectroscopy	III
Infant Formula	Magnesium	AOAC 984.27	ICP emission spectroscopy	III
Infant Formula	Manganese	AOAC 984.27	ICP emission spectroscopy	III
Infant Formula	Phosphorus	AOAC 984.27	ICP emission spectroscopy	III
Infant Formula	Potassium	AOAC 984.27	ICP emission spectroscopy	III
Infant Formula	Sodium	AOAC 984.27	ICP emission spectroscopy	III
Infant Formula	Zinc	AOAC 984.27	ICP emission spectroscopy	III
Infant Formula	Folic acid	J AOAC Int. 2000:83; 1141-1148	Optical Biosensor Immunoassay	IV
Infant Formula	Folic acid	J Chromatogr. A., 928, 77-90, 2001	HPLC, incorporating immunoaffinity clean-up and conversion to 5-methyltetrahydrofolate	IV

2.2. MILK AND MILK PRODUCT

Commodity	Provision	Method	Principle	Type
Milk and Milk Products				
Butter	Copper	ISO 5738 IDF 76 AOAC 960.40	Photometry, diethyldithiocarbamate	II
Cheese	Citric acid	ISO/TS 2963 IDF/RM 34	Enzymatic method	IV
Cheese	Citric acid	AOAC 976.15	Photometry	II
Cottage cheese	Milk fat	ISO 8262-3 IDF 124-3	Gravimetry (Weibull-Berntrop) (for samples containing lactose over 5%)	I
<u>Cottage cheese</u>	<u>Milkfat</u>	<u>ISO 1735 IDF 5</u>	<u>Gravimetry ((Schmid-Bondzynski-Ratzlaff)) (for samples containing lactose up to 5%)</u>	<u>I</u>
Evaporated milks	Solids, total	ISO 6731 IDF 21	Gravimetry, drying at 102 °C	I
Milk fat products	Vegetable fat (sterols)	ISO 12078 IDF 159	Gas chromatography	II
		ISO 18252 IDF 200	Gas chromatography	III
Sweetened Condensed Milks	Milk Protein in MNSF ¹⁵	ISO 8968-1 IDF 20-1	Titrimetry (Kjeldahl)	I
Whey powders	Copper	AOAC 985.35	Atomic absorption spectrophotometry	II
Whey powders	Copper	ISO 5738 IDF 76	Photometry (diethyldithiocarbamate)	III
Milk fat products	Vegetable fat (sterols)	ISO 12078 IDF 159	Gas chromatography	II
		ISO 18252 IDF 200	Gas chromatography	III
Butter	Vegetable fat (sterols)	ISO 12078 IDF 159	Gas chromatography	II
Butter	Vegetable fat (sterols)	ISO 18252 IDF 200	Gas chromatography	III
Dairy fat spreads	Vegetable fat (sterols)	ISO 12078 IDF 159	Gas chromatography	II
Dairy fat spreads	Vegetable fat (sterols)	ISO 18252 IDF 200	Gas chromatography	III
Creams, whipped creams and fermented creams	Milk solids not fat (MSNF)	AOAC 920.116	Gravimetry	I
Edible casein products	Lead	AOAC 972.25 (Codex general method)	Atomic absorption spectrophotometry	III

Commodity	Provision	Method	Principle	Type
Milk and Milk Products				
Edible casein products	Lead	AOAC 982.23 (Codex general method)	Anodic stripping voltametry	III
Whey powders	Lead	AOAC 972.25 (Codex general method)	Atomic absorption spectrophotometry	II
Fermented milks	Milkfat	AOAC 989.05	Gravimetry (Röse-Gottlieb)	I
Note 15: milk total solids and milk solids-not-fat (MSNF) content include water or crystallization of lactose				

PART 3

EDITORIAL AMENDMENTS OF METHODS OF ANALYSIS FOR ADOPTION BY CAC42

Commodity	Provision	Method	Principle	Type
Milk and Milk Products				
Blend of evaporated skimmed milk and vegetable fat	Milk solids-not-fat ¹⁵ (MSNF)	ISO 6731 IDF 21 And ISO 1737 IDF 13	Calculation from total solids content and fat content Gravimetry, drying at 102°C and Gravimetry (Röse-Gottlieb)	I
Blend of evaporated skimmed milk and vegetable fat	Milk protein in MSNF ¹⁵	ISO 6731 IDF 21 and ISO 1737 IDF 13 and ISO 8968-1 IDF 20-1	Calculation from total solids content, fat content and protein content Gravimetry, drying at 102°C and Gravimetry (Röse-Gottlieb) and Titrimetry (Kjeldahl)	IV

Commodity	Provision	Method	Principle	Type
Milk and Milk Products				
Blend of evaporated skimmed milk and vegetable fat	Milk protein in MSNF ¹⁵	ISO 6731 IDF 21 And ISO 1737 IDF 13 and AOAC 991.20	Calculation from total solids content, fat content and protein content Gravimetry, drying at 102°C and Gravimetry (Röse-Gottlieb) and Titrimetry (Kjeldahl)	IV
Reduced fat blend of evaporated skimmed milk and vegetable fat	Milk solids-not-fat (MSNF) ¹⁵	ISO 6731 IDF 21 and ISO 1737 IDF 13	Calculation from total solids content and fat content Gravimetry, drying at 102°C and Gravimetry (Röse-Gottlieb)	I
Reduced fat blend of evaporated skimmed milk and vegetable fat	Milk protein in MSNF ¹⁵	ISO 6731 IDF 21 and ISO 1737 IDF 13 and ISO 8968-1 IDF 20-1	Calculation from total solids content, fat content and protein content Gravimetry, drying at 102°C and Gravimetry (Röse-Gottlieb) and Titrimetry (Kjeldahl)	IV
Reduced fat blend of evaporated skimmed milk and vegetable fat	Milk protein in MSNF ¹⁵	ISO 6731 IDF 21 and ISO 1737 IDF 13 and AOAC 991.20	Calculation from total solids content, fat content and protein content Gravimetry, drying at 102°C and Gravimetry (Röse-Gottlieb) and Titrimetry (Kjeldahl)	IV

Commodity	Provision	Method	Principle	Type
Milk and Milk Products				
Blend of skimmed milk and vegetable fat in powdered form	Milk protein in MSNF ¹⁵	ISO 5537 IDF 26 and ISO 1736 IDF 9 and ISO 8968-1 IDF 20-1	Calculation from total solids content fat content and protein content Gravimetry, drying at 87°C and Gravimetry (Röse-Gottlieb) and Titrimetry (Kjeldahl)	IV
Blend of skimmed milk and vegetable fat in powdered form	Milk protein in MSNF ¹⁵	ISO 5537 IDF 26 and ISO 1736 IDF 9 and AOAC 991.20	Calculation from total solids content fat content and protein content Gravimetry, drying at 87°C and Gravimetry (Röse-Gottlieb) and Titrimetry (Kjeldahl)	IV
Reduced fat blend of skimmed milk powder and vegetable fat in powdered form	Milk protein in MSNF ¹⁵	ISO 5537 IDF 26 and ISO 1736 IDF 9 and ISO 8968-1 IDF 20-1	Calculation from total solids content, fat content and protein content Gravimetry, drying at 87°C and Gravimetry (Röse-Gottlieb) and Titrimetry (Kjeldahl)	IV

