CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture Organization of the United Nations

World Health Organization

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REP21/MAS

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

44th Session

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REPORT OF THE 41st SESSION OF THE CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

Virtual

17 – 21 and 25 May 2021

TABLE OF CONTENTS

SUMMARY AND STATUS OF WORK

Responsible Party	Purpose	Text / Topic	Code / Reference	Step	Para(s)
Members CCEXEC81 CAC44	Adoption / Revocation / amendments	Methods of analysis / performance criteria for provisions in Codex standards	CXS 234 - 1999	-	24(i), 42(i)
CAC44	Editorial amendments	Provision in Section 3.3 of the *Standard for Edible Casein Products* (	CXS 290-1995)	-	24(ii)
Members CCEXEC81 CAC44	Adoption	*Guidelines on Measurement Uncertainty*	CXG 54 – 2004	8	70(i)
		General Guidelines on Sampling	CXG 50 – 2004	5	110(i)
CCNFSDU	Information / Action	Methods in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* / methods to measure sweetness in drink / product for young children with added nutrient / drink for children	CXS234 – 1999 CXS 72-1981 / CXS 156 - 1987	-	8 - 10
CCAFRICA	Action	Methods of analysis in the standard for dried meat	CXS 234 – 1999	-	12 and 24(iii)
CCNASWP	Action	Methods of analysis for provisions in the standards for fermented noni juice and kava	CXS 234 – 1999	-	13 – 17 and 24(iii)
CCSCH	Information	Methods of analysis for provisions in standards for various spices and culinary herbs	CXS 234-1999	-	21
CCFO	Action / information	Methods of analysis for provisions in standards for fats and oils	CXS 234 – 1999	-	51 (i – iii)
All relevant committees	Information / comments	Revision of the General Guidelines on Sampling	CXG 50-2004	-	110(iv)
	Information	Review / update of methods of analysis in the General Standard for Methods of Analysis and Sampling	CXS 234-1999	-	6
Members /PWG on endorsement / CCMAS42	Action	Methods of analysis for moisture in dried milk	CXS 234-1999		42(ii)
EWG (USA) / PWG on endorsement CCMAS42	Review / update	Processed fruit and vegetables workable package	CXS 234 - 1999	-	24(iv), 43
EWG (The Netherlands) / PWG on endorsement CCMAS42	Review / update	Fats and oils workable package	CXS 234 – 1999	-	51(iv)

Responsible Party	Purpose	Text / Topic	Code / Reference	Step	Para(s)
EWG (Canada) / PWG on endorsement CCMAS42	Review / update	Cereals, pulses and legumes workable packages	CXS 234 - 1999	-	55
PWG (USA / Australia) CCMAS42	Endorsement	Methods of analysis and sampling and other related matters	CXS 234 – 1999	-	24(iv)
Germany CCMAS42	Drafting Discussion	Information document: support the application of *Guidelines on Measurement Uncertainty*	-	-	70(i)
EWG (NZ / Germany) CCMAS42	Drafting Comments Discussion	Revision of the *Guidelines on Sampling*	CXG 50 - 2004	6/7	110(ii)
Members / Switzerland / CCMAS42	Comments discussion	Criteria to select Type II methods from multiple Type III methods	Information document: *Comprehensive guidance for the process of submission, consideration and endorsement of methods for inclusion in CXS234*	-	119(i)

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
CCAFRICA	FAO/WHO Coordinating Committee for Africa
CCASIA	FAO/WHO Coordinating Committee for Asia
CCNASWP	FAO/WHO Coordinating Committee for North America and South West Pacific
CCNE	FAO/WHO Coordinating Committee for Near East
CCCF	Committee on Contaminants in Foods
CCFO	Committee on Fats and Oils
CCMAS	Committee on Methods of Analysis and Sampling
CCNFSDU	Committee on Nutrition and Foods for Special Dietary Uses
CCPFV	Committee on Processed Fruits and Vegetables
CCSCH	Committee on Spices and Culinary Herbs
CRD	Conference room document
DHA	docosahexaenoic acid
EU	European Union
EWG	Electronic working group
EPA	eicosapentaenoic acid
FAO	Food and Agriculture Organization of the United Nations
IAM	Interagency Meeting
IDF	International Dairy Federation
ISO	International Organization for Standardization
NFCSO	National Food Chain Safety Office (Hungary)
ML	Maximum level
MU	Measurement uncertainty
PWG	Physical working group
SDO	Standards development organisations
USPC	United States Pharmacopeial Convention
WG	Working group
WHO	World Health Organization

LIST OF CRDS

CRD No.	Agenda Item	Submitted by
01	Division of Competence	EU (Division of Competence between EU and its Member States)
02	Agenda item 2,3,4.1 and 4.2	Report of PWG
03	Agenda item 2	AOAC/ICC
04	Agenda item 3	AOAC, ISO and IDF
05	Agenda item 2	AOAC, ISO and IDF
06	Agenda item 4.1	IDF/ISO
07	Agenda item 3	New Zealand
08	Agenda item 4.2	GOED
09	Agenda item 4.2	Thailand and AOCS
10	Agenda item 3,7,and 8	Nigeria
11	Agenda item 5	Nigeria, Thailand, AAFCO
12	Agenda item 2	IACST
13	Agenda item 6	Thailand, EU
14	Agenda item 7	El SALVADOR EU
15	Agenda item 8	EU
16	Agenda item 9	The report of IAM
17	Agenda 3, 4.1 and 4.2	NMKL
18	Agenda 4.1	Uruguay
19	Agenda 2, 3.and 5	EU
20	Agenda 5 and 7	Senegal
21	Agenda 3,4,5,6,7, and 8	India
22	Agenda 3,4.1,4.2,5 and7	Mali
23	Agenda 3,4.1,4.2,5 and8	Chili
24	5	Brasil, Costa Rica, Chile, Ecuador, Honduras, Panamá, Trinidad y Tobago, Uruguay and Venezuela
25	4.1	Argentina, Bolivia, Brasil, Chile, Colombia, Costa Rica, Ecuador, Honduras, Panamá, Paraguay, Trinidad y Tobago, Uruguay, Venezuela

INTRODUCTION

1. The Codex Committee on Methods of Analysis and Sampling (CCMAS) held its 41st Session virtually from 17 – 21 and on 25 May 2021, 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 Zsuzsa Farkas, Food Chain Data Scientist, Digital Food Institute acted as the Vice-Chairperson. The Session was attended by 83 Member Countries and 1 Member Organization and 21 observer organizations. A list of participants is given in Appendix I.

OPENING OF THE SESSION

2. The Session was opened by Dr Lajos Bognár, chief veterinary officer of Hungary who welcomed delegates to CCMAS41 and reminded the Committee of the importance of trust, which is built through the continuous cooperation between countries on determining food standards and the work of laboratories all around the world, 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 Szabolcs Szigeti, Regional Office for Europe of World Health Organization (WHO) also addressed the Committee.

Division of Competence[1]

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 as the agenda for the session.

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

5. CCMAS noted the matters for information and that matters for action related to methods of analysis had been considered by the Working Group (WG) on Endorsement and would be further considered under Agenda Item 3.

6. CCMAS also confirmed its continued liaison with other Codex committees on the use of the *General Standard on Methods of Analysis and Sampling* (CXS 234-1999) as the single reference for methods of analysis and sampling as requested by CCEXEC77.

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

7. 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 WG 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 (CCNFSDU41)

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

8. CCMAS agreed:

   i. to submit the AOAC 2011.14 / ISO 15151 | IDF 229 in CXS 234 as Type III for calcium, copper, iron, magnesium, manganese, phosphorus, potassium, sodium and zinc in infant formula as previously endorsed for adoption by CAC44 and inclusion in CXS234;

   ii. to inform CCNFSDU:

   - of the above decision as it was not possible to develop numeric criteria in this case as CCNFSDU had agreed to retain the Type II methods. Numeric criteria would not solely apply to Type III methods, but also remove the designation of Type II methods.
   - that the methods for fructans, beta-carotene and lycopene were not endorsed as there were no accompanying provisions in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CXS 72-1981) and to request CCNFSDU to provide a rationale to support their proposal for methods for these ingredients / nutrients. CCNFSDU should be informed

1 CRD1
2 CX/MAS 21/41/1,
3 CX/MAS 21/41/2,
4 CX/MAS 21/41/3, CX/MAS 21/41/3 Add.1.

that all proposed methods of analysis must have direct pertinence to the Codex standard to which they are directed.

9. CCMAS did not agree to a proposal to include a note to CXS234 to clarify that the two methods for fructans listed in CXS 234 were not applicable for infant formula and that this matter could be considered in future once a reply was received from CCNFSDU.

Methods to measure sweetness in drink/product for young children with added nutrient / drink for children

10. CCMAS agreed to inform CCNFSDU that there were no known validated methods to measure sweetness of carbohydrate sources and therefore no way to determine compliance for such a provision.

FAO/WHO Coordinating Committee for Asia (CCASIA)

11. CCMAS endorsed the methods of acidity and moisture for laver products as Type I, noting that extension to a new matrix of a previously validated method does not require a full collaborative study.

FAO/WHO Coordinating Committee for Africa (CCAFRICA)

Methods of analysis for provisions in the Standard for dried meat

12. CCMAS agreed to:

i. inform CCAFRICA that only the methods for water activity and determination of ash were endorsed and would be included in CXS 234;

ii. request feedback on the remaining methods as follows:

- Only one method can be endorsed for moisture and therefore to indicate their preference for either AOAC 950.46B or ISO 1442.
- ISO 1443 is for the determination of total fat and AOAC 960.39 is for the determination of crude fat. CCAFRCA should consider if the determination crude fat or the determination of total fat is the correct provision.
- For determination of crude protein, a conversion factor must be used to convert the nitrogen results measured by the method to a crude protein value and only one method can be endorsement for this provision. CCAFRICA should consider whether method AOAC 928.08 or ISO 937 is preferred and whether it agrees with the conversion factor of 6.25 identified by CCMAS.
- Multiple methods were identified for determination of chloride. Only one method can be endorsed as Type II and the rest of the methods will be listed as Type III. CCAFRICA should consider which method amongst the following, ISO 1841-1 or ISO 1841-2 or AOAC 935.47 and 937,09b is their preference for a Type II method.

FAO/WHO Coordinating Committee for North America and the South West Pacific(CCNASWP)

Methods of analysis for provisions in the draft regional standard for fermented noni fruit juice

13. CCMAS did not endorse:

- the AOAC 983.17 / EN 12143 / IFUMA 8 / ISO 2173 as the appropriateness of extending the methods to noni juice needed further evaluation by CCMAS; and noted the offer of IFU to do a small single or inter-laboratory study to determine its fitness for purpose in noni juice;
- the methods for the identification of scopoletin and deacetylasperulosidic acid noting that changes needed to be made to the methods to give a clear indication of the solid phase extraction separation mode needed and agreed to request CCNASWP to provide clarification.

14. CCMAS agreed to inform CCNASWP accordingly.

Methods of analysis for provisions in the regional standard for kava products for use as a beverage when mixed with water

15. CCMAS noted that the review of the references did not produce a clear procedure for determining kava lactone or flavokavins, and that it appeared there were different sections within each reference that needed to be followed and that the 2016 reference may not be required for flavokavins.

16. CCMAS agreed to request CCNASWP to consider producing a single stepwise method or SOP which would capture the necessary steps for each provision in one easy to follow document.

17. CCMAS encouraged delegates to work with the delegates to CCNASWP in this regard.

Committee on Processed Fruits and Vegetables (CCPFV)

Methods of analysis for moisture in dried fruits (prunes and raisins)

18. CCMAS noted the method for determination of moisture was listed in CXS 234 for raisins, and that the proposal was to extend it also to prunes in view of the development of a more general standard for dried fruits by CCPFV. However, CCMAS did not take a decision at this time noting the concerns expressed with the use of AOAC 972.20 for determining moisture in prunes as the equipment needed to apply the method might not be available in future. It was agreed that the availability of equipment to apply the method, and information can be provided to CCMAS42 for further consideration.

19. CCMAS agreed to retain the method as listed in CXS234 for raisins for the time being.

Sampling plans

20. CCMAS did not endorse the proposed sampling plans at this time noting the ongoing work on the revision of the *General Guidelines on Sampling* (CXG50-2004). CCMAS was advised to consider CRD 7 that contains examples of sampling plans for Gochujang and to request further comments on the proposals in CRD 7.

Committee on Spices and Culinary Herbs (CCSCH)

Methods of analysis in standards for dried oregano, dried roots, rhizomes and bulb – dried or dehydrated ginger, dried floral parts – cloves, dried basil, and dried seeds (nutmeg)

21. CCMAS endorsed the methods for provisions in dried oregano and noted that the WG on endorsement will consider the other methods submitted by CCSCH (CX/MAS 21/41/3 Add.1) at CCMAS42.