Commodity	Provision	Method	Principle	Type
Milk and Milk Products				
Reduced fat blend of skimmed milk powder and vegetable fat in powdered form	Milk protein in MSNF ¹⁵	ISO 5537 IDF 26 and ISO 1736 IDF 9 and AOAC 991.20	Calculation from total solids content fat content and protein content Gravimetry, drying at 87°C and Gravimetry (Röse-Gottlieb) and Titrimetry (Kjeldahl)	IV
Cheese (and cheese rind)	Natamycin	ISO 9233-1 IDF 140-1	Molecular absorption spectrophotometry	III
Cheese (and cheese rind)	Natamycin	ISO 9233-2 IDF 140-2	HPLC-UV	II
Cheeses, individual	Milkfat in dry matter	ISO 5534 IDF4 and ISO 1735 IDF 5	Calculation from dry matter content and fat content Gravimetry, drying at 102°C and Gravimetry (Schmid-Bondzynski-Ratzlaff)	I
Cheeses in brine	Milkfat in dry matter (FDM)	ISO 5534 IDF4 and ISO 1735 IDF 5	Calculation from dry matter content and fat content Gravimetry, drying at 102°C and Gravimetry (Schmid-Bondzynski-Ratzlaff)	I
Edible casein products	Milk Protein (total N x 6.38)in dry matter	ISO 5550 IDF 78 and ISO 8968-1 IDF 20-1	Calculation from dry matter content and protein content Gravimetry, drying at 102°C and Titrimetry (Kjeldahl)	I

Commodity	Provision	Method	Principle	Type
Milk and Milk Products				
Evaporated milks	Milk Protein in MSNF ¹⁵	ISO 6731 IDF 21 and ISO 1737 IDF 13 and ISO 8968-1 IDF 20-1	Calculation from total solids content fat content and protein content Gravimetry, drying at 102°C and Gravimetry (Röse-Gottlieb) and Titrimetry (Kjeldahl)	I
Mozzarella	Milkfat in dry matter – with high moisture	ISO 5534 IDF4 and ISO 1735 IDF 5	Calculation from dry matter content and fat content Gravimetry, drying at 102°C and Gravimetry (Schmid-Bondzynski-Ratzlaff)	I
Mozzarella	Milkfat in dry matter – with low moisture	ISO 5534 IDF4 and ISO 1735 IDF 5	Calculation from dry matter content and fat content Gravimetry, drying at 102°C and Gravimetry (Schmid-Bondzynski-Ratzlaff)	I
Milkfat products	Milkfat purity	ISO 17678 IDF 202	Calculation from determination of triglycerides by gas chromatography - <u>FID</u>	I
Butter	Milkfat purity	ISO 17678 IDF 202	Calculation from determination of triglycerides by gas chromatography - <u>FID</u>	I
Dairy fat spreads	Milkfat purity	ISO 17678 IDF 202	Calculation from determination of triglycerides by gas chromatography - <u>FID</u>	I

Note 15: milk total solids and milk solids-not-fat (MSNF) content include water or crystallization of lactose

Part 4**METHODS OF ANALYSIS CONSIDERED AND RETAINED UNCHANGED – FOR INFORMATION**

Commodity	Provision	Method	Principle	Type
Milk and Milk Products				
Blend of evaporated skimmed milk and vegetable fat	Total fat	ISO 1737 IDF 13	Gravimetry (Röse-Gottlieb)	I
Reduced fat blend of evaporated skimmed milk and vegetable fat	Total fat	ISO 1737 IDF 13	Gravimetry (Röse-Gottlieb)	I
Blend of skimmed milk and vegetable fat in powdered form	Total fat	ISO 1736 IDF 9	Gravimetry (Röse-Gottlieb)	I
Blend of skimmed milk and vegetable fat in powdered form	Water ¹⁶	ISO 5537 IDF 26 These methods will be further reviewed in the next round of discussion on the dairy workable package (see REP19/MAS, para. 17)	Gravimetry, drying at 87 °C	I
Reduced fat blend of skimmed milk powder and vegetable fat in powdered form	Total fat	ISO 1736 IDF 9	Gravimetry (Röse-Gottlieb)	I
Reduced fat blend of skimmed milk powder and vegetable fat in powdered form	Water ¹⁶	ISO 5537 IDF 26 These methods will be further reviewed in the next round of discussion on the dairy workable package (see REP19/MAS, para. 17)	Gravimetry, drying at 87 °C	I
Blend of sweetened condensed skimmed milk and vegetable fat	Sucrose	ISO 2911 IDF 35	Polarimetry	IV
Blend of sweetened condensed skimmed milk and vegetable fat	Total fat	ISO 1737 IDF 13	Gravimetry (Röse-Gottlieb)	I
Reduced fat blend of sweetened condensed skimmed milk and vegetable fat	Total fat	ISO 1737 IDF 13	Gravimetry (Röse-Gottlieb)	I
Butter	Milk solids-not-fat ¹⁵ (MSNF)	ISO 3727-2 IDF 80-2	Gravimetry	I

Commodity	Provision	Method	Principle	Type
Milk and Milk Products				
Butter	Salt	ISO 1738 IDF 12/ AOAC 960.29	Titrimetry (Mohr: determination of chloride, expressed as sodium chloride)	III
Cheese	Milkfat	ISO 1735 IDF 5	Gravimetry (Schmid-Bondzynski-Ratzlaff)	I
Cheese	Propionic acid	ISO/TS 19046-1 IDF/RM 233-1	Gas Chromatography – FID	IV
Cheese	Propionic acid	ISO/TS 19046-2 IDF/RM 233-2	Ion exchange chromatography-UV	IV
Cheese	Sodium chloride	ISO 5943 IDF 88	Potentiometry (determination of chloride, expressed as sodium chloride)	II
Cheeses, individual	Dry matter (Total solids) ¹⁵	ISO 5534 IDF 4	Gravimetry, drying at 102°C	I
Cottage cheese	Fat-free dry matter	ISO 5534 IDF 4 and ISO 1735 IDF 5	Calculation from dry matter content and fat content Gravimetry, drying at 102 °C and Gravimetry (Schmid-Bondzynski-Ratzlaff)	I
Cheese, Unripened Including Fresh Cheese	Milk Protein	ISO 8968-1 IDF 20-1	Titrimetry, Kjeldahl	I
Cream and Prepared Creams	Milk protein	ISO 8968-1 IDF 20-1	Titrimetry (Kjeldahl)	I
Cream	Milkfat	ISO 2450 IDF 16	Gravimetry (Röse-Gottlieb)	I
Cream	Solids ¹⁵	ISO 6731 IDF 21	Gravimetry (drying at 102°C)	I
Creams Lowered in Milkfat Content	Milkfat	ISO 2450 IDF 16 / AOAC 995.19	Gravimetry (Röse-Gottlieb)	I
Cream cheese	Dry matter	ISO 5534 IDF 4	Gravimetry drying at 102 °C	I
Cream cheese	Moisture on fat free basis	ISO 5534 IDF 4 and ISO 1735 IDF 5	Calculation from fat content and moisture content Gravimetry drying at 102°C and Gravimetry (Schmid-Bondzynski-Ratzlaff)	I