Dairy package (Appendix I of CX/MAS 21/41/4)

Methods of analysis for ash in dairy permeate powders

22. CCMAS confirmed that the AOAC 930.30 for determination of ash in dairy permeate powders was identical to NMKL 173 and endorsed the methods as Type I.

Methods of analysis for free acidity in edible casein products

23. CCMAS agreed to amend the provision for “acids, free” to “free acidity” in edible casein products and agreed to request CAC44 to make an editorial amendment to the provision in Section 3.3. *Standard for Edible Casein Products* (CXS 290-1995) by changing “maximum free acid” to “maximum free acidity” as this was a more appropriate description of the provision.

Conclusion

24. CCMAS agreed to:

i. submit the methods for adoption / revocation by CAC44 (Appendix II);

ii. submit the editorial amendment to Section 3.3 of the *Standard for Edible Casein Products* (CXS 290-1995) to CAC44 for adoption;

iii. refer the relevant matters identified to CCNFSDU, CCAFRICA (Appendix II, part 4.1), CCNASWP (Appendix, part 4.2)and CCFO (Appendix II, part 4.3);

iv. 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 by Codex Committees for endorsement, including the proposals on the workable packages: fats and oils, cereals, pulses and legumes; and processed fruits and vegetables (see Agenda Item 4); and the methods deferred by this Session.

REVIEW OF METHODS OF ANALYSIS IN CXS234 (Agenda Item 4)

Dairy workable package (Agenda item 4.1)[5]

25. The United States of America, Chair of the EWG, introduced the item, explained the process followed by the EWG, the key results/recommendations, and issues that needed further discussion by CCMAS. He noted that the methods presented in Appendix II, CX/MAS 21/41/4, had been considered by the WG on endorsement and recommendations of the WG were considered under Agenda item 3, but that further discussion and decision was needed on the points in paras 26 – 29 and Appendix II of CX/MAS 21/41/4.

5 CX/MAS 21/41/4

26. CCMAS considered the points needing further consideration and made the following comments and decisions

Removal of the commodity milk products from CXS 234

27. CCMAS agreed to remove the commodity "milk products" from CXS 234, noting that information captured in the commodity "milk products" was already captured for the specific commodity listings and that the removal of this category from CXS234 would therefore not affect availability of methods of analysis.

Numeric criteria in place of methods for iron, copper and lead

28. The EWG Chair clarified that the numeric criteria were based on the maximum levels for iron and copper in milkfat products and edible casein products as listed in the respective corresponding commodity standards, i.e. *Standard for Milkfat Products* (CXS280-1973) and *Standard for Edible Casein* (CXS290-1995). However, for lead in butter there was currently no ML, so the numeric criteria were based on secondary milk products MLs in the *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995).

29. There was general support for the criteria approach.

30. Noting the practice by CCMAS to list also example methods that meet the criteria, two observers and a member expressed the view that while methods could be listed as examples for copper and iron, for lead there were currently no methods that would meet the criteria. Their preference was to not proceed with numeric criteria at this point, but to continue listing the current methods in CXS234.

31. The Chairperson clarified that the inclusion of example methods, while it was current practice, did not imply their use, neither endorsement by CCMAS, and that where methods did not exist, it would allow SDOs to address these shortcomings.

Conclusion

32. CCMAS agreed to the numeric criteria for iron and copper and to include examples of applicable methods including those currently listed in CXS 234 as examples for further review at its next session. CCMAS noted that for iron in Milkfat Products there were no applicable methods identified. For lead, CCMAS agreed to the numeric criteria, but not to include examples at this time and to retain the current methods in CXS234 for review at its next session. CCMAS also agreed to include the commodity name from the commodity standard and the commodity name from CXS 193 in parentheses (e.g. butter (secondary milk products), to help identify the source of the criteria.

33. CCMAS also noted that CCCF at it next session would be considering a discussion paper on the review methods for lead, amongst others, and the possibility to develop numeric criteria. It was expected that CCCF would be reporting to CCMAS in 2022 and further consideration could be given to this matter at the next session.

Peroxide value in milk fat and determination of milk fat purity by GC analysis of triglycerides

34. CCMAS agreed to:

- remove from CXS 234 AOAC 965.33 for determination of peroxide value in milk fat; and
- retain the methods ISO 17678 | IDF 202 as Type I methods for determination of milk fat purity by GC analysis of triglycerides in CXS 234.

Fermented Milk products – bacterial starter cultures

35. CCMAS agreed to align the provision in CXS234 with that in the *Standard for Fermented Milk Products* (CXS 243-2003) and with the scope of ISO 27205 |IDF 149 to read: *"sum of microorganisms constituting the starter culture (Bacteria in fermented milk deriving (or originating) from starter culture)."*

Moisture

36. CCMAS could not reach consensus on method ISO 5537 | IDF 26 for determination of moisture content in dried milk.

37. Proposals were made for AOAC 927.05 as the preferred Type I method, noting that:

- this was a standard method widely used for determination of moisture in dried milk in many countries around the world; and
- the ISO |IDF method had limitations for use especially since the equipment and utensils were not widely available, were costly and led to environmental waste, and was therefore not accessible to many countries.

38. Those members supporting the AOAC 927.05 also reminded the Committee that not only should CCMAS consider performance data but also should look into applicability, availability and cost of methods in line with the criteria for selection of methods set out in the Procedural Manual.

39. The EWG Chair explained, that it was necessary to consider performance data to evaluate replacement of a Type I method which was already listed in CXS234 for many years, and reminded CCMAS that according to its own rules in the *Comprehensive guidance for the process of submission, consideration and endorsement of methods for inclusion in CXS234*, performance / validation data should be submitted in the template provided 60 days prior to a Session of CCMAS. He acknowledged that when evaluating methods for inclusion in CXS234, consideration should also be given to accessibility and cost implications.

40. The observer from IDF, drawing attention to CRD6, provided a history of the updating of the ISO method over time to allow better precision and presented some of their research into the use of the ISO | IDF method. It had been shown that equipment was available on the market, and some laboratories had built equipment for application of the method in-house, and supported the retention of the current method as Type I and proposed that AOAC 927.05 could be endorsed as Type IV.

Conclusion

41. CCMAS agreed to consider this matter at its next session.

Conclusion

42. CCMAS agreed to:

    i. submit the methods and numeric criteria as endorsed (Appendix II, Part1) and request revocation of the methods for milk products (Appendix II, Part 2) to CAC44 for adoption and inclusion in CXS234;

    ii. defer decision on the methods for moisture content to CCMAS42; and agreed:

        - to request the PWG on endorsement to consider this matter;
        - to assess the data to support if AOAC 927.05 is fit for purpose and that such data should be submitted according to the template in *Comprehensive guidance for the process of submission, consideration and endorsement of methods for inclusion in CXS234;* and
        - consideration should also be given to the accessibility and cost of the methods recommended for endorsement.

Other matters

43. In view of the near completion of the review of the dairy workable package, CCMAS agreed to:

    i. start the review of methods in the processed fruit and vegetables package;

    ii. establish an EWG Chaired by the United States of America, and working in English, to review the package and prepare proposals for consideration by CCMAS42.

Fats and Oils workable package (Agenda Item 4.2)[6]

44. The Netherlands, Chair of the EWG, introduced the item, explained the process followed by the WG and the key recommendations as presented in CX/MAS 21/41/5.

45. The EWG Chair explained that:

- the review focused on checking the "fitness for purpose" of methods in CXS 234, and consideration of their Typing. New methods were not considered at this point and that such methods could go through the normal endorsement process on recommendation of the relevant commodity committee, e.g. CCFO;
- there were certain issues on which further discussion was needed and that might need to be referred also to CCFO; and
- review of the methods related to provisions in the *Standard for Olive Oils and Olive Pomace Oils* (CXS 33-1981) should be suspended pending the ongoing revision of this standard in CCFO.

Discussion

46. CCMAS considered the proposals in CX/MAS 21/41/5, Appendix I and in addition to some editorial or other corrections to either the method or principle, made the following comments and decisions.

[6] CX/MAS 21/41/5

47. CCMAS:

- agreed to not consider the methods for olive oils and olive pomace oils at this time in view of the ongoing work in CCFO. This part of the package could be reconsidered in future upon finalization of the revision of the *Standard for Olive Oils and Olive Pomace Oils* by CCFO;
- endorsed some of the methods for provisions pertaining to fat spreads and blended spreads; fats and oils (all); fats and oils not covered by individual standards; fish oils; named animal fats; named vegetable oils; and named animal fats (Appendix II, Part 1). In particular, CCMAS noted that for fish oils, methods for arsenic should determine inorganic arsenic. Currently there is not a provision for inorganic arsenic in fish oil and therefore no numeric criteria have been developed and no applicable methods have been endorsed. CCMAS also noted, the criteria approach could be considered for the methods for determination of total arsenic in fats and oils (all) and inorganic arsenic in fish oils and agreed to request CCFO to consider the criteria approach, and that pending feedback from CCFO, criteria could be developed, if a provision exists, by the EWG for consideration by the next session.;
- agreed that specific feedback was needed from CCFO on the following matters to guide further work on the review by the EWG before the methods could be considered for endorsement:

  Fats and oils

  - What would be the trade impact on the retyping of one of 2 (two) proposed methods for determination of synthetic antioxidants in fats and oils. It was noted that AOCS and ISO are collaborating to produce identical methods to replace AOCS Ce-6-86 by 2023.

  Fish oils

  - What would be the trade impact on the retyping of the method AOCS Ce 2-66 and AOCS Ce 1i-07 for fatty acid composition in fish oils as Type II;
  - Consider the trade impact of retyping the ISO methods to Type III.

  Named animal fats

  - What would be the trade impact on the retyping of the methods for fatty acid composition as Type II; and
  - Noting that the methods currently listed in CXS 234 for titre, ISO 935 and AOCS Cc 12-59 were not identical and therefore cannot both be Type I methods, and noting that ISO 935 is more "fit for purpose", what would be the trade impact on retyping the ISO method as Type I. AOCS Cc 12-59 is proposed as Type IV.

  Named vegetable oils

  - Whether the methods for Crismer value and Halphen test are still in active use; and
  - ISO 18609 is not identical to ISO 3596 and AOCS Ca 6b-53. ISO 18609 is a method which produces systematically underestimated results. What would be the impact for trade if ISO 18609 were retyped to Type IV.

48. CCMAS noted that the proposals agreed by CCMAS for methods on the fats and oils package should be referred to CCFO for their information, agreement and /or further comment in line with the procedure agreed by CCMAS37 (REP16/MAS Appendix IV).

49. Furthermore, to simplify the review process on this package, any new methods could be put directly to CCFO and submitted to CCMAS through the normal endorsement procedures. In this regard, CCMAS noted the intervention from an observer that two important methods used in industry globally for quantification of omega-3-fatty acids, EPA, DHA and total omega-3-fatty acids in fish oils were not listed, namely, the European Pharmacopoeia method 2.4.29 and the United States Pharmacopoeia Method USP401 and would be brought to the attention of CCFO.

50. CCMAS did not discuss the methods for Vitamins A and D in fish oils; and carotenoids and relative density in named vegetable oils and agreed to refer these to the EWG for further consideration. (Appendix II, Part 5).

Conclusion

51. CCMAS agreed to:

i. Refer the endorsed methods to CCFO for their comments and/or agreement (Appendix II, Part 4.3) and if there is agreement on the methods, these could go directly to CAC44 for adoption;

ii. Refer the questions in paragraph 47 and the related methods (Appendix II, Part 4.4) to CCFO for their consideration and reply;

iii. Inform CCFO that work on the review of methods for provisions in the *Standard for Olive Oils and Olive Pomace Oils* (CXS 33-1981) would be considered in future upon completion of the revision of the Standard by CCFO;

iv. Re-establish the EWG on the review of the fats and oils package, chaired by The Netherlands, and working in English to

- Continue reviewing the remaining methods in Appendix II, Part 5
- To consider replies from CCFO and the issues raised;
- Prepare revised proposals for consideration by CCMAS42.

Cereals, pulses and legumes workable package (Agenda Item 4.3)[7]

52. The observer from AACCI introduced the item, described the progress made and explained that workbooks were being reviewed by relevant SDOs.

53. It was clarified that the purpose of the review is to ensure that the methods of analysis listed in CXS 234 are fit-for-purpose and to retype if necessary, but to facilitate the review process, not to add new methods unless necessary.

54. CCMAS noted that good progress had been made on workbooks by the relevant SDOs and in line with previous processes for the review of workable packages, agreed with the proposal of the Chairperson that the continued reviewed of the workable package should continue through an EWG.

Conclusion

55. CCMAS agreed to establish an EWG chaired by Canada, working in English only, to continue the review on the cereals, pulses and legumes workable package and to work in close coordination with the relevant SDOs (AACCI, AOAC and ISO).

REVISION OF THE GUIDELINES ON MEASUREMENT UNCERTAINTY (CXG54–2004) (at Step 7) (Agenda Item 5)[8]

INFORMATION DOCUMENT: GUIDELINES ON MEASUREMENT UNCERTAINTY: Procedures for the Estimation of Measurement Uncertainty (Agenda Item 6)[9]

56. Germany introduced the item and recalled that CCMAS40 (2019) had advanced the revised Guidelines (REP 19/MAS, Appendix IV) to CAC42 (2019) for adoption at Step 5. CAC42 had adopted the Guidelines at Step 5 and advanced it to Step 6. In view of the additional time at the disposal of the Committee due to the postponement of CCMAS41 from 2020 to 2021, Germany addressed the comments in reply to the different circular letters to produce a revised draft as presented in CX/MAS 21/41/7.

57. Germany outlined the key changes made and reminded CCMAS that the aim of CXG54 was to provide basic information and orientation on estimating measurement uncertainty while remaining concise, and for this reason, it was proposed to make available more in-depth information and examples in an information document.

58. The EWG Chair further reminded the Committee that CCMAS had previously agreed that the Guidelines would exclude sampling uncertainty, but that CXG50, CXG54 and the Information Document may lay the groundwork for a discussion of sampling uncertainty in a possible subsequent guidance document.

59. CCMAS considered the revised draft and noted that it addressed all the concerns and comments raised by members and observers and was ready to be advanced to Step 8 and in addition to editorial changes, inclusion of additional references, made the following additional amendments.

Introduction

60. CCMAS agreed to refer to *analytical* measurements throughout the document and that, as the content of these Guidelines was general, the term “analytical” was broad enough to cover chemical, physical and microbiological measurements.

Scope

61. CCMAS did not agree to amend the scope to explain why the Monte Carlo Method was not addressed in the Guidelines, but agreed to add JCGM 101 (Monte Carlo Method) as one of the common procedures for estimating measurement uncertainty (paragraph 13).

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7 CX/MAS 21/41/6
8 CX/MAS 21/41/7
9 CX/MAS 21/41/8

62. CCMAS recalled that the revision of these Guidelines was to make it simpler and to provide overarching principles and guidance on measurement uncertainty, rather than to provide too much detailed explanation on how to conduct different techniques available to estimating measurement uncertainty, and that further details on the Monte Carlo Method could be addressed in the associated information document where more specific options were provided on how to estimate measurement uncertainty.

Terms and Definitions

63. CCMAS agreed to:

- delete the definition for "increment" as not needed in these Guidelines; and to clarify the definition of "lot";
- delete the date of publication from the reference documents from SDOs (e.g. ISO) in line with a previous agreement of the Committee; and noted that the latest edition of any of references should be consulted or used.
- retain the definition of sample size as suitable for the purposes of these Guidelines, i.e. to sample/take a collection of items from a lot so that the sample size is the number of items in the sample. This must not be confused with the laboratory sample, which serves as the basis for further subsampling *within the laboratory* to obtain test samples and test portions.

64. CCMAS did not agree to include definitions for measurement uncertainty contribution, expanded uncertainty and combined uncertainty as they were available in other documents from internationally recognized organizations and the general nature of these Guidelines did not require such level of detail for the definitions of these terms.

paragraph 17

65. Noting that the excel formula would be difficult to translate into other languages, and its application could be restrictive, CCMAS agreed to replace the paragraph by more general text given the generic scope of the document and that the excel formula or other more suitable mathematical formulas could be taken up in the information document.

paragraph 19 (b)

66. CCMAS agreed to amend this paragraph to make sure not to exclude methods which have been validated in a collaborative study and for consistency with similar approaches in other sections of the Guidelines (e.g. paragraph 15).

paragraph 21

67. Noting that ISO/IEC 17025 requires that laboratories should use validated methods regardless of whether they are involved in import/export control, while *Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Foods* (CXG27-1997) which requires that laboratories which are part of food import/export control should comply with ISO/IEC 17025, CCMAS agreed to amend the new paragraph 22 by including reference to CXG27 to reflect that these Guidelines were also applicable to laboratories involved in import/export of foods and laboratories should use validated methods in line with ISO/IEC 17025.

Uses of measurement uncertainty

paragraph 22

68. CCMAS agreed to retain this paragraph as amended by Germany based on the written comments submitted to this session and to clarify that (i) uses of measurement uncertainty cited in this section were not exhaustive and (ii) uses of measurement uncertainty are not limited to acceptance sampling or conformity assessment.

Examples of situations occurring when measurement uncertainty is considered

69. CCMAS agreed to retain the examples, and to clarify the text explained that the maximum levels indicated in the figure 1 were equally applicable to contaminants and other residues levels.

Conclusion

70. CCMAS agreed:

i. to advance the revised Guidelines to Step 8 for adoption by CAC44 (Appendix III); and

ii. to request Germany to revise the information document taking into account the comments and decisions made at the session, for circulation for comments and consideration by CCMAS42.

REVISION OF THE GENERAL GUIDELINES ON SAMPLING (CXG 50-2004) (at Step 4) (Agenda Item 7)[10]

71. New Zealand, as Chair of the EWG introduced the item, explained the process followed by the WG, the progress made and the key outcomes of the work. She further explained the key features of the revised document and that it was being presented as a package, i.e. the revised Guideline together with 2 supporting documents, i.e. the guide to the selection and design of sampling plans and the e-book.

72. The EWG Chair recalled that the aim of the revision was to provide simpler and more easily understandable Guidelines in particular for use by Codex commodity committees, and emphasized that (i) the revised Guideline focused on principles of sampling and (ii) the information document provided a step by step procedure to the design of the sampling plan and (iii) the e-book provided for user-friendly technology in the form of apps.

Introduction

73. Drawing attention also to the written comments submitted the EWG Chair provided clarification on the following issues raised:

Impact of the revised CXG50 on existing sampling plans

74. The EWG Chair recalled that CCMAS39 (2018) had agreed[11] that once the revision was completed, all committees would have an opportunity to review their sampling plans and revise as appropriate taking into account the new revised Guideline.

e-book app validation and debugging

75. The EWG Chair clarified that the work on the apps and the e-book, including documentation to accompany the apps, was not yet completed. It was planned to complete the e-book during the next year and written comments submitted on the e-book would be taken into consideration at this time. However, it was important to note that all apps are based on either peer reviewed papers published in statistical journals or are the application of standard statistical theory.

General considerations

76. CCMAS first considered whether to proceed with the package as presented, followed by a detailed consideration of the revised Guidelines, to identify critical points that may need further discussion in the EWG, with the aim of advancing it to Step 5 at this session, and to enable the EWG to continue work on the finalization of the Guidelines with a view to advancing it to Step 8 at the next session of CCMAS.

Additional considerations

77. CCMAS agreed that the revised Guidelines would be presented as a package for use by governments and Codex committees.

78. To a question raised on whether it wouldn't be more appropriate to first get input from commodity committees on whether the revised Guidelines would meet their needs, since the initial request had come from a commodity committee to revise CXG50 into a more easily understood and useable document, the Codex Secretariat clarified that commodity committees, were informed of the ongoing work, but had received no feedback on this.

79. The EWG chair further informed that:

- there would be undue delay in the work on the Guidelines if CCMAS were to wait on the feedback from each of the commodity committees as there was no synchronicity between the meetings of CCMAS and that of commodity committees;
- besides the feedback provided by commodity committees, it was equally important for countries to provide comments to circular letters; and
- there should be consultation at the national level between delegates to CCMAS and their counterparts to commodity committees to ensure that the Guidelines met the required needs.

Discussion

80. CCMAS considered a revised draft prepared by New Zealand based on the comments received, and attention was drawn to three key issues addressed in the revised draft:

- the relationship between relevant ISO standards, i.e. ISO 2859 and ISO 3951, noting that ISO standard-based plans are relevant in certain situations and that there was a need to marry this with the design of sampling

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10 CX/MAS 21/41/9; CX/MAS 21/41/9-Add.1 (Australia, Canada, Cuba, Egypt, Iran, Iraq, Japan, Morocco, Paraguay, Peru, Philippines, Thailand, United Arab Emirates, United Kingdom, EURACHEM and IAEA)

11 REP18/MAS (para. 69)

plans to control both consumers' risks and producers' risks in the revised Guidelines; ISO plans were included in the revised Guideline and considered as special cases of the general attributes and variables plans

- terminology and content relating to measurement uncertainty and conformity assessment were clarified to align with the revised CXG54. References to conformity testing in the revised CXG54 were removed.
- Information on bulk materials and inhomogeneous lots was included and an overview provided, and this was in line with the terms of reference for the work and the priority list previously agreed[12] by CCMAS39.

81. CCMAS in addition to editorial corrections and inclusion of additional definitions and references, made the following decisions or comments. Critical points identified including amendments to improve clarity, were put in square brackets for further consideration by the EWG:

General issues

82. Some delegations noted that sampling is an essential element for the verification of provisions in Codex standards. The current Guidelines were sometimes difficult to understand and implement by Codex committees and member countries. The revision should therefore attain the overall goal to simplify the structure and language to provide effective guidance to Codex committees and members. They welcomed further developments in this direction.

83. The EWG Chair noted that the current Guidelines require a reasonable level of statistical understanding to be able to design sampling plans and this was the basis for the revision. The revised Guidelines focus on the principles of sampling, especially on the understanding of risks, and how to apply these risks in the design of a sampling plan. The EWG Chair however noted that statistical sampling plans can never be simple but the supporting documents, i.e. the e-book application and the Guide for the selection and design of sampling plans, would further support better understanding and implementation of the revised Guidelines by Codex committees and member countries.

84. CCMAS agreed that:

- the Guidelines were applicable to both safety and quality provisions and inserted a note to indicate that wherever reference was made to "quality", it referred to both "food safety and quality" parameters;
- the section "Terminology" should be combined with the section on "Definitions";
- information notes would be an integral part of the revised Guidelines; and
- terms should be aligned and consistently applied/used throughout the revised Guidelines.

Specific issues

Preamble

85. CCMAS agreed that the inclusion of additional sub-sections to provide clear description of the purpose, target audience and users of sampling plans should be further considered by the EWG.

Scope

86. In reply to a question on whether lots having "a mix of things" could still be assumed to be homogeneous, the EWG Chair noted that it might not be possible to give general advice on this matter as it would vary depending on the nature of the product, manufacturing processes, variation between batches, etc. and as such it would be a matter to consider for each individual commodity. However, there might be room for better clarification in the revised Guidelines and the EWG could consider this matter further. CCMAS concurred with this approach.

Definitions

Decision rule

87. There was an exchange of views on the appropriateness to refer to "acceptance criterion/rule" as opposed to "decision rule" as more appropriate for the acceptance or rejection of the lot and for consistency with ISO 17025. Another view was to keep "decision rule" for measurement uncertainty only.

88. The EWG Chair indicated that for the purposes of these Guidelines, the definition of "acceptance criterion" given in ISO 17025 was rather vague and so did not sufficiently address the needs of CXG50, however, whichever term was finally used, it should be consistently apply across the revised Guidelines.

89. CCMAS agreed that the EWG would further consider this issue and agreed that a definition for "decision rule" was also needed to be included in the revised Guidelines.

12 REP18/MAS, Appendix VI

Confidence

90. CCMAS agreed that the term "risk" associated to "consumers' risk" should be further considered in the EWG as the term "risk" in Codex is usually associated to exposure to hazardous materials and generally refers to food safety risk, and to consider to align this section with the term "probability of wrongly accepting a lot" used in the *Principles for the Use of Sampling and Testing in International Food Trade* (CXG 83-2013). The same considerations should also apply to "producer's risk".

Lot: Information Note

91. CCMAS agreed that the EWG would further develop an information note for the definition of lot.

Measurement error
Measurement uncertainty

92. CCMAS agreed that the EWG should consider aligning the definitions of these terms with those available from Codex i.e. *Guidelines on Analytical Terminology* (CXG 72-2009) or from other recognized international organizations e.g. JCGM.

Standard

93. CCMAS agreed that the EWG should further consider this term to avoid confusion with the term "Codex standards" including the appropriateness of its retention or removal from the revised Guidelines.

Design of sampling plans

Consumer's risk and producer's risk

94. The terminology used should also be aligned and consistently applied across the Guidelines (e.g. quality level/percentage non-conforming).

95. There was an exchange of views on the issue of the levels of consumer's risk and producer's risk vis-à-vis the stringency table and whether the example~~s~~ should be removed as it could be interpreted as part of the provision of the revised Guidelines.

96. The EWG Chair explained that the intention of the section was to present a concept on how to establish relativity between different sampling plans having different levels of risk, and was not intended to recommend any specified levels of consumer's risk.