Commodity	Provision	Method	Principle	Type
Milk and Milk Products				
Dairy permeate powders	Milkfat	ISO1736 IDF9	Gravimetry(Röse-Gottlieb)	I
Dairy permeate powders	Nitrogen	ISO8968-1 IDF20-1	Titrimetry (Kjeldahl)	I
Dairy permeate powders	Moisture ¹⁷	ISO5537 IDF26	Gravimetry,drying at 87°C	I
Edible casein products (caseins obtained by rennet precipitation and of caseinates, with the exception of ammonium caseinate)	Ash (including P ₂ O ₅)	ISO 5545 IDF 90	Gravimetry, ashing at 825 °C	I
Edible casein products (acid caseins, of ammonium caseinates, of their mixtures with rennet casein and with caseinates, and of caseins of unknown type)	Ash (including P ₂ O ₅)	ISO 5544 IDF 89	Gravimetry, ashing at 825 °C	I
Edible casein products	Copper	ISO 5738 IDF 76	Colorimetry (diethyldiethiocarbamate)	III
Edible casein products	Lead	ISO/TS 6733 IDF/RM 133	Spectrophotometry (1,5-diphenylthiocarbazone)	IV
Edible casein products	Sediment (scorched particles)	ISO 5739 IDF 107	Visual comparison with standard disks, after filtration	IV
Edible casein products	Water ¹⁷	ISO 5550 IDF 78	Gravimetry, drying at 102 °C	I
Emmental	Propionic acid	ISO/TS 19046-1 IDF/RM 233-1	Gas Chromatography -FID	IV
Emmental	Propionic acid	ISO/TS 19046-2 IDF/RM 233-2	Ion exchange chromatography - UV	IV
Evaporated milks	Milkfat	ISO 1737 IDF 13	Gravimetry (Röse-Gottlieb)	I
Fermented milks	Colony-forming units of yeasts and/or moulds	ISO 6611 IDF 94	Colony-count at 25 °C	IV
Milk powders and cream powders	Acidity, titratable	ISO 6091 IDF 86	Titrimetry, titration to pH 8.4	I
Milk powders and cream powders	Milkfat	ISO 1736 IDF 9	Gravimetry (Röse-Gottlieb)	I
Milk powders and cream powders	Water ¹⁷	ISO 5537 IDF 26	Gravimetry, drying at 87°C	I

Commodity	Provision	Method	Principle	Type
Milk and Milk Products				
Milkfat products	Fatty acids, free (expressed as oleic acid)	ISO 1740 IDF 6	Titrimetry	I
Milkfat products (anhydrous milkfat)	Peroxide value	AOAC 965.33	Titrimetry	I
Milkfat Products (anhydrous milkfat)	Peroxide value (expressed as meq. of oxygen/kg fat)	ISO 3976 IDF 74	Photometry	I
Milkfat products	Water ¹⁷	ISO 5536 IDF 23	Titrimetry (Karl Fischer)	II
Sweetened condensed milk	Milkfat	ISO 1737 IDF 13	Gravimetry (Röse-Gottlieb)	I
Sweetened Condensed Milks	Solids ¹⁵	ISO 6734 IDF 15	Gravimetry, drying at 102 °C	I
Whey cheeses by coagulation	Milkfat	ISO 1735 IDF 5	Gravimetry (Schmid-Bondzynski-Ratzlaff)	I
Whey cheeses by coagulation	Milkfat in dry matter	ISO 5534 IDF 4 and ISO 1735 IDF 5	Calculation from dry matter content and fat content Gravimetry, drying at 102°C and Gravimetry (Schmid-Bondzynski-Ratzlaff)	I
Whey powders	Ash	ISO 5545 IDF 90	Gravimetry, ashing at 825°C	IV
Whey Powders	Lactose	ISO 5765-1/2 IDF 79-1/2	Enzymatic method: Part 1 - Glucose moiety or Part 2 - Galactose moiety	II
Whey powders	Milkfat	ISO 1736 IDF 9	Gravimetry (Röse-Gottlieb)	I
Whey powders	Water ¹⁷	ISO 5537 IDF 26	Gravimetry, drying at 87°C	I

Note 15: milk total solids and milk solids-not-fat (MSNF) content include water or crystallization of lactose

Note 16: water content excluding the crystallized water bound to lactose (generally known as “moisture content”)

Note 17: moisture content excluding water of crystallization of lactose

PART 5**METHODS OF ANALYSIS FOR CONSIDERATION BY CCNFSDU**

Commodity	Provision	Method	Principle	Proposed Type
Infant Formula	Calcium	AOAC 2011.14 / ISO 15151 IDF 229	ICP emission spectroscopy	III
Infant Formula	Copper	AOAC 2011.14 / ISO 15151 IDF 229	ICP emission spectroscopy	III
Infant Formula	Iron	AOAC 2011.14 / ISO 15151 IDF 229	ICP emission spectroscopy	III
Infant Formula	Magnesium	AOAC 2011.14 / ISO 15151 IDF 229	ICP emission spectroscopy	III
Infant Formula	Manganese	AOAC 2011.14 / ISO 15151 IDF 229	ICP emission spectroscopy	III
Infant Formula	Phosphorus	AOAC 2011.14 / ISO 15151 IDF 229	ICP emission spectroscopy	III
Infant Formula	Potassium	AOAC 2011.14 / ISO 15151 IDF 229	ICP emission spectroscopy	III
Infant Formula	Sodium	AOAC 2011.14 / ISO 15151 IDF 229	ICP emission spectroscopy	III
Infant Formula	Zinc	AOAC 2011.14 / ISO 15151 IDF 229	ICP emission spectroscopy	III

RECOMMENDATIONS OF METHODS OF ANALYSIS FOR CONSIDERATION BY CCSCH¹*Methods of analysis for provisions in the proposed draft Standard for Dried or Dehydrated Garlic*

Parameter	Method	Principle	Type ²
Moisture	AOAC 986.21	Distillation	I
Total Ash <u>on dry basis</u>	AOAC 986.21 and ISO 928	Calculation Distillation and Gravimetry	I
Acid Insoluble Ash <u>on dry basis</u>	AOAC 986.21 and ISO 930	Calculation Distillation and Gravimetry	I
Extraneous Matter	ISO 927	Visual Examination followed by Gravimetry	I
Foreign Matter	ISO 927	Visual Examination followed by Gravimetry	I
Insects//Insect Fragments	ISO 927	Visual Examination	IV
Live Insects	ISO 927	Visual Examination	IV
Live Insects	AOAC 960.51	Visual Examination	IV
<u>Mammalian Excreta</u>	Macroanalytical Procedure Manual, USFDA, Technical Bulletin V.39 B (For whole)	Visual Examination	IV
<u>Mammalian Excreta</u>	AOAC 993.27 (For Ground)	Enzymatic Detection Method	IV
Cold Water Soluble Matter <u>on dry basis</u>	ISO 941 and AOAC 986.21	Calculation Extraction followed by Gravimetry	I
Volatile Organic Sulfur Compounds Content <u>on a dry basis</u>	ISO 5567 and AOAC 986.21	Calculation Distillation followed by Titrimetry	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 (For whole)	IV

¹ The methods of analysis for the provisions in the remaining standards for spices and culinary herbs should be considered in the light of these recommendations

Methods of analysis for provision in the proposed draft Standard for Dried Oregano

Parameter	Method	Principle	Type³
Moisture	ISO 939	Distillation	I
Total ash on dry basis	ISO 939 and ISO 928	Calculation Gravimetry and distillation	I
Acid-insoluble ash on dry basis	ISO 930 and ISO 939	Calculation Gravimetry and distillation	I
Volatile oils on a dry basis	ISO 939 and ISO 6571	Calculation Distillation and Distillation	I
Extraneous vegetable matter	ISO 927	Visual examination followed by Gravimetry	I
Foreign matter	ISO 927	Visual examination followed by Gravimetry	I
Mammalian excreta	Macroanalytical Procedure Manual, USFDA, Technical Bulletin V.39 B (For whole)	Visual examination	IV
Other excreta	AOAC 993.27 (For Ground)	Visual examination	IV
Whole dead insect	ISO 927	Visual examination	IV
Whole dead insect	MPM V-8 Spices, Condiments, Flavours and Crude Drugs A. General methods for spices herbs and botanicals (V 32)	Visual examination	IV
Insect fragments	AOAC 969.44	Flotation method	IV
Insect fragments	AOAC 975.49	Flotation method	IV

**DRAFT PREAMBLE AND DOCUMENT STRUCTURE FOR THE GENERAL STANDARD ON
METHODS OF ANALYSIS AND SAMPLING (CXS 234-1999)**

(at Step 5/8)

INTRODUCTION

1. This Standard contains definitions, lists of methods of analysis, method performance criteria, descriptions of some methods and a list of methods of sampling. The methods of analysis and sampling contained in this Standard are the recommended ones to be used to assess compliance for a specific provision described in Codex standards and can be used for reference, in calibration of methods in use or introduced for routine examination and control purposes.
2. It is recommended that this Standard should be read in conjunction with the related Codex Standards, guidelines and other documents¹.
3. In case of disputes of analytical results, guidance is given in the *Guidelines for Settling Disputes over Analytical (Test) Results* (CXG 70-2009), including guidance on the use of methods of analysis.