97. CCMAS agreed that this matter should be further considered by the EWG.

Nature of the specification limit

98. CCMAS agreed that the question on whether the term "specification limit" should be limited for use with individual items should be further considered by the EWG.

Lot Homogeneity

99. CCMAS agreed that the EWG would further clarify this section.

Sampling Plans

Table 1. References to the selection of sampling plans

100. CCMAS agreed that the EWG would further clarify the Table.

Inclusion of ISO sampling plans

101. CCMAS agreed that the EWG would further discuss the inclusion of these plans in the revised Guidelines.

Retesting

102. A concern was expressed on how retesting would be managed in a practical way. Using the guidance provided in the revised Guidelines this should ensure that retesting did not increase producer's risk and did not interfere with other guidance provided by Codex in particular the *Guidelines for Setting Disputes on Analytical (Test) Results* (CXG 70-2009).

103. CCMAS agreed that the EWG would consider this matter further.

Measurement of Error – Measurement of uncertainty

104. It was noted that the measurement error was not consistent with the current Guidelines and therefore the value of 10% should be reconsidered. In addition, there was a need to clarify between measurement error and measurement uncertainty, including uncertainty from sampling, and so the diagrams showing the effect of measurement error should be reconsidered to make it consistent with measurement uncertainty.

105. CCMAS agreed that the EWG would consider this matter further.

Lot size versus sample size

106. A question was made on the statement that a lot size does not play an important role would be true for continuous lot inspection but not for isolated lot inspection and that the main focus of CXG50 is isolated lots.

107. CCMAS agreed that the EWG would consider this matter further.

Reinspection

108. A concern was expressed regarding reinspection especially when there is no evidence of significant sampling or measure error and that further consideration of this section was needed to ensure that producer risk is protected. CCMAS agreed that the EWG could consider this matter further.

E-book and Guidelines on Sampling (supporting / information document)

109. CCMAS41 did not discuss the e-book and supporting guidelines for the design and selection of sampling plans on the understanding that these two supporting documents would be further developed by the EWG.

Conclusion

110. CCMAS agreed:

i. to forward the revised *General Guidelines on Sampling* (CXG 50-2004) to CAC 44 for adoption at Step 5 (Appendix IV); and

ii. to re-establish the EWG chaired by NZ and co-chaired by Germany, to continue to:

- revise the *General Guidelines on Sampling* paying particular attention to the key issues identified at the Session and that are in square brackets;
- develop the supporting documents: e-book and the guide to the selection and design of sampling plans, taking into account all written comments submitted; and
- to provide a revised draft package for consideration by CCMAS42.

iii. that the Codex Secretariat together with the Chair of the EWG would explore holding a webinar to help inform delegates of some of the key issues under discussion in the EWG to facilitate discussion and completion of the Guideline.

iv. to inform other relevant Codex Committees of the ongoing work on the revision of the *General Guidelines on Sampling* and invite any comments as relevant.

111. The Chairperson encouraged all delegates to actively participate in the EWG and to consult also with their country delegates to commodity committees to ensure that the revised Guidelines would meet the needs of commodity committees.

DISCUSSION PAPER ON THE CRITERIA FOR SELECTION OF TYPE II METHODS FROM MULTIPLE TYPE III METHODS (Agenda Item 8)[13]

112. Switzerland introduced the item and explained that CCMAS40 (2019) had agreed that a discussion paper would be prepared on criteria for the selection of Type II methods from multiple Type III methods in CXS 234. In view of the additional time at the disposal of the Committee due to its postponement from 2020 to 2021, Switzerland used the opportunity to revise the original paper (CX/MAS 20/41/10) based on comments submitted to CL2020/31-MAS.

113. She explained some of the key changes made in preparing the final agenda paper, CX/MAS 21/41/10 and that while CCMAS40 had requested that criteria be developed, criteria had been changed to rules to avoid confusion with the method performance criteria.

114. The paper set out

- the prerequisites for endorsement of methods as Type III, and the proposed decision rules for selection of Type II methods from multiple Type III methods. The proposed decision rules had been verified using specific commodity-provision combinations with multiple Type III methods included in CXS 234 and by the EWG on the review of methods on fats and oils.

[13] CX/MAS 21/41/10,

115. She further drew attention to a comment made by the USA that the rules which currently states that a "*method should cover the commodity from the provision*", should not conflict with the Procedural Manual which states that "*methods applicable uniformly to various groups of commodities should be given preference over methods which apply only to individual commodities*", and that a proposal had been prepared to address this concern for consideration by CCMAS.

116. Switzerland recommended that CCMAS include the "rules for the selection of Type II methods from multiple Type III methods" in the Information Document: *Comprehensive Guidance for the process of submission, consideration and endorsement of methods for inclusion in CXS 234*.

Discussion

117. While there was support for the paper and its inclusion in the Information Document, comments were made that the paper could be improved to reflect the need to carefully consider the practicability, applicability in normal laboratory conditions and availability of the methods selected as Type II. Such methods should also be available to all countries worldwide and that the cost of such methods, should also be taken into account when selecting a Type II method.

118. It was clarified that:

- CCMAS could apply the "rules" on a case by case basis and that a footnote had been added to indicate this;
- the "rules" would not replace the approach to use numeric criteria, but would be useful in those cases where a preference is expressed for a Type II method and to select such a Type II method from multiple Type III methods;
- It was also clarified, that the "rules" should be read in conjunction with the existing *Principles for the Establishment of Codex Methods of Analysis* (Procedural Manual); that they are aimed at assisting the process of selection of a Type II method from multiple Type III methods; and that it should be borne in mind that the document is a living document and as the "rules" are applied and experience gained, it could be revised to better meet the needs of the Committee.

Conclusion

119. CCMAS:

i. agreed to circulate the proposed rules for selection of Type II methods from multiple Type III methods (Appendix V) for comments, further revision by Switzerland and consideration at CCMAS42; and

ii. noted that the processes already in place would continue to be applied when addressing the Typing of methods.

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

120. 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.

121. CCMAS noted that several of the issues raised in CRD 16, had been considered under relevant agenda items.

122. The Observer in particular highlighted the use of the Guidance document on methods submission adopted in 2019; the publication of a revised version of ISO 5725-2 detailing collaborative study procedures; publications of an alternative statistical approach by AOAC; the work of the SDOs on the Methods Workable Packages; and the updates from SDOs on their work.

123. CCMAS thanked the members of IAM for their contribution to the work of the Committee.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 10)

124. CCMAS noted that no matters were proposed for discussion under this item.

DATE AND PLACE OF NEXT SESSION (Agenda Item 11)

125. CCMAS was informed that the 42nd 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.

[14] CRD16 (Report of IAM)

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APPENDIX II

PART 1. METHODS OF ANALYSIS FOR ADOPTION BY CAC44

1.1 CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES (CCNFSDU)

1.2 FAO/WHO COORDINATING COMMITTEE FOR ASIA (CCASIA)

1.3 FAO/WHO COODINATING COMMITTEE FOR AFRICA (CCAFRICA)

1.4 FAO/WHO COORDINATING COMMITTEE FOR NORTH AMERICA AND THE SOUTH WEST PACIFIC (CCNASWP)

1.5 FAO/WHO COORDINATING COMMITTEE FOR THE NEAR EAST (CCNE)

1.6 CODEX COMMITTEE ON PROCESSED FRUITS AND VEGETABLES (CCPFV)

1.7 CODEX COMMITTEE ON SPICES AND CULINARY HERBS (CCSCH)

1.8 MILK AND MILK PRODUCTS

PART 2. METHODS OF ANALYSIS FOR REVOCATION BY CAC44

2.1 CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES (CCNFSDU)

2.2 CODEX COMMITTEE ON PROCESSED FRUIT AND VEGETABLES (CCPFV)

2.3 MILK AND MILK PRODUCTS

PART 3. AMENDMENTS

PART 4. METHODS OF ANALYSIS REFERRED

4.1 CCAFRICA

4.2 CCNASWP

4.3 and 4.4 CCFO

PART 5. FATS AND OILS PACKAGE FOR CONSIDERATION BY EWG

PART 1

METHODS OF ANALYSIS FOR ADOPTION BY CAC44

(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

Dietary fibre: Applicable to the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997): Table of Conditions for Claims

Commodity	Provision	Method	Principle	TYPE
All Foods (1)	Method applicable for determining the content of dietary fibres of higher and lower molecular weight. The method is applicable in food that may, or may not, contain resistant starches	**ICC Standard No.185 / AOAC 2017.16 / AACC 32-60.01**	Enzymatic-Gravimetry High Pressure Liquid Chromatography	I

Commodity	Provision	Method	Principle	Type
Infant Formula	Thiamine	AOAC 2015.14 / ISO 21470	Enzymatic digestion and UHPLC-MS/MS	II
		EN 14122	HPLC with pre- or post-column derivatization to thiochrom	~~II~~ III
	Riboflavin	AOAC 2015.14 / ISO 21470	Enzymatic digestion and UHPLC-MS/MS	II
		EN 14152	HPLC	~~II~~ III
	Niacin	AOAC 2015.14 / ISO 21470	Enzymatic digestion and UHPLC-MS/MS	II
		EN 15652	HPLC	~~II~~ III
		AOAC 985.34	Microbioassay and turbidimetry	III
	Vitamin B_6	AOAC 2015.14 / ISO 21470	Enzymatic digestion and UHPLC-MS/MS	II
		AOAC 2004.07 / EN 14164	HPLC	~~II~~ III
		AOAC 985.32	Microbioassay	III
		EN 14166	Microbioassay	III
	Choline	AOAC 2015.10 / ISO 21468	UHPLC-MS/MS	II
		AOAC 999.14	Enzymatic Colorimetric Method with limitations on applicability due to choline and ascorbate concentration	~~II~~ III
	Carnitine	AOAC 2015.10 / ISO 21468	UHPLC-MS/MS	II
	Biotin	AOAC 2016.02 / ISO 23305	HPLC-UV	II
		EN 15607	HPLC-fluorescence	III
Follow up Formula	Vitamin K	**AOAC 2015.09 / ISO 21446**	**HPLC -FLD**	**II**

Commodity	Provision	Method	Principle	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**	**ICP emission spectroscopy**	**III**
Infant formula	Sodium	**AOAC 2011.14 / ISO 15151 |IDF**	**ICP emission spectroscopy**	**III**
Infant formula	Zinc	**AOAC 2011.14 / ISO 15151 |IDF**	**ICP emission spectroscopy**	**III**

1.2 FAO/WHO COORDINATING COMMITTEE FOR ASIA (CCASIA)

Commodity	Provision	Method	Principle	Type
Laver products	Acidity: acid value for the extracted oil	ASIA21-CRD2(oil extn)/ and ISO 660 | AOCS Cd 3d-63	Extraction of oil Titrimetry	I
Laver Products	Moisture Content	AOAC 925.45	Gravimetry, drying at atmospheric pressure	I

1.3 FAO/WHO COORDINATING COMMITTEE FOR AFRICA (CCAFRICA)

Commodity	Provision	Method	Principle	Type
Dried meat	Determination of ash	ISO 936	Gravimetry	**I**
Dried meat	Determination of water activity	ISO 18787	Electrometry	**II**

1.4 FAO/WHO COORDINATING COMMITTEE FOR NORTH AMERICA AND SOUTH WEST PACIFIC (CCNASWP)

Commodity	Provision	Method	Principle	Type
Fermented noni fruit juice	pH value	NMKL 179 / AOAC 981.12	Potentiometry	II
Fermented noni fruit juice	Ethanol	IFUMA 52	Enzymatic determination	IV
Fermented noni fruit juice	Ethanol	AOAC 2016.12	Headspace GC-FID	IV
Fermented noni fruit juice	Ethanol	AOAC 2017.07	Enzymatic determination	IV
Kava products for use as a beverage when mixed with water	Moisture	AOAC 925.45	Gravimetry	I

1.5 FAO/WHO COORDINATING COMMITTEE FOR NEAR EAST (CCNE)

Commodity	Provision	Method	Principle	Type*
Mixed Zaatar	Sodium chloride (dry weight basis)	ISO 939 and AOAC 971.27	Calculation by moisture and ash Distillation and Titrimetry	I
Mixed Zaatar	Moisture	ISO 939	Distillation	I
Mixed Zaatar	Acid-insoluble ash (dry weight basis)	ISO 939 and AOAC 941.12 (corrected for moisture by ISO 939)	Calculation by moisture and ash Distillation and Gravimetry, Furnace, 550°C	I
Mixed Zaatar	Extraneous Matter	ISO 927	Visual examination Gravimetry	I
Mixed Zaatar	Foreign Matter	ISO 927	Visual examination, Gravimetry	I
Mixed Zaatar	Insects/-/Insect Fragments	ISO 927	Visual Examination	IV
Mixed Zaatar	Insect/Insect Fragments	AOAC 969.44	Visual Examination	IV
Mixed Zaatar	Insect/Insect Fragments	AOAC 975.49	Visual Examination	IV

Mixed Zaatar	Mould damage	Method V-8 Spices, Condiments, Flavors and Crude Drugs (Macroanalytical Procedure Manual, FDA, Technical Bulletin Number 5)	Visual Examination ~~(~~	IV
Mixed Zaatar	Mammalian Excreta	Macroanalytical Procedure Manual, USFDA, Technical Bulletin V.39 B (For whole)	Visual Examination	IV
Mixed Zaatar	Mammalian Excreta	AOAC 993.27 (For Ground)	Enzymatic Detection Method	IV

1.6 CODEX COMMITTEE ON PROCESSED FRUITS AND VEGETABLE (CCPFV)

Commodity	Provision	Method	Principle	Type
Gochujang	Capsaicin	Journal of AOAC International Vol. 91. No. 2, 2008. pp 387-391	HPLC-Fluorescence	IV
Gochujang	Capsaicin	Journal of AOAC International Vol. 91. No. 2, 2008. Pp 387-391	Gas chromatography-FID	IV
Gochujang	Crude protein	AOAC 984.13 (Nitrogen conversion factor: 6.25)	Titrimetry, Kjeldahl	I
Gochujang	Moisture	AOAC 945.43	Gravimetry	I
Chili sauce	pH	NMKL 179 (general method) / AOAC 981.12	Potentiometry	II
Chili sauce	Fill of Containers	CAC/ RM 46 (For glass container)	Gravimetry ~~Weighing~~	I
Dried fruits	Identification of defects	Described in the standard	Visual Examination	I
Dried fruits (except prunes and raisins	Moisture	AOAC 934.06	Gravimetry (vacuum oven)	I

1.7 CODEX COMMITTEE ON SPICES AND CULINARY HERBS (CCSCH)

Commodity	Provision	Method	Principle	Type
Dried oregano	Moisture	ISO 939	Distillation	I
Dried oregano	Total ash (dry weight basis)	ISO 939 and ISO 928	Calculation from moisture and ash Distillation and Gravimetry	I
Dried oregano	Acid-insoluble ash (dry weight basis)	ISO 939 and ISO 930	Calculation from moisture and ash Distillation and Gravimetry	I

Commodity	Provision	Method	Principle	Type
Dried oregano	Volatile oils (dry weight basis)	ISO 939 and ISO 6571	Calculation from moisture and volatile oils Distillation and Distillation	I
Dried oregano	Extraneous matter	ISO 927	Visual examination followed by Gravimetry	I
Dried oregano	Foreign matter	ISO 927	Visual examination followed by Gravimetry	I
Dried oregano	Mammalian excreta Other excreta	Macroanalytical Procedure Manual, USFDA, Technical Bulletin V.39 B (For whole) https://www.fda.gov/food/laboratory-methods-food/mpm-v-8-spices-condiments-flavors-and-crude-drugs#v32	Visual examination	IV
Dried oregano	Whole dead insect	ISO 927	Visual examination	IV
Dried oregano	Whole dead insect	MPM V-8 Spices, Condiments, Flavours and Crude Drugs A. General methods for spices herbs and botanicals (V 32) https://www.fda.gov/food/laboratory-methods-food/mpm-v-8-spices-condiments-flavors-and-crude-drugs#v32	Visual examination	IV
Dried oregano	Mould visible	Method V-8 Spices, Condiments, Flavors and Crude Drugs (Macroanalytical Procedure Manual, FDA Technical Bulletin Number 5) https://www.fda.gov/food/laboratory-methods-food/mpm-v-8-spices-condiments-flavors-and-crude-drugs#v32	Visual examination	IV
Dried oregano	Insect Damage	ISO 927	Visual examination	I

1.8 MILK AND MILK PRODUCTS

Commodity	Provision	Method	Principle	Type
Milkfat Products	Milkfat (Total Fat)	ISO 17189 | IDF 194	Gravimetry (Direct Determination of fat using solvent extraction)	I
Milk and Milk Products	Melamine	ISO DIS 23970 | IDF 252	LC-MS/MS	II
Butter	Milkfat (Total Fat)	ISO 17189 | IDF 194	Gravimetry Direct determination of fat using solvent extraction	I
Butter	Salt	ISO 15648 | IDF 179	Potentiometry (determination of chloride, expressed as sodium chloride)	II
Butter	Water[1]	ISO 3727-1 | IDF 80-1	Gravimetry	I
Dairy fat spreads	Milkfat (Total Fat)	ISO 17189 | IDF 194	Gravimetry Direct determination of fat using solvent extraction	I
Edible casein products	~~Acids, free~~ ~~Maximum~~ Free acidity	ISO 5547 | IDF 91	Titrimetry (aqueous extract)	~~IV~~ I
Edible casein products	Lactose	ISO 5548 | IDF 106	Photometry (phenol and H_2SO_4)	IV
Edible casein products	Milkfat (Total Fat)	ISO 5543 | IDF 127	Gravimetry (Schmid-Bondzynski-Ratslaff)	I
Edible casein products	pH	ISO 5546 | IDF 115	Electrometry	~~IV~~ II
Emmental	Calcium >= 800mg/100g	ISO 8070 | IDF 119	Flame atomic absorption	~~IV~~ III
Emmental	Calcium >= 800mg/100g	AOAC 2015.06 / ISO 21424 | IDF 243	ICP mass spectrometry	II
Emmental	Calcium >= 800mg/100g	AOAC 2011.14 / ISO 15151 | IDF 229	ICP emission spectroscopy	III
Fermented milks	Dry matter (total solids)[2]	ISO 13580 | IDF 151	Gravimetry (drying at 102 °C)	I

[1] Water content excluding the crystallized water bound to lactose (generally known as “moisture content”)
[2] Milk total solids and Milk solids-not-fat (MSNF) content include water of crystallization of lactose

Commodity	Provision	Method	Principle	Type
Fermented milks	Total acidity expressed as percentage of lactic acid	ISO/TS 11869 | IDF/RM 150	Potentiometry, titration to pH 8.30	~~I~~ ~~II~~ IV
Fermented milks	Sum of microorganisms constituting the starter culture (Bacteria in fermented milk deriving (or originating) from starter culture) ~~Microorganisms constituting the starter culture~~	ISO 27205 | IDF 149 (Annex A)	Colony count at 25 °C, 30 °C, 37 °C and 45 °C according to the starter organism in question	I ~~IV~~
Milk powders and cream powders	Scorched particles	ISO 5739 | IDF 107	Visual comparison with standard disks, after filtration	IV
Milk powders and cream powders	Scorched particles	ADPI Scorched Particles, 2016	Visual comparison with standard disks, after filtration	IV
Milk powders and cream powders	Solubility Index	ISO 8156 | IDF 129	Centrifugation	I
Whey cheeses by concentration (carbohydrate contents below 5%)	Milkfat (Total Fat)	ISO 1854 | IDF 59	Gravimetry (Röse Gottlieb)	I
Whey cheeses by concentration (does not dissolve completely in the ammonia, contains FFA in significant quantities or carbohydrate content >5%)	Milkfat (Total Fat)	ISO 8262-3 | IDF 124-3	Gravimetry (Weibull-Berntrop)	I
Whey cheeses by concentration (for carbohydrate content under 5%)	Milk fat in dry matter (Total fat in dry matter)	ISO 1854 | IDF 59 and ISO 2920 | IDF 58	Calculation from fat content and dry matter content Gravimetry (Röse Gottlieb) Gravimetry, drying at 88 °C	I
Whey cheeses by concentration (does not dissolve completely in the ammonia, contains FFA in significant quantities or, carbohydrate content >5%)	Milk fat in dry matter (Total fat in dry matter)	ISO 8262-3 | IDF 124-3 and ISO 2920 | IDF 58	Calculation from fat content and dry matter content Gravimetry (Weibull-Berntrop) Gravimetry, drying at 88 °C	I
Dairy permeate powders	Ash	NMKL 173 / AOAC 930.30	Gravimetry (ashing at 550 °C)	I

Numeric performance criteria for methods of analysis for copper and iron in milk fat products

Commodity	Provision	ML (mg/kg)	LOD (mg/kg)	LOQ (mg/kg)	RSDR (%)	Recovery	Minimum Applicable Range		Examples of applicable methods that meet the criteria	Principle
							Minimum	Maximum		
Milk fat products	Copper	0.05	0.010	0.020	44.0	60-115%	0.028	0.072	AOAC 2015.06 / ISO 21424 | IDF 243	ICP mass spectrometry
									ISO 5738|IDF 76	Photometry, diethyldithiocarbamate
									AOAC 960.40	Photometry, diethyldithiocarbamate
Milk fat products	Iron	0.2	0.020	0.040	40.8	80-110%	0.08	0.32	**AOAC 2015.06 / ISO 21424 | IDF 243**	**ICP mass spectrometry**

Numeric performance criteria for copper and iron in edible casein products

Commodity	Provision	ML (mg/kg)	LOD (mg/kg)	LOQ (mg/kg)	RSDR (%)	Recovery	Minimum Applicable Range Minumum	Maximum	Examples of applicable methods that meet the criteria	Principle
Edible casein products	Copper	5	0.50	1.0	25.1	80-110%	3.1	6.9	**AOAC 2015.06 / ISO 21424 | IDF 243 AOAC 2011.14 / ISO 15151 | IDF 229**	**ICP mass spectrometry ICP emission spectroscopy**
Edible casein products	Iron	20	2.0	4.0	20.4	80-110%	13,9	26.1	**AOAC 2015.06 / ISO 21424 | IDF 243 AOAC 2011.14 / ISO 15151 | IDF 229**	**ICP mass spectrometry ICP emission spectroscopy**
	Iron (in roller dried caseinates)	50	5.0	10.0	17.8	90-107%	36.7	63,3	**AOAC 2015.06 / ISO 21424 | IDF 243 AOAC 2011.14 / ISO 15151 | IDF 229**	**ICP mass spectrometry ICP emission spectroscopy**

Numeric Performance criteria for lead in edible casein and whey powders

Commodity	Provision	ML (mg/kg)	LOD (mg/kg)	LOQ (mg/kg)	RSDR (%)	Recovery	Minimum Applicable Range Minumum	Maximum	Examples of applicable methods that meet the criteria	Principle
Butter, Edible casein products and whey powders (secondary milk products)	Lead	0.02	0.004	0.008	≤ 44	60-115%	0.011	0.029	-	-

Part 2

METHODS OF ANALYSIS FOR REVOCATION BY CAC44

2.1 CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES (CCNFSDU)

Commodity	Provision	Method	Principle	Type
All Foods (1)	Method applicable for determining the content of dietary fibres of higher and lower molecular weight. The method is applicable in food that may, or may not, contain resistant starches	AOAC 2009.01 / AACC Intl 32-45.01	Enzymatic-Gravimetry High Pressure Liquid Chromatography	I
Special Foods	Vitamin D	AOAC 936.14	Rat bioassay	IV
Follow-up formula	Vitamin K	AOAC 999.15 / EN 14148 (vitamin K1) (Measures either aggregated cis + trans K1 or can measure individual cis and trans forms depending on LC column.)	HPLC with C30 column to separate the cis- and the trans- K vitamins	II

2.2 CODEX COMMITTEE ON PROCESSED FRUITS AND VEGETABLES (CCPFV)

Commodity	Provision	Method	Principle	Type
Gochujang	Capsaicin	AOAC 995.03	HPLC	II
Gochujang	Capsaicin	Described in the Standard (Annex D)	Gas chromatography	IV
Gochujang	Moisture	AOAC 934.01 (≤ 70°C, ≤ 50 mm Hg))	Gravimetry	I

2.3 MILK AND MILK PRODUCTS

Commodity	Provision	Method	Principle	Type
Milk and Milk Products	Melamine	ISO/TS 15495 | IDF/RM 230	LC-MS/MS	IV
Whey powders	Moisture, "Free"	ISO 2920 | IDF 58	Gravimetry (drying at 88°C ±2°C)	IV
Milk products	Iron	ISO 6732 | IDF 103	Photometry (bathophenanthroline)	IV
Milk products (products not completely soluble in ammonia)	Milkfat (Total Fat)	ISO 8262-3 | IDF 124-3	Gravimetry (Weibull-Berntrop)	I
Milk products	Iron	NMKL 139 AOAC 999.11 (Codex general method)	Atomic absorption spectrophotometry	II
Milk products	Iron	AOAC 984.27	Inductively Coupled Plasma optical emission spectrophotometry	III
Milkfat products	Copper	AOAC 2015.06 / ISO 21424 | IDF 243	ICP mass spectrometry	II
Milkfat products	Copper	ISO 5738|IDF 76	Photometry, diethyldithiocarbamate	III
Milkfat products	Copper	AOAC 960.40	Photometry, diethyldithiocarbamate	IV
Milkfat products (anhydrous milkfat)	Peroxide value	AOAC 965.33	Titrimetry	I