PART I. PREAMBLE**1. Scope**

This Standard is intended to provide a single reference to methods of analysis and sampling for food as adopted by the Codex Alimentarius Commission.

This Standard is not applied to methods of analysis and sampling for residues of pesticides or veterinary drugs in food, the assessment of micro biological quality and safety in food, and the assessment of specifications for food additives.

2. Definition of Terms

2.1 Codex Methods of Analysis: methods for the verification of provisions in Codex Standards. The methods are classified as Defining Methods (Type I), Reference Methods (Type II), Alternative Approved Methods (Type III), & Tentative Methods (Type IV) (see Codex Procedural Manual, Section II: Elaboration of Codex texts, Definition of types of methods of analysis).

2.2 Methods of Analysis Principle: The science-based analytical principle of the method of analysis, described concisely, focusing on the technique.

2.3 Provision: Attribute of a commodity that needs to be confirmed by analysis to ensure that it conforms to that standard.

2.4 Method performance criteria: Set of performance characteristics to which a method used must comply when determining a provision.

PART II. METHODS OF ANALYSIS

The part II contains 3 sections.

Section I

This section presents all the methods by commodities and provisions.

Method listed in this section could be used for any purpose in line with the principle of this standard and Codex Procedural Manual. They could be used for national regulation, control and inspection. In addition to method Type I and II, method Type III and IV can be used in case of disputes, if it was agreed between the respective competent authorities or other trade parties, according to the *Guidelines for Settling Disputes on Analytical (Test) Results* (CXG 70-2009).

The most updated version of the method should be used in application of ISO/IEC 17025 unless it is not appropriate or possible to do so.

¹ Harmonized IUPAC Guidelines for the Use of Recovery Information in Analytical Measurement (CXG 37-2001), Harmonized IUPAC Guidelines for Single-Laboratory Validation of Methods of Analysis (CXG 49-2003), Guidelines on Sampling (CXG 50-2004), Guidelines on Measurement Uncertainty (CXG 54-2004), Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories (CXG 65-1997), protocols for method performance determination through collaborative study. (CXG 64-1995 and ISO 5725), Food Control Laboratory Management: Recommendations (CXG 28-1995).

Each line of the methods list corresponds to one method of analysis or more than one when multiple methods are needed to reach a result. In case of multiple methods use, they are called complementary being presented on table with an “and” between them. When a provision is determined by calculation, a brief description of the calculation shall be given in the principle column.

When the methods are in the same row separated by a vertical bar "|", they are identical and published in a single document by different standards development organizations. When methods are separated by a forward slash "/", technical procedures are identical but published in separate documents which may have different editorial formats.

When there is the letter “M” on “Method” Column, a full description of method is provided in Section III. When there is the letter “C” on column “Criteria/Type”, a method performance criterion is provided in Section II.

Section II

This section presents method performance criteria.

Section III

This section presents complete descriptions of methods of analysis

SECTION I – METHODS OF ANALYSIS AND METHOD PERFORMANCE CRITERIA BY COMMODITY

This section contains:

- a) Commodity;
- b) Provision;
- c) Method;
- d) Principle;
- e) Codex Standard
- f) Criteria/Type.

SECTION II – PROVISIONS FOR WHICH THERE ARE METHOD PERFORMANCE CRITERIA

This section contains:

- a) Commodity;
- b) Provision;
- c) Maximum level (ML)
- d) Minimum applicable range;
- e) Limit of detection (LOD);
- f) Limit of quantification (LOQ);
- g) RSD_R (Relative Standard Deviation of Reproducibility);
- h) % Recovery;
- i) Examples of Methods that meet the criteria and their principles also can be mentioned. However, any method that complies with the established performance criteria can be used;
- j) Principle.

SECTION III – COMPLETE DESCRIPTION OF THE METHODS OF ANALYSIS

This section contains:

- a) Description and scope of the method that includes the commodity and provision.

PART III. METHODS OF SAMPLING BY COMMODITY CATEGORIES AND NAMES

This part contains:

- a) The name of the commodity/product;
- b) Identification of method of sampling;
- c) Notes.

Appendix IV

PROPOSED DRAFT REVISION OF THE *GUIDELINES ON MEASUREMENT UNCERTAINTY (CXG 54 – 2004)*

(at Step 5)

1. Analytical measurement results in food control are used to assess whether food products meet relevant specifications. The accuracy of measurement results is affected by various error components, and it is important to ensure these errors are properly considered. Since the true value of the quantity being measured is unknown, errors cannot be known exactly. The focus thus shifts to an evaluation of the uncertainty associated with a measurement result. All measurement results have an associated uncertainty; the non-estimation of measurement uncertainty does not mean that there is no uncertainty. The estimation of measurement uncertainty is required to establish the metrological traceability of the measurement results. Accordingly, measurement uncertainty is of utmost importance in analytical testing and subsequent decision-making. It should be noted that, in this guideline, the evaluation of sampling uncertainty is not included.

2. The Codex Alimentarius Commission has developed *Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Foods (CXG 27-1997)*. They recommend that laboratories involved in food control for import/export should adopt the general criteria set forth in ISO/IEC 17025 [1]. This standard requires that where necessary for the interpretation of the test results and where applicable measurement uncertainty shall be included in the test report. The ISO/IEC 17025 standard also requires that the measurement uncertainty and its level of confidence must be made available to the user (customer) of the results, on request. The use of measurement uncertainty in establishing decision rules must be documented. In summary, the ISO/IEC 17025 standard requires that information regarding measurement uncertainty must be provided in test reports insofar as it is relevant to the validity or application of the test results, in response to a customer's request, or when the uncertainty affects compliance to a specification limit.

Scope

3. This guideline covers general aspects of measurement uncertainty for quantitative analysis, gives definitions of measurement uncertainty and related terminology and clarifies the role of measurement uncertainty in the interpretation of test results and the relationship between measurement uncertainty and sampling plans. This guideline does not address the uncertainty component associated with sampling and focuses on uncertainty contributions which arise in connection with obtaining a test sample from the laboratory sample, taking a test portion from a test sample (i.e. the errors due to the heterogeneity¹ between test portions) and the analysis of a test portion in the laboratory.

4. While the role of chemical analysis in food control often involves *quantitative* analytical measurement results, *qualitative* results are also relevant. For the estimation of the measurement uncertainty associated with qualitative results, a different approach should be applied than for quantitative results.

Prerequisites

5. Laboratories which perform measurements in chemical analysis should have effective quality assurance procedures in place (properly trained staff, equipment maintenance, calibration of equipment, reference materials and standards, documentation, participation in proficiency tests, quality control charts etc.), which can be used for the evaluation of measurement uncertainty. Furthermore, sufficient statistical knowledge either by qualified staff or external consultants is recommended, in order to ensure that statistical methods, mathematical formulas and decision rules are correctly applied, and that criteria for producer and consumer risks are met. Examples and explanations of decision rules can be found in ISO 10576 and JCGM 106:2012.

Terms and definitions

6. For the purposes of this guideline, the terms and definitions of the following documents apply.

¹ The heterogeneity between test portions is composed of compositional heterogeneity (CH) and distributional heterogeneity (DH). Both of these lead to random errors when selecting a test portion, known as Fundamental Sampling Error – also called Fundamental Variability – and Grouping and Segregation Error. Fundamental variability results from CH and is the variability between test portions that remains even under the best achievable degree of particle size reduction. The fundamental variability has a dominant effect on total variability when the “target compound” is predominantly located in a specific fraction of the particles (there is a low number of particles with relatively high concentrations of the target compound). The fundamental variability can be controlled by collecting a sufficient test portion mass. Grouping and segregation error results from DH and is the non-random distribution (spatial or temporal) of the “target compound” within the material from which a test portion is selected. The grouping and segregation error can be controlled through the collection of a sufficient number of random increments to comprise a test portion.

7. Guidelines on analytical terminology (CXG 72-2009)
- JCGM 200:2012 International vocabulary of metrology – Basic and general concepts and associated terms (VIM)
- ISO 3534-1:2006 Statistics – Vocabulary and symbols – Part 1: General statistical terms and terms used in probability
- ISO 3534-2:2006 Statistics – Vocabulary and symbols – Part 2: Applied statistics
- ISO 2859-1:2014 Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
- ISO 3951-1:2016 Sampling procedures for inspection by variables – Part 1: Specification of single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL
- ISO 6498:2012 Animal feeding stuffs -- Guidelines for sample preparation ISO 10725:2000 Acceptance sampling plans and procedures for the inspection of bulk materials

8. For convenient reference, the following definitions are provided here:

laboratory sample

sample as prepared (from the lot) for sending to the laboratory and intended for inspection or testing

test sample

subsample or sample prepared from the laboratory sample and from which test portions will be taken

test portion

quantity of material drawn from the test sample (or from the laboratory sample if both are the same)

inspection by variables

inspection by measuring the magnitude of a characteristic of an item

lot

a lot is a definite quantity of some commodity manufactured or produced under conditions, which are presumed uniform for the purpose of these Guidelines.

sample

set of one or more items taken from a lot and intended to provide information on the lot

item

that which can be individually described and considered

sample size

number of items in the sample

sampling plan

combination of sample size(s) to be used and associated lot acceptability criteria

sampling increment

amount of bulk material taken in one action by a sampling device

composite sample

aggregation of two or more sampling increments taken from a lot for inspection of the lot

General considerations

9. When a measurement is performed, it is generally assumed that a “true value” of the quantity being measured exists. However, this true value is unknown and is thus only available as a reference value or a conventional true value. For this reason, measurement error cannot be reliably estimated and the focus shifts to the evaluation of measurement uncertainty. Measurement uncertainty is expressed as an interval within which values which can reasonably be attributed to the measured quantity will lie with a stated coverage probability. It is assumed that any necessary bias correction has been correctly performed. Since all measurement results are subject to error, laboratories are expected to estimate and, if necessary, report the measurement uncertainty associated with every result.

10. Measurements are affected by many influences – e.g. effects which arise in connection with changes in temperature, pressure, humidity, matrix variability or with the judgement of the analyst. These errors can be classified as either *systematic* or *random*. The term *bias* is often used to refer to a systematic error. Even if all *systematic* error components could be evaluated and corrected for, measurement results would remain subject to random errors which cannot be corrected for, leading to an uncertainty range. An example of the manner in which a random error manifests itself is the dispersion of measurement results observed when measurements are performed within one laboratory under near-identical, i.e. repeatability, conditions. The individual components of measurement uncertainty should be identified and estimated. Some of these components can be evaluated from the statistical distribution of a series of measurement results and characterized by standard deviations. The other components, which can also be characterized by standard deviations, are evaluated on the basis of distributional assumptions derived from experience or other information. All components of uncertainty, including those arising from systematic effects such as the uncertainty of bias corrections and reference standards, contribute to the dispersion.

11. It is important to note that time and financial resources do not allow for the evaluation and correction of all measurement errors. For this reason, the focus lies on the identification and evaluation of the *main* components of measurement uncertainty.

Uncertainty components

12. While performing a measurement, it is important to consider all possible uncertainty components which will influence the result of the measurement. Typical uncertainty components include effects associated with instrumental equipment, analyst, sample matrix, method, calibration, time and environment. These sources may not be independent, in which case the respective correlations should be taken into account in the uncertainty budget – i.e. in the computation of the total uncertainty. Moreover, under certain circumstances, the effect associated with a particular uncertainty component may change over time and a new estimation of measurement uncertainty may be necessary as a result. For more information on this subject, please refer to the EURACHEM / CITAC Guide CG 4.

Procedures for Estimating Measurement Uncertainty

13. There are many procedures available for estimating the uncertainty of a measurement result, notably those described in ISO/IEC Guide 98-3:2008 and EURACHEM / CITAC Guide CG 4. The Codex guidelines do not recommend a particular approach for estimating measurement uncertainty, but it is important that whatever approach is used be scientifically acceptable². Choosing the appropriate procedure depends on the type of analysis, the method used, the required level of reliability, and the urgency of the request for an estimate of measurement uncertainty. In general, procedures are based either on a “bottom-up” approach or on a “top-down” approach, with the latter using data from collaborative trials, proficiency studies, validation studies or intra-laboratory quality control samples, or a combination of such data.

14. Most common approaches for the evaluation of measurement uncertainty:

- Modelling (Classical ISO GUM)
 - Bottom-up component-by-component evaluation according to ISO GUM
- Single-lab validation
 - Top-down approach e.g. according to Nordtest TR 537, NMKL procedure No. 5, EURACHEM / CITAC Guide CG 4 (uncertainty of results obtained using the same procedure in a single laboratory varying conditions as described above)
- Interlaboratory validation
 - Top-down approach using the reproducibility standard deviation (ISO 21748) (uncertainty of results obtained using the same procedure in different laboratories)
- Proficiency testing (PT)
 - Top-down approach using the target reproducibility standard deviation (uncertainty of results obtained by analysing the same sample(s) in different laboratories)

² The expression “scientifically acceptable” is used here to mean either that the approach has been previously described in an international standard or guideline or that, upon expert scrutiny, it would be agreed that the approach is appropriate.

15. These procedures are not equivalent and may produce different estimates of the measurement uncertainty. In the top-down approach, the reproducibility standard deviation obtained from collaborative studies is often used as a measure of measurement uncertainty. The matrix mismatch uncertainty component should be adequately taken into account during the estimation of measurement uncertainty. To overcome this deficiency different matrices and concentration levels – depending on the scope of the method – could be used. In the case of a single-lab validation study, intermediate precision (within-lab reproducibility) is used for the estimation of the uncertainty and the laboratory bias is therefore missing with the result that the uncertainty may have been underestimated. Depending on the case, this can be addressed e.g. by estimating and correcting for the bias via a recovery experiment (with the uncertainty of the recovery correction duly taken into account in the uncertainty) or by simulating the laboratory bias by varying influencing effects like analytical instruments, analysts, time span, equipment for sample preparation etc.

16. In addition to the fact that these procedures may vary with regard to the influencing effects included there is also often considerable variation due to random variability of the standard deviation figures (intermediate precision (within-lab reproducibility), reproducibility, repeatability). Therefore, both the chosen approach for estimating measurement uncertainty (in-house validation, collaborative study, bottom up etc.) and the estimated level of confidence of the measurement uncertainty should be provided.

17. Almost all uncertainty data are expressed as standard deviations or functions of standard deviations. If a standard deviation is calculated using a small amount of data there is considerable uncertainty in the estimate of measurement uncertainty obtained.

18. If the estimate of a standard deviation is obtained from a low number of tests run by a single laboratory or from a collaborative study conducted by a low number of laboratories each with a single measurement, the true standard deviation can be up to 2-3 times the estimated standard deviation. This factor can be calculated with the following Excel formula: $\text{SQRT}((N-1)/\text{CHISQ.INV}(0.05,N-1))$. This uncertainty of measurement uncertainty components should be taken into account in the design of experimental studies and the evaluation of measurement uncertainty. .