Part 3

Amendments to CXS 234 for adoption by CAC44

Commodity	Provision	Method	Principle	Type
Blend of skimmed milk and vegetable fat in powdered form	~~Water[3]~~ Water[2] (Moisture)	ISO 5537 | IDF 26	Gravimetry, drying at 87 °C	I
Reduced fat blend of skimmed milk powder and vegetable fat in powdered form	~~Water[1]~~ Water[2] (Moisture)**¡Error! Marcador no definido.**	ISO 5537 | IDF 26	Gravimetry, drying at 87 °C	I
Dairy permeate powders	Moisture[4]	ISO5537| IDF26	Gravimetry,drying at 87°C	I
Milk powders and cream powders	Water[2] (Moisture)	ISO 5537 | IDF 26	Gravimetry, drying at 87°C	I
Whey powders	Water[2] (Moisture)	ISO 5537 | IDF 26	Gravimetry, drying at 87°C	I

Part 4

4.1 Referral to CCAFRICA

METHODS OF ANALYSIS FOR PROVISIONS IN THE DRAFT STANDARD FOR DRIED MEAT

Method	Provision	Principle	Type
AOAC 950.46B	Determination of Moisture Content	Gravimetry	I
ISO 1442	Determination of Moisture Content	Gravimetry	I
ISO 1443	Determination of Total Fat	Gravimetry	I
AOAC 960.39	Determination of Crude Fat	Gravimetry	I
AOAC 928.08	Determination of Crude Protein (Nitrogen x conversion factor 6.25?)	Kjeldahl	I
ISO 937	Determination of Crude Protein (Nitrogen x conversion factor 6.25?)	Kjeldahl	I
ISO 1841-1	Determination of chloride (expressed as sodium chloride-edible Salt	Volhard method	II or III
ISO 1841-2	Determination of chloride (expressed as sodium chloride-edible Salt	Potentiometric	II or III

[3] Water content excluding the crystallized water bound to lactose (generally known as “moisture content”)

[4] Moisture content excluding the water of crystallization of lactose

AOAC 935.47 and 937.09 B	Determination of chloride (expressed as sodium chloride-edible Salt	Volhard method	II or III

4.2 For referral to CCNASWP

METHODS OF ANALYSIS FOR PROVISIONS IN THE REGIONAL STANDARD FOR KAVA PRODUCTS FOR USE AS A BEVERAGE WHEN MIXED WITH WATER

Provision	Method	Principle	Type
Noble kava varieties (total kava lactones)	Lebot V, Legendre L (2016), Comparison of kava (Piper methysticum Forst.) varieties by UV absorbance of acetonic extracts and high-performance thin-layer chromatography. Journal of Food Composition and Analysis 48:25-33. http://dx.doi.org/10.1016/j.jfca.2016.01.009 Section 2.3 for UV Absorbance and Lebot V, Michalet S, Legendre L. (2019). Kavalactones and flavokavins profiles contribute to quality assessment of kava (Piper methysticumG.Forst.), the traditional beverage of the Pacific. Beverages 2019, 5, 34; https://doi.org/10.3390/beverages5020034 Sections 2.2, 2.3, and 3.1 for procedures	High performance thin layer chromatography and~~/or~~ UV absorbance of acetonic extracts measured at 440 nm (less or equal to 0.9)	IV
[Flavokavins	~~Lebot V, Legendre L (2016), Comparison of kava (Piper methysticumForst.) varieties by UV absorbance of acetonic extracts and high-performance thin-layer chromatography. Journal of Food Composition and Analysis 48:25-33. http://dx.doi.org/10.1016/j.jfca.2016.01.009~~ ~~and~~ Lebot V, Michalet S, Legendre L. (2019). Kavalactones and flavokavins profiles contribute to quality assessment of kava (Piper methysticumG.Forst.), the traditional beverage of the Pacific. Beverages 2019, 5, 34; https://doi.org/10.3390/beverages5020034	High performance thin layer chromatography and/or UV absorbance of acetonic extracts measured at 440 nm (less or equal to 0.9)]	IV

4.3 FOR REFERRAL TO CCFO

(endorsed by CCMAS, for consideration by CCFO)

Commodity	Provision	Method	Principle	Type
~~**Fat spreads and blended spreads**~~	~~Fat content~~	~~ISO 17189 | IDF 194~~	~~Gravimetry~~	~~I~~
Fat spreads and blended spreads	Total fat	ISO 17189 | IDF 194	Gravimetry. Direct determination of fat using solvent extraction.	I

Commodity	Provision	Method	Principle	Type
~~**Fats and Oils (all)**~~	~~Arsenic~~	~~AOAC 942.17~~	~~Colorimetry (molybdenum blue)~~	~~III~~
Fats and Oils (all)	Arsenic	AOAC 963.21 and AOAC 942.17	Kjeldahl flask digestion and colorimetry (molybdenum blue)	III
~~**Fats and Oils (all)**~~	~~Arsenic~~	~~AOAC 952.13~~	~~Colorimetry (diethyldithiocarbamate)~~	~~II~~
Fats and Oils (all)	Arsenic	AOAC 963.21 and AOAC 952.13	Kjeldahl flask digestion and colorimetry (diethyldithiocarbamate)	**III**
~~**Fats and Oils (all)**~~	~~Arsenic~~	~~AOAC 986.15~~	~~Atomic absorption spectrophotometry~~	~~III~~
Fats and Oils (all)	Arsenic	AOAC 986.15	Atomic absorption spectrophotometry (hydride generation)	**II**
~~**Fats and Oils (all)**~~	~~Insoluble impurities~~	~~ISO 663~~	~~Gravimetry~~	~~I~~
Fats and Oils (all)	Insoluble impurities	ISO 663	Calculation from total insoluble content in *n*-hexane or light petroleum. Gravimetry, drying at 103 °C	I
~~**Fats and Oils (all)**~~	~~Lead~~	~~AOAC 994.02; or ISO 12193; or AOCS Ca 18c-91~~	~~Atomic absorption spectrophotometry (direct graphite furnace)~~	~~II~~
Fats and Oils (all)	Lead	AOAC 994.02 / ISO 12193 / AOCS Ca 18c-91	Atomic absorption spectrophotometry (direct graphite furnace)	II
~~**Fats and Oils (all)**~~	~~Matter volatile at 105°C~~	~~ISO 662~~	~~Gravimetry (open-drying)~~	~~I~~
Fats and Oils (all)	Moisture and volatile matter	ISO 662	Gravimetry, drying at 103 °C	I
~~**Fats and Oils (all)**~~	~~Soap content~~	~~BS EN ISO 10539 or AOCS Cc 17-95~~	~~Gravimetry~~	~~I~~
Fats and Oils (all)	Soap content	ISO 10539 / AOCS Cc 17-95	Titrimetry (Colorimetric)	I
~~**Fats and Oils not covered by individual standards**~~	~~Acid value~~	~~ISO 660; or AOCS Cd 3d-63~~	~~Titrimetry~~	~~I~~

Commodity	Provision	Method	Principle	Type
Fats and Oils not covered by individual standards	Acidity: acid value	ISO 660 / AOCS Cd 3d-63	Titrimetry	I
~~**Fats and Oils not covered by individual standards**~~	~~Copper and Iron~~	~~AOAC 990.05; or ISO 8294; or AOCS Ca 18b-91~~	~~Atomic absorption spectrophotometry (direct graphite furnace)~~	~~II~~
Fats and Oils not covered by individual standards	Copper and Iron	AOAC 990.05 / ISO 8294 / AOCS Ca 18b-91	Atomic absorption spectrophotometry (direct graphite furnace)	II
~~**Fats and Oils not covered by individual standards**~~	~~Peroxide value~~	~~AOCS Cd 8b-90 ISO 3960~~	~~Titrimetry using iso-octane~~	~~I~~
Fats and Oils not covered by individual standards	Peroxide value	AOCS Cd 8b-90 / ISO 3960 / NMKL 158	Titrimetry (Colorimetric)	I
~~**Fish oils**~~	~~Acid value~~	~~AOCS Ca 5a-40 AOCS Cd 3d-63 ISO 3960 NMKL 38~~	~~Titration~~	~~I~~
Fish oils	Acidity: acid value	AOCS Ca 5a-40 / AOCS Cd 3d-63 / ISO 660 / NMKL 38	Titrimetry	I
~~**Fish oils**~~	~~Peroxide value~~	~~AOCS Cd 8b-90 ISO 3960 NMKL 158~~	~~Titration~~	~~I~~
~~**Fish oils**~~	~~Peroxide value~~	~~European Pharmacopoeia 2.5.5 (Part B Iso-octane as solvent)~~	~~Titration~~	~~I~~
Fish oils	Peroxide value	AOCS Cd 8b-90 / ISO 3960 / NMKL 158 / European Pharmacopoeia 2.5.5	Titrimetry (Colorimetric)	I
~~**Fish oils**~~	~~Phospholipids~~	~~USP-FCC 10 2S (Krill oil): Phospholipids Nuclear Magnetic Resonance, Appendix IIC~~	~~NMR Spectroscopy~~	~~I~~
Fish oils	Phospholipids	USP-FCC 12 2S (krill oil - phospholipids)	Nuclear Magnetic Resonance Spectroscopy	I
~~**Fish oils**~~	~~Triglycerides~~	~~AOCS Cd 11d-96~~	~~HPLC-ELSD~~	~~III~~
Fish oils	Triglycerides	AOCS Cd 11d-96	Liquid chromatography with evaporative light scattering detection	**II**

Commodity	Provision	Method	Principle	Type
~~**Fish oils**~~	~~Triglycerides~~	~~European Pharmacopoeia 1352 (Omega-3 acid triglycerides): Oligomers and partial glycerides~~	~~HPLC-RI~~	~~III~~
Fish oils	Triglycerides	European Pharmacopoeia 1352	Liquid chromatography with refractive index detection	III
~~**Fish oils**~~	~~Triglycerides~~	~~USP 40-NF35 (Omega-3 Acid Triglycerides):Content of oligomers and partial glyceride~~	~~HPLC-RI~~	III
Fish oils	Triglycerides	USP 40 NF37	Liquid chromatography with refractive index detection	III
~~**Named Animal Fats**~~	~~Acidity~~	~~ISO 660; or AOCS Cd 3d-63~~	~~Titrimetry~~	~~I~~
Named Animal Fats	Acidity: acid value	ISO 660 / AOCS Cd 3d-63	Titrimetry	I
~~**Named Animal Fats**~~	~~Copper and Iron~~	~~AOAC 990.05; or ISO 8294; or AOCS Ca 18b-91~~	~~Atomic absorption Spectrophotometry (direct graphite furnace)~~	~~II~~
Named Animal Fats	Copper and Iron	AOAC 990.05 / ISO 8294 / AOCS Ca 18b-91	Atomic absorption Spectrophotometry (direct graphite furnace)	II
~~**Named Animal Fats**~~	~~Iodine value (IV)~~	~~ISO 3961; or AOAC 993.20; or AOCS Cd 1d-92~~	~~Wijs-Titrimetry~~	~~I~~
Named Animal Fats	Iodine value	ISO 3961 / AOAC 993.20 / AOCS Cd 1d-92 / NMKL 39	Titrimetry (Wijs)	I
~~**Named Animal Fats**~~	~~Peroxide value~~	~~AOCS Cd 8b-90; or ISO 3960~~	~~Titrimetry using iso-octane~~	~~I~~
Named Animal Fats	Peroxide value	AOCS Cd 8b-90 / ISO 3960 / NMKL 158	Titrimetry (Colorimetric)	I
~~**Named Animal Fats**~~	~~Refractive index~~	~~ISO 6320; or AOCS Cc 7-25~~	~~Refractometry~~	~~II~~
Named Animal Fats	Refractive index	ISO 6320 / AOCS Cc 7-25	Refractometry	II
~~**Named Animal Fats**~~	~~Relative density~~	~~ISO 6883, with the appropriate conversion factor; or AOCS Cc 10c-95~~	~~Pycnometry~~	~~I~~
Named Animal Fats	Relative density	ISO 6883, with the appropriate conversion factor / AOCS Cc 10c-95	Pycnometry	I