19. It is recommended that laboratories which perform food testing with quantitative methods should always evaluate measurement uncertainty. In cases where a rigorous evaluation cannot be made, measurement uncertainty should at least be estimated on the basis of principles, experience and “state of the art” knowledge based e.g. on results from comparable laboratories, concentration levels, matrices, analytical methods or analytes.

20. In order to demonstrate that a laboratory is competent in the application of a validated method, there are two possible approaches:

a. the laboratory uses a validated in-house test method with established limits regarding the major measurement uncertainty components along with the exact manner in which relevant quantities must be calculated

b. the laboratory uses an official and/or standardized method with established method performance characteristics and verifies that it can meet and/or exceed the within laboratory performance parameters in accordance with the official standardized method and that all the critical influences are under control

21. Most of the methods used in food testing and recommended in Codex documents are well-recognized methods which have been reliably validated. As long as the laboratory's competence in the application of a validated method has been demonstrated following either one of the two approaches described, the measurement uncertainty evaluation/estimation is considered to have been successfully performed and any requirements regarding the measurement uncertainty are considered to have been met.

22. The *Guidelines for the Assessment of the Competence of Testing Laboratories involved in the Import and Export Control of Food* (CXG 27-1997) requires laboratories involved in the import/export of foods to comply with the general criteria set forth in ISO/IEC 17025. This standard requires laboratories to use validated methods; it is thus usually recommendable to use data from the interlaboratory or single-lab validation study rather than another approach such as the bottom-up approach. In Section 7.6.2 of the EURACHEM / CITAC Guide CG 4 EURACHEM / CITAC Guide CG 4, a procedure for evaluating measurement uncertainty using collaborative study data is provided. The EURACHEM / CITAC Guide CG 4 EURACHEM / CITAC Guide CG 4 also references ISO 21748 as the primary source for the estimation of uncertainty on the basis of “collaborative study data acquired in compliance with ISO 5725”.

Uses of measurement uncertainty

23. Measurement uncertainty has several uses including:

- Reporting of measurement results (see ISO/IEC 17025):

Typically, the measurement uncertainty is reported as the expanded measurement uncertainty U , i.e. as the standard uncertainty u multiplied by a coverage factor $k = 2$, which for a normal (Gaussian) distribution corresponds to a coverage probability of approximately 95 %. Note: The higher the uncertainty of the standard deviation used for the calculation of the measurement uncertainty, the lower the coverage probability of the latter. In such cases it may be sensible to increase the coverage factor k by taking the corresponding factor of the Student t distribution.

- Assessing the performance of laboratories (see ISO 13528)
- For the design of acceptance sampling (see ISO 3951 and GL50):
- The determination of sample size and acceptance number for inspection by attributes, and of sample size and acceptability constant for inspection by variables is based on the procedures and the sampling plans provided in ISO standards and/or Codex guidelines. This calculation has to take into account the components of measurement uncertainty.
- For comparison between measurement results and true/reference values (ISO 5725-6)

How to report measurement uncertainty in test results

24. In accordance with ISO/IEC 17025 measurement uncertainty should be reported to allow for a decision as to whether a *laboratory sample* meets a specification on the basis of an analytical result.

25. However, ISO/IEC 17025 does not state how measurement uncertainty should be taken into account. It is clear, however, that it is not sufficient to consider measurement uncertainty only, but it is necessary to include information on the method bias (if significant) and on whether or not a correction was applied. .

Examples of Situations occurring when measurement uncertainty is considered

26. The figure below illustrates how measurement uncertainty can affect decisions whether the true values conform to specification limits. However, this figure is for illustrative purposes of the principle. Measurement uncertainty intervals such as those in Figure 1 cannot be used as a valid product assessment procedure.

27. The decision whether the *laboratory sample* meets the specification or not depends on the rules which the different parties involved have agreed to apply.

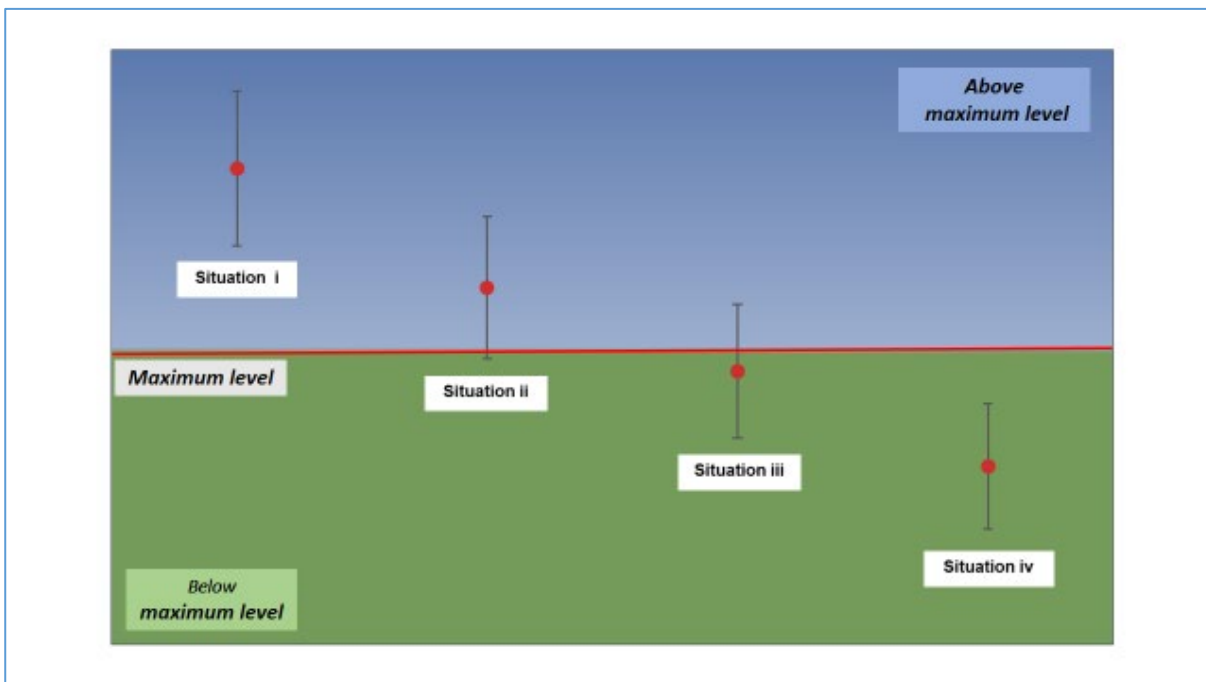


Figure 1: Taking into account the expanded measurement uncertainty in the comparison of test results with a Maximum Level. For each situation, the red point represents an individual test result and the vertical bar represents the associated measurement uncertainty interval.

Situation i

The analytical result minus the expanded measurement uncertainty exceeds the maximum level. The conclusion is that it lies above the specification.

Situation ii and iii

The analytical result differs from the maximum level by less than the expanded measurement uncertainty. The standard interpretation here is the outcome is inconclusive. Action on this result depends on existing agreements between the trading partners.

Situation iv

The analytical result is below the maximum level by more than the expanded measurement uncertainty. The decision is that it lies below the specification.

Note: The measurement uncertainty interval used in Figure 1 and its comparison to the maximum level is not intended to be used for lot acceptance sampling or conformity assessment but to illustrate the interrelation of the analytical test result and its measurement uncertainty with regard to a maximum level.

Note: The implications of situations *i* to *iii* in the case of testing MRL compliance are extensively discussed in the *Guidelines on estimation of uncertainty of results* (CXG 59-2006). If, as in situations *ii* and *iii*, it cannot be concluded beyond reasonable doubt (in relation to the consumer and producer risks involved) that the MRL is exceeded or that a compliant test result has been obtained, the decision will depend on national practices and on existing agreements between the trading partners, which may thus have a considerable impact on the acceptance of trade consignments. This question is addressed in the guideline CXG 83-2013 "Principles for the Use of Sampling and Testing in International Food Trade". It is stated that "the exporting country and the importing country should agree on how the analytical measurement uncertainty is taken into account when assessing the conformity of a measurement against a legal limit".

Name	Meaning	Example	Relevant Type	Separator in CX S234
Complementary	Two or more methods required to determine/calculate the required answer	ISO 5534 IDF 4 and ISO 1735 IDF 5	All Types	and

Description of Method Typing from Procedural Manual

<p>Methods of Analysis</p> <p>Definition of types of methods of analysis</p> <p>(a) Defining Methods (Type I)</p> <p>Definition: A method which determines a value that can only be arrived at in terms of the method per se and serves by definition as the only method for establishing the accepted value of the item measured.</p> <p>Examples: Howard Mould Count, Reichert-Meissl value, loss on drying, salt in brine by density.</p> <p>b) Reference Methods (Type II)</p> <p>Definition: A Type II method is the one designated Reference Method where Type I methods do not apply. It should be selected from Type III methods (as defined below). It should be recommended for use in cases of dispute and for calibration purposes.</p> <p>Example: Potentiometric method for halides.</p> <p>(c) Alternative Approved Methods (Type III)</p> <p>Definition: A Type III Method is one which meets the criteria required by the Committee on Methods of Analysis and Sampling for methods that may be used for control, inspection or regulatory purposes.</p> <p>Example: Volhard Method or Mohr Method for chlorides</p> <p>(d) Tentative Method (Type IV)</p> <p>Definition: A Type IV Method is a method which has been used traditionally or else has been recently introduced but for which the criteria required for acceptance by the Committee on Methods of Analysis and Sampling have not yet been determined.</p> <p>Examples: chlorine by X-ray fluorescence, estimation of synthetic colours in foods.</p>
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Table 2.2: Guidance on Method Listing in CXS 234

Types	Further explanation	Coexistence with other types	Examples
I	Need validation data. ⁵	There can be only one Type I method listed for each commodity and provision (unless complementary or identical). No other Type II or Type III methods can be listed for same commodity and provision.	Determination of nitrogen content by Kjeldahl, determination of fat by Weibull-Berntrop,
II	Need validation data. ⁴	There can be only one Type II method listed for each commodity and provision (unless identical or complementary).	Chromatography, spectrophotometry
III	Need validation data. ⁴	Multiple Type III methods can be listed for a commodity and provision, but cannot exist without a Type II method.	Chromatography, spectrophotometry

⁵ Precision figures for methods are an important aspect of assessing the performance of methods and that for newly developed / proposed Type I methods, precision figures should be presented as part of the data reviewed during the endorsement process. Lack of such data would not cause a change in the method type or revocation of a method.

Types	Further explanation	Coexistence with other types	Examples
IV	No or insufficient validation data.	<p>Can be listed as alternative to Type I/II/III if deemed useful by CCMAS.</p> <p>More than 1 Type IV method may be listed for each commodity and provision.</p> <p>May be only method type listed when there are no other methods that meet the general criteria for selection of methods.</p>	

3. Process for the submission of methods of analysis for provisions in Codex Documents

3.1 Steps in the process

- i. Signaling and capturing the need for a method when a new or amended provision or reference to the provision is incorporated in a Codex document.
- ii. Initiative of one or more SDOs, Codex Members, or other Codex related entities (e.g. Bureau International des Poids et Mesures, International Oil Council) to identify an existing candidate method or to develop and validate the candidate method.
- iii. Submission of the candidate method to the relevant Codex Committee, or directly to CCMAS when the relevant committee has been adjourned. (See Section 3.2 ii).
- iv. A candidate method may be submitted directly to CCMAS for review and endorsement, even when the relevant Codex Committee is active. If endorsed, the method will be referred to the relevant Codex Committee for approval prior to submission to CAC.
- v. Review of the method suitability (fitness for purpose) by the relevant Codex Committee and submission to CCMAS for review.
- vi. Review, assign typing, endorsement of the method by CCMAS including decision on submission of a proposal to CAC for adoption of the method and inclusion in CXS 234, optionally indicating replacement or retyping of already listed method(s) in CXS 234. (See Section 3.4).
- vii. Decision on adoption by CAC and inclusion in CXS 234, optionally replacing or editing already listed method(s) in CXS 234.

3.2 Acceptance of methods of analysis

The Codex Committees should submit methods to CCMAS for endorsement in line with the Procedural Manual. Codex standards for products in commercial trade between countries need to be defined by each committee.

- i. All proposed methods of analysis must have direct pertinence to the Codex Standard to which they are directed.
- ii. Each provision in a standard needs to have an attribute (e.g. limit value, maximum or minimum level, a description) and a suitable method of analysis for use should a dispute arise.
- iii. When a committee develops a standard, during the development process and before submission of a method to CCMAS, the committee should:
 - a. Consider the criteria approach in place of recommending specific methods;
 - b. Determine if a suggested method of analysis is fit for purpose in consultation with relevant trade organizations, referee laboratories, competent authorities and standards development organizations;
 - c. Determine if there are validation data available for the method and analyte in the commodity or food;
 - d. Determine if the suggested method of analysis has been studied by one or more SDOs;

- e. Consult the appropriate SDOs on the validation and publication status and applicability of the methods;
 - f. whenever possible, provide information to CCMAS for each individual analytical method proposed, relating to specificity, accuracy, precision (repeatability, reproducibility) limit of detection, sensitivity, applicability and practicability, as appropriate⁶ (see Annex I)
- iv. Proposal of methods of analysis to CCMAS for endorsement should be carried out with the knowledge that the methods of analysis meet the above criteria (iii. a-f).
- a. Proposals should include the information presented in the template in Annex 1 to allow the Committee to assess and compare the actual analytical performance of the method to the provision specifications in the relevant Codex Standard. CCMAS delegates and observers are expected to review this information prior to endorsing the method for inclusion in CXS 234.
 - b. Methods of analysis elaborated by international organizations occupying themselves with a food or group of foods are preferred.
 - c. Methods which have been validated in interlaboratory trials are preferred.
- v. Committees are encouraged to offer proposals for the Typing of a method and the Principle (definition of the technique) according to the requirements of CXS 234. CCMAS will confirm these proposals and also consider the advice of relevant SDOs.
- vi. Method proposals should be supplied to CCMAS well in advance (60 days) of a physical meeting to enable receipt of comments from interested parties.
- a. Delegates, SDOs and observers are strongly encouraged to provide written comments in a timely fashion (30 days, prior to the meeting).

3.3 Endorsement by CCMAS of a proposed method of analysis is a multi-stage process:

- i. Proposed methods are reported to the committee under Agenda Item 2 and Agenda Item 3 of the CCMAS Provisional Agenda.
- ii. Methods together with their Typing and Principle are discussed by the Physical Working Group (PWG) on Methods Endorsement, generally held immediately prior to CCMAS.
 - 1. Delegates and observers are encouraged to review the methods and make any recommendations on possible alternative methods or identical methods in writing prior (30 days) to the PWG and according to CCMAS timelines.
 - 2. If recommendations of alternative methods or identical methods are made during the PWG and not prior to the PWG, discussion and endorsement of these methods may be held for discussion at the next meeting of the committee to allow for adequate review of the recommendations.
- iii. The PWG report recommends endorsement and typing or denial of methods to the committee.
- iv. CCMAS discusses the report of the Physical Working on Methods Endorsement in plenary.
- v. Methods endorsed by CCMAS are forwarded to CAC for adoption, except if methods have been submitted directly to CCMAS and without prior input of the relevant active Codex Committee (Section 3.1 iv).