Commodity	Provision	Method	Principle	Type
~~**Named Animal Fats**~~	~~Saponification value~~	~~ISO 3657; or AOCS Cd 3-25~~	~~Titrimetry~~	~~I~~
Named Animal Fats	Saponification value	ISO 3657 / AOCS Cd 3-25	Titrimetry (Colorimetric)	I
~~**Named Animal Fats**~~	~~Unsaponifiable matter~~	~~ISO 3596; or ISO 18609; or AOCS Ca 6b-53~~	~~Titrimetry after extraction with diethyl ether~~	~~I~~
Named Animal Fats	Unsaponifiable matter	ISO 3596 / ISO 18609 / AOCS Ca 6b-53	Gravimetry, drying at 103 °C and titrimetry (colorimetry)	I
~~**Named Vegetable Oils**~~	~~Acidity~~	~~ISO 660; or AOCS Cd 3d-63~~	~~Titrimetry~~	~~I~~
Named Vegetable Oils	Acidity: acid value	ISO 660 / AOCS Cd 3d-63 / AOCS Ca 5a-40	Titrimetry	I
~~**Named Vegetable Oils**~~	~~Apparent density~~	~~ISO 6883, with the appropriate conversion factor; or AOCS Cc 10c-95~~	~~Pycnometry~~	~~I~~
Named Vegetable Oils	Apparent density	ISO 6883, ~~with the appropriate conversion factor~~ / AOCS Cc 10c-95	Pycnometry	I
Named Vegetable Oils	Baudouin test (modified Villavecchia or sesame seed oil test)	AOCS Cb 2-40	Colour reaction	I
~~**Named Vegetable Oils**~~	~~Carotenoids, total~~	~~BS 684 Section 2.20~~	~~Spectrophotometry~~	~~II~~
Named Vegetable Oils	Carotenoids, total	BS684-2.20	Spectrophotometry	II
~~**Named Vegetable Oils**~~	~~Copper and Iron~~	~~ISO 8294; or AOAC 990.05; or AOCS Ca 18b-91~~	~~AAS~~	~~II~~
Named Animal Fats	Copper and Iron	AOAC 990.05 / ISO 8294 / AOCS Ca 18b-91	Atomic absorption Spectrophotometry (direct graphite furnace)	II
~~**Named Vegetable Oils**~~	~~GLC ranges of fatty acid composition~~	~~ISO 5508 and ISO 12966-2; or AOCS Ce 2-66 and Ce 1—62 or Ce 1h-05~~	~~Gas chromatography of methyl esters~~	~~II~~
Named Vegetable Oils	Fatty acid composition	ISO 12966-2 and ISO 12966-4 / AOCS Ce 2-66 and AOCS Ce 1h-05	Gas Chromatography of methyl esters	II
Named Vegetable Oils	Free fatty acids	ISO 660 / AOCS Cd 3d-63 / AOCS Ca 5a-40	Titrimetry	I
~~**Named Vegetable Oils**~~	~~Insoluble impurities~~	~~ISO 663~~	~~Gravimetry~~	~~I~~

Commodity	Provision	Method	Principle	Type
Named Vegetable Oils	Insoluble impurities	ISO 663	Calculation from total insoluble content in *n*-hexane or light petroleum. Gravimetry, drying at 103 °C	I
~~**Named Vegetable Oils**~~	~~Iodine value (IV)~~	~~ISO 3961; or AOAC 993.20; or AOCS Cd 1d-92; or NMKL 39~~	~~Wijs Titrimetry~~	~~I~~
Named Vegetable Oils	Iodine value	ISO 3961 / AOAC 993.20 / AOCS Cd 1d-92 / NMKL 39	Titrimetry (Wijs)	I
~~**Named Vegetable Oils**~~	~~Lead~~	~~AOAC 994.02; or ISO 12193; or AOCS Ca 18c-91~~	~~Atomic Absorption~~	~~II~~
Named Vegetable Oils	Lead	AOAC 994.02 / ISO 12193 / AOCS Ca 18c-91	Atomic absorption spectrophotometry (direct graphite furnace)	II
~~**Named Vegetable Oils**~~	~~Moisture & volatile matter at 105°C~~	~~ISO 662~~	~~Gravimetry~~	~~I~~
Named Vegetable Oils	Moisture and volatile matter	ISO 662	Gravimetry, drying at 103 °C	I
~~**Named Vegetable Oils**~~	~~Peroxide value (PV)~~	~~AOCS Cd 8b-90; or ISO 3960~~	~~Titrimetry~~	~~I~~
Named Vegetable Oils	Peroxide value	AOCS Cd 8b-90 / ISO 3960 / NMKL 158	Titrimetry (Colorimetric)	I
~~**Named Vegetable Oils**~~	~~Refractive index~~	~~ISO 6320; or AOCS Cc 7-25~~	~~Refractometry~~	~~II~~
Named Vegetable Oils	Refractive index	ISO 6320 / AOCS Cc 7-25	Refractometry	II
~~**Named Vegetable Oils**~~	~~Reichert value and Polenske value~~	~~AOCS Cd 5-40~~	~~Titrimetry~~	~~I~~
Named Vegetable Oils	Reichert-Meissl value and Polenske value	AOCS Cd 5-40	Calculation from soluble and insoluble volatile fatty acids. Titrimetry (Colorimetric).	I
~~**Named Vegetable Oils**~~	~~Relative density~~	~~ISO 6883, with the appropriate conversion factor; or AOCS Cc 10c-95~~	~~Pycnometry~~	~~I~~
Named Vegetable Oils	Relative density	ISO 6883~~, with the appropriate conversion factor~~ / AOCS Cc 10c-95	Pycnometry	I
~~**Named Vegetable Oils**~~	~~Saponification value (SV)~~	~~ISO 3657; or AOCS Cd 3-25~~	~~Titrimetry~~	~~I~~

Commodity	Provision	Method	Principle	Type
Named Vegetable Oils	Saponification value	ISO 3657 / AOCS Cd 3-25	Titrimetry (Colorimetric)	I
~~**Named Vegetable Oils**~~	~~Slip point~~	~~ISO 6321 for all oils; AOCS Cc 3b-92 for all oils except palm oils; AOCS Cc 3-25 for palm oils only~~	~~Open ended capillary tube~~	~~I~~
Named Vegetable Oils	Slip point	ISO 6321 / AOCS Cc 3b-92 for all oils except palm oils or AOCS Cc 3-25 for palm oils only	Open ended capillary tube	I
~~**Named Vegetable Oils**~~	~~Soap content~~	~~BS 684 Section 2.5 withdrawn for BS EN ISO 10539 or AOCS Cc 17-95~~	~~Gravimetry~~	~~I~~
~~**Named Vegetable Oils**~~	~~Sterol content~~	~~ISO 12228; or AOCS Ch 6-91~~	~~Gas chromatography~~	~~II~~
Named Vegetable Oils	Sterol composition and total sterols	ISO 12228-1 / AOCS Ch 6-91	Thin-layer chromatography and gas chromatography	II
~~**Named Vegetable Oils**~~	~~Tocopherol content~~	~~ISO 9936; or AOCS Ce 8-89~~	~~HPLC~~	~~II~~
Named Vegetable Oils	Tocopherol content	ISO 9936 / AOCS Ce 8-89	Liquid chromatography with fluorescence detection	II

Part 4.4 Referral to CCFO: For consideration and reply by CCFO

Commodity	Provision	Method	Principle	Type
~~**Fats and oils**~~	~~Butylhydroxyanisole, butylhydroxytoluene, tert-butylhydroquinone, & propyl gallate~~	~~AOAC 983.15; or AOCS Ce 6-86~~	~~Liquid chromatography~~	~~II~~
Fats and oils	Synthetic antioxidants	AOAC 983.15	Liquid chromatography	**II / III**
Fats and oils	Synthetic antioxidants	AOCS Ce 6-86	Liquid chromatography	**II / III**
• *What would be the impact for trade of retyping one of the proposed methods to Type II?* • *AOAC and ISO are collaborating to produce identical methods to replace AOCS Ce 6-86 by 2023.*				
~~**Fish oils**~~	~~Fatty acid composition~~	~~AOCS Ce 1a-13~~	~~Capillary GLC~~	~~III~~
~~**Fish oils**~~	~~Fatty acid composition~~	~~AOCS Ce 2-66~~	~~Preparation of methyl esters by fatty acids~~	~~III~~
Fish oils	Fatty acid composition	AOCS Ce 2-66 and AOCS Ce 1a-13	Gas Chromatography of methyl esters	**III/~~IV/~~ ~~Remo~~**

Commodity	Provision	Method	Principle	Type
				~~**val**~~
	Type II from Type III selection suggests either (i) remain Type III, (ii) Type IV or (iii) removal from STAN 234.			
~~**Fish oils**~~	~~Fatty acid composition~~	~~AOCS Ce 1b-89~~	~~GLC~~	~~III~~
Fish oils	Fatty acid composition *Type II from Type III selection comes unanymously to conclusion: Type III*	AOCS Ce 1b 89	Gas Chromatography of methyl esters	III
~~**Fish oils**~~	~~Fatty acid composition~~	~~AOCS Ce 2b-11~~	~~Alkali hydrolysis~~	~~III~~
Fish oils	Fatty acid composition *Type II from Type III selection comes unanymously to conclusion: Type III*	AOCS Ce 2b-11 and AOCS Ce 1i-07 ~~or AOCS Ce 1j-07~~	Gas Chromatography of methyl esters	III
Fish oils	Fatty acid composition	AOCS Ce 2b-11 and AOCS Ce 1j-07	Gas Chromatography of methyl esters	III
~~**Fish oils**~~	~~Fatty acid composition~~	~~AOCS Ce 1i 07~~	~~Capillary GLC~~	~~III~~
~~**Fish oils**~~	~~Fatty acid composition~~	~~ISO 12966-2~~	~~Gas chromatography~~	~~III~~
~~**Fish oils**~~	~~Fatty acid composition~~	~~ISO 5508~~	~~Gas chromatography~~	~~III~~
Fish oils	Fatty acid composition *Type II from Type III selection comes unanymously to conclusion: Type III*	ISO 12966-2 and ISO 12966-4	Gas Chromatography of methyl esters	III
Fish oils	Fatty acid composition *Type II from Type III selection comes unanymously to conclusion: Type II*	AOCS Ce 2-66 and AOCS Ce 1i-07	Gas Chromatography of methyl esters	~~III~~ **II**
• *What would be the impact for trade when endorsing the AOCS methods for Type II?*				
~~**Named Animal Fats**~~	~~GLC ranges of fatty acid composition~~	~~ISO 5508 and ISO 12966-2; or AOCS Ce 2-66 and Ce 1e-91 or Ce 1f-96~~	~~Gas chromatography of methyl esters~~	~~II~~
Named Animal Fats	Fatty acid composition **Canada: Replace AOCS Ce 1f-96 with Ce 1j-07.*	ISO 12966-2 and ISO 12966-4 / AOCS Ce 2-66 and Ce ~~1f-96~~ 1j-07	Gas Chromatography of methyl esters	II

Commodity	Provision	Method	Principle	Type
	Retype to Type III, including the ISO methods. *Suggest AOCS Ce 2-66 and Ce1j-07 as Type II.*			
• *What would be the impact for trade when endorsing the AOCS methods for Type II?*				
~~**Named Animal Fats**~~	~~Titre~~	~~ISO 935; or AOCS Cc 12-59~~	~~Thermometry~~	~~I~~
Named Animal Fats	Titre	ISO 935	Thermometry	I
Named Animal Fats	Titre	AOCS Cc 12-59	Thermometry	IV
• *The methods are not identical and can therefore not be endorsed as Type I. Given the review of this EWG, the ISO method is a more fit for purpose method. What would be the impact for trade upon retyping?*				
Named Vegetable Oils	Crismer value	AOCS Cb 4-35 and AOCS Ca 5a-40	Calculation from individual fatty acid composition (gas chromatography of methyl esters) and turbidity	I
Named Vegetable Oils	Halphen test	AOCS Cb 1-25	Colorimetry	I
• *Are the above methods for Crismer value and Halphen test still in active use?*				
~~**Named Vegetable Oils**~~	~~Unsaponifiable matter~~	~~ISO 3596; or ISO 18609; or AOCS Ca 6b-53~~	~~Gravimetry~~	~~I~~
Named Vegetable Oils	Unsaponifiable matter **Canada: solvents differ between methods*	ISO 3596 / ISO 18609 / AOCS Ca 6b-53	Gravimetry, drying at 103 °C and titrimetry (colorimetry)	I
• *ISO 18609 is not identical to ISO 3596 and AOCS Ca 6b-53. ISO 18609 is a method which produces systematically underestimated results. What would be the impact for trade if ISO 18609 would be retyped to Type IV?*				

Part 5

Review of methods in the fats and oils package for consideration by EWG on fats and oils workable package

Commodity	Provision	Method	Principle	Type
~~**Fish oils**~~	~~Vitamin A~~	~~EN 12823-1 (Determination of vitamin A by high performance liquid chromatograph – Part 1: Measurement of all-E-retinol and 13-Z-retinol~~	~~LC~~	~~III~~
~~**Fish oils**~~	~~Vitamin A~~	~~European Pharmacopoeia Monograph on Cod Liver Oil (Type A), monograph 01/2005:1192, with LC end-point 2.2.29~~	~~LC~~	~~III~~
Fish oils	Vitamin A (all-E-retinol and 13-Z-retinol)	EN 12823-1	Liquid chromatography	II
Fish oils	Vitamin A (all-E-retinol)	European Pharmacopoeia 2398	Liquid chromatography	III
~~**Fish oils**~~	~~Vitamin D~~	~~EN 12821 (Determination of vitamin D by high performance liquid chromatography – Measurement of cholecalciferol (D3) or ergocalciferol (D2))~~	~~LC~~	~~III~~
~~**Fish oils**~~	~~Vitamin D~~	~~NMKL 167 (Cholecalciferol (vitamin D3) and Ergocalciferol (vitamin D2)). Determination by HPLC in foodstuffs~~	~~LC~~	~~III~~
Fish oils	Vitamin D (Vitamin D2 and D3)	EN 12821 / NMKL 167	Calculation from vitamin D2 or D3 concentration, preparative column chromatography and liquid chromatography	II

Appendix III

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

(at Step 8)

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 evaluation of measurement uncertainty is required to establish the comparability of measurement results. Accordingly, measurement uncertainty is of utmost importance in analytical testing and subsequent decision-making.