3.4 Revocation/removal by CCMAS of a method of analysis listed in CXS 234:

CCMAS has agreed (REP16 MAS, Appendix IV) to an on-going periodic (10 years) review of methods. This periodic review is partly intended to capture methods that need to be revoked/removed. Additionally, the following steps are applicable to initiate the revocation/removal of a method outside of the periodic review process:

⁶ Procedural Manual: *Relations between Commodity Committees and General subject Committees, Methods of Analysis and sampling, normal practices*

- i. The recognition that a method is obsolete, inappropriate (no longer fit for purpose) or has been withdrawn by the relevant SDO should be brought to the attention of CCMAS by Codex Committee members, member countries, observers and SDOs.
- ii. When a method becomes obsolete the committee originally proposing the method of analysis should be informed and should find a replacement and bring it to the attention of CCMAS.
- iii. The SDO should bring the information directly to CCMAS if the Codex Committee is adjourned or otherwise inactive/unresponsive.
- iv. The opinion of the SDO which owns the method should be recognized by CCMAS.
- v. Proposals for a replacement are encouraged and will be deliberated by CCMAS.
- vi. If CCMAS identifies an obsolete or inappropriate method it should alert the committee (if active) of proposed removal from CXS 234, to allow the committee to respond to the revocation.

3.5 The role of SDOs in Codex Committees

To play a positive role in the maintenance of methods of analysis for use in the Codex system, SDOs wishing to maintain ownership and exercise their rights as methods providers (intellectual property and copyright issues) should undertake the following oversight activities:

- i. Have Codex Alimentarius observer status
- ii. Follow the activities of relevant Codex committees
- iii. Contribute timely written comments on relevant issues
- iv. Provide method performance data and other relevant information to the CCMAS during method review
- v. Contribute oral comments during plenary proceedings
- vi. Inform Codex of changes in SDO activities (for instance in a report/brief news item or through joint contributions of the InterAgency meeting)
- vii. Bring to the attention of CCMAS actions at a Codex committee which may lead to a change in requirements for a method of analysis
- viii. Bring to the attention of a Codex committee actions by CCMAS which may lead to a change in requirements for a method of analysis
- ix. Provide Codex Alimentarius with assistance when deliberations involve technical details or a deeper understanding of analytical issues
- x. Encourage horizontal and regional committees to seek the advice of relevant SDOs on analytical issues at all stages of standard development, including contacting those organizations not participating during a discussion.
- xi. Ascertain that references in CXS 234 to their standards are correct and kept up to date.

3.6 The role of SDOs at CCMAS in the methods endorsement process

SDOs should be:

- i. The provider of accurate information regarding the status of an analytical method and its stage within the organization's method evaluation process (e.g. publication status, SLV, full collaborative study or anecdotal or PT data collection) and its fitness for purpose.
- ii. In agreement when methods are "Identical" or have sufficient differences to affect the analytical outcome. SDOs are to provide this assurance to CCMAS.
- iii. Able to consider scope and scope extension vs "Codex general methods".
- iv. Able to provide advice on method typing as these criteria are specific to Codex, and not generally used by SDOs outside of CCMAS.

3.7 Replacement of Type I methods

This sub-section is applicable to the replacement of a Type I method with a new Type I or with Type II/III method(s).

- i. Codex committee, either through members or consultation with SDO, proposes to replace an existing Type I method
- ii. The new method may be an empirical or rational method
- iii. The new method is referred, reviewed and endorsed as outlined in sub-section 3.1
- iv. As part of the endorsement a time frame to complete the change is established
- v. If adopted by the Commission, the new method would replace the older method in CXS 234 at designated date.

3.8 Type IV methods and their transitioning to other method types

- i. New candidate methods may only be typed as Type I, II or III when submitted with a full set of validation data, e.g. precision data obtained in conformity with internationally accepted standards. With the submission of other lesser validation data these methods will be listed as Type IV.
- ii. Existing Type I methods without a full set of validation data are to be considered on a case-by-case basis by the relevant SDO(s) on:
 - a. the feasibility of collecting and submitting the missing validation data to Codex
 - b. the availability of an alternative candidate-method to become the Type I method
 - c. the rationale for keeping the existing Type I method in place as is
 - d. the rationale for retyping the method or revocation of the method.
- iii. A method typed as Type IV may be retyped after the submission of acceptable validation data from the SDO, or method owner, to CCMAS. A method should not remain as Type IV indefinitely.
- iv. Where two methods are proposed as Type I for a particular provision, the relevant SDOs shall determine if the methods are Identical (in which case they can both be listed) or if, based on the performance data or other information, one better meets the required criterion than another. In cases where there is a regional preference for one method over another, the relevant Codex committee should decide, and provide justification on, which method to put forward to CCMAS.

3.9. Presentation of methods for incorporation into CXS 234

CXS 234 is a summary document that contains all the methods of analysis that cover provisions contained in Codex Standards but excludes methods for pesticides and veterinary drugs in food, the assessment of micro biological quality and safety in food, and the assessment of specifications for food additives. In time this will be the sole reference for these methods.

- i. Information required:
 - a. An attribute in a Codex standard with a limit/range of values or a characteristic (authenticity)
 - b. A suitable method for the analysis, preferably from an accepted SDO
 - c. Principle
 - d. Codex Typing
 - e. Assurance that sufficient testing has been carried out to generate precision data
 - f. Validation data that prove fitness for purpose⁷
- ii. Correct use of separators between methods presented in CXS 234 (as per Table 2.1).
- iii. If separator is not applicable (e.g. not Identical), methods should be listed in separate rows.

⁷ Degree to which data produced by a measurement process enables a user to make technically and administratively correct decisions for a stated purpose. *Guidelines on Analytical Terminology* (CXG 72-2009)

Annex I

Template for submissions of methods for Endorsement of Methods of Analysis and Sampling

Executive Summary (if long document)

Insert a brief summary of the submission and the recommendations to CCMAS.

Agenda Item #3: Endorsement of Methods of Analysis Provisions and Sampling Plans in Codex Standards

Codex Committee on

Methods of analysis for provisions in the Standard for (CXS....)

Method(s) for provision 1

- If relevant, reminder of the decision from Codex Committee.
- Title and description of Method A. Scope, validated matrice(s). Indicate where the method is published, and where the validated data/report of collaborative study is published.
- Description of the principle (including reagents, standards, temperatures, equipments...)
- If other methods are already listed in CXS 234, brief description of current method(s) (method B), and how the new proposed method compares to it.

Include a Summary table of the validation data for each attribute (repeatability, reproducibility, recovery and limit of quantitation, if data is not protected by copyright). The table and/or text above may include other relevant information from the collaborative study.

Attribute – XXX	Method A	Method B
Matrices, samples used in collaborative study		
Concentration range of matrices validated		
Repeatability (RSD _r or s _r)		
Reproducibility (RSD _R or s _R)		
Recovery range from SLV/MLT		
Accuracy (Certified materials)		
Limit of Quantitation		
CXS XX provision 1		

[Note: SLV refers to Single Laboratory Validation. MLT refers to Multi-Laboratory Testing studies (i.e. collaborative studies).]

Summary of proposed changes in CXS 234, including retyping of existing methods and recommendations to CCMAS

Table 1. Recommended Methods of Analysis and Sampling (CXS 234-1999)

Commodity	Provision	Method	Principle	CXS	Proposed Type
Commodity	Provision	New method A	Principle		II
		Existing method B retyped	Principle		III
		Existing method C no change	Principle		III
		Existing method proposed to be removed	Principle		III

Recommendations to CCMAS

XXX recommends CCMAS to take the following actions:

1. Endorse Method A as Type II for the determination of attribute(s) in commodity A and reclassify the following existing Type II methods as Type III:
 - a. Method B
 - b. Method C