2. This Guideline does not provide guidance for the evaluation of the contribution to total uncertainty due to sampling neither does it provide guidance as to how to take measurement uncertainty into account in the specification of sampling plans for acceptance sampling in connection with lot inspection. 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. The latter 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 conformity 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 in conformity assessment and in specifying sampling plans for the inspection of lots. 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 heterogeneity[1] between test portions) and the analysis of a test portion in the laboratory.

4. Analytical measurements in food control are often *quantitative*, but *qualitative* test results are also relevant. While an evaluation or estimation of measurement uncertainty is not required for qualitative results, it is recommended that laboratories identify factors which have an influence on such test results and establish quality assurance procedures to control relevant effects.

Prerequisites

5. Laboratories which perform analytical measurements 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 (JCGM 106: and ISO 10576).

Terms and definitions

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

    - CXG 72-2009 (Guidelines on Analytical Terminology)

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[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 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.

- JCGM 200 International vocabulary of metrology – Basic and general concepts and associated terms (VIM)
- ISO 3534-1 Statistics – Vocabulary and symbols – Part 1: General statistical terms and terms used in probability
- ISO 3534-2 Statistics – Vocabulary and symbols – Part 2: Applied statistics
- ISO 2859-1 Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
- ISO 3951-1 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 Animal feeding stuffs -- Guidelines for sample preparation
- ISO 10725 Acceptance sampling plans and procedures for the inspection of bulk materials
- ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories

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

- **Inspection by variables**: Inspection by measuring the magnitude of a characteristic of an item.
- **Item**: That which can be individually described and considered.
- **Laboratory sample:** Sample as prepared (from the lot) for sending to the laboratory and intended for inspection or testing.
- **Lot:** A lot is a definite quantity of some commodity manufactured or produced under similar conditions.
- **Measurement uncertainty:** Parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand (i.e. the quantity intended to be measured).
- **Sample:** Set of one or more items taken from a lot and intended to provide information on the lot.
- **Sampling plan:** Specified sample size, methodology for the selection of samples and lot acceptability criteria.
- **Sample size:** Number of items in the sample.
- **Test portion:** Quantity of material drawn from the test sample (or from the laboratory sample if both are the same).
- **Test sample:** Subsample or sample prepared from the laboratory sample and from which test portions will be taken

General considerations

8. 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 attributed to the measured quantity will lie with a stated coverage probability. The uncertainty of a measurement result reflects the lack of exact knowledge of the value of the measurand. Since all measurement results are subject to error, laboratories are expected to estimate and, if necessary, report the measurement uncertainty associated with every result.

9. Measurements are affected by many influences – e.g. effects which arise in connection with changes in temperature, pressure, humidity, matrix variability or with the judgment 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. Both systematic and random components of measurement uncertainty should be summarily quantified. Components of measurement uncertainty can be evaluated from the statistical distribution of a series of measurement results and characterized by standard deviations. 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.

10. 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. However it is of utmost importance to identify and evaluate systematic components of measurement uncertainty since these cannot be reduced by repeated measurements. Whenever possible test methods should be used that have been validated by collaborative studies. In case that there are two methods with identical measurement uncertainty, the method with lower systematic error should be preferred.

Uncertainty components

11. 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: Quantifying Uncertainty in Analytical Measurement, Sections 7.3.1, 7.13.2 and 7.13.3.

Procedures for estimating measurement uncertainty

12. There are many approaches available for estimating the uncertainty of a measurement result, notably those described in CGM 100 Evaluation of measurement data – Guide to the expression of uncertainty in measurement and EURACHEM / CITAC Guide CG 4: Quantifying Uncertainty in Analytical Measurement. These Codex Guidelines do not recommend a particular approach for estimating measurement uncertainty, but it is important that whatever approach is used be scientifically acceptable[2]. Among such scientifically acceptable approaches, none may be said to be better than any other – i.e. there is no "hierarchy" among such approaches. Choosing the appropriate approach depends on the type of measurement or 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 studies, proficiency studies, validation studies, intra-laboratory quality control samples, or a combination of such data. For microbiological testing, the procedure described in ISO 19036 follows a "top-down" approach.

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

- Modelling (ISO GUM)
    - Bottom-up component-by-component evaluation according to JCGM 100 or according to JCGM 101 (Monte-Carlo Method)
- Single-lab validation
    - Top-down approach e.g. according to Nordtest TR 537, NMKL procedure No. 5, EURACHEM / CITAC Guide: Quantifying Uncertainty in Analytical Measurement (uncertainty of results obtained using the same procedure in a single laboratory under varying conditions)
- Interlaboratory validation
    - Top-down approach using the reproducibility standard deviation (ISO 5725-2, ISO 5725-3 and ISO 21748) (uncertainty of results obtained using the same procedure in different laboratories)
- Proficiency testing (PT)
    - Top-down approach using the standard deviation for proficiency assessment (uncertainty of results obtained by analysing the same sample(s) in different laboratories)

14. 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 an estimate of measurement uncertainty. The matrix mismatch uncertainty component should be adequately

[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.

taken into account during the estimation of measurement uncertainty. Different matrices and concentration levels – depending on the scope of the method – could be used to overcome this deficiency. 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. Certified reference materials can also be used to estimate bias and its uncertainty.

15. In addition to the fact that these procedures may differ depending on 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 available on request.

16. 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.

17. The reliability of the measurement uncertainty components should be taken into account in the design of experimental studies and the evaluation of the measurement uncertainty. This is especially important if the estimate of a standard deviation is derived from a low number of tests run by a single laboratory or from a collaborative study conducted with a low number of laboratories.

18. Even if some components of measurement uncertainty cannot be evaluated, such components can often 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.

19. 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 a method which has been validated in a collaborative study and thus has ~~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

20. 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.

21. According to CXG 27, laboratories involved in import and export control of food should comply with ISO/IEC17025. ISO/IEC 17025 requires laboratories to use validated methods (see Section 7.2); thus, data from the interlaboratory or single-lab validation study can be used for the estimation of measurement uncertainty following the top-down approach. In Section 7.6.2 of the EURACHEM / CITAC Guide: Quantifying Uncertainty in Analytical Measurement, a procedure for evaluating measurement uncertainty using collaborative study data is provided. The EURACHEM / CITAC Guide: Quantifying Uncertainty in Analytical Measurement 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

22. Measurement uncertainty has several uses including, but not limited to:

    - Reporting of measurement results (see Section 7.8.3.1 c) in 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.

- For conformity assessment, to assess whether the true value of the tested laboratory sample (i.e. of an individual item) complies with a specification (see paragraphs 26 and 27). Examples and explanations of decision rules can be found in Section 8 of JCGM 106 and in Section 6 of ISO 10576-1. An illustration is provided in Figure 1, below.
- For the design of acceptance sampling plans based on inspection by variables. The determination of sample size and acceptability constant for inspection by variables plans is based on the procedures and the sampling plans provided in ISO standards and/or Codex guidelines, e.g. ISO 3951-2 and CXG 50-2004 (*General Guidelines on Sampling*). When measurement uncertainty is non-negligible in relation to the process standard deviation, the different components of measurement uncertainty should be taken into account in the design of the plan (see for instance Annex P in ISO 3951-2).
- Assessing the performance of laboratories (see Sections 9.6 and 9.7 of ISO 13528)
- For the characterization of certified reference materials
- For comparison between measurement results and true/reference values (ISO 5725-6)

Note 1: *It is important to distinguish between the conformity of an individual item and the conformity of a lot consisting of a number (sometimes a very large number) of items. In the latter case, lot acceptance is determined on the basis of a sample of randomly selected items. The combination of inspection by attributes plans with the classification of each item as conforming or nonconforming via the type of approach described in Figure 1 (see below) does not constitute an effective lot inspection procedure (even if the measurement uncertainty includes a sampling component), as it would require a large increase in sample size to satisfactorily control consumer and producer risks.*

Note 2*: Information regarding the individual components of measurement uncertainty is required in the design of inspection by variables plans (in cases where measurement uncertainty is non-negligible in relation to the process standard deviation). Such information may not be available if the measurement uncertainty is reported as a single number.*

How to report measurement uncertainty in test results

23. In accordance with Section 7.8.3.1 c) and 7.8.6 in 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.

24. However, ISO/IEC 17025 does not specify exactly which information should be reported. It is clear, however, that it would be useful to include information as to whether a correction for method bias was applied and whether the contribution corresponding to uncertainty of bias correction is included in the reported measurement uncertainty. The reader is also referred to the ILAC Guidelines ILAC-G17 (Measurement Uncertainty in Testing) and ILAC-G8 (Guidelines on Decision Rules and Statements of Conformity), as well as to the Eurachem / CITAC Guide: Use of Uncertainty Information in Compliance Assessment.

Examples of situations occurring when measurement uncertainty is considered

25. Figure 1 illustrates how measurement uncertainty can affect the decision whether the true value of a laboratory sample (i.e. an individual item) conforms to a specification limit. The procedure illustrated in Figure 1 is not always suitable and is merely intended to illustrate the basic principle only. Measurement uncertainty intervals such as those in Figure 1 cannot be used as a valid conformity assessment procedure.

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

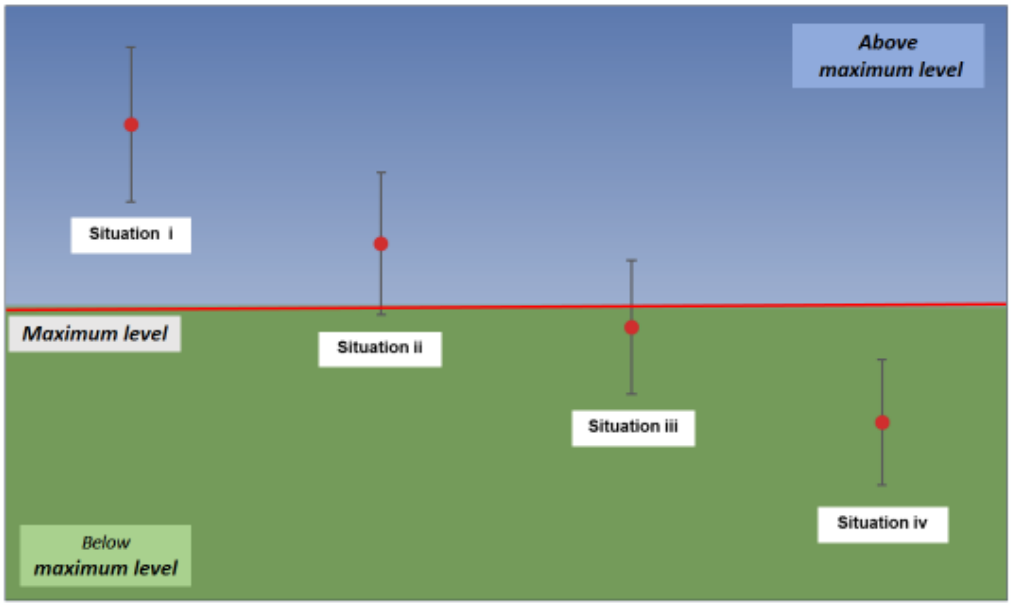


Figure 1: The diagram shows how measurement uncertainty can be taken into account in connection with the conformity assessment of an individual item against a specification. Such a procedure is not suitable for lot inspection. For each situation, the red point represents an individual test result and the vertical bar represents the expanded measurement uncertainty interval.

Situation i

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

Situations 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 the true value lies below the specification.

Note: The implications of situations i to iii in the case of testing MRL compliance are extensively discussed in ~~the~~ CXG 59-2006 (*Guidelines on Estimation of Uncertainty of Results*). 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 or maximum level is exceeded or that the item is compliant, 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 Section 4 of CXG 83-2013 (*Principles for the Use of Sampling and Testing in International Food Trade*). It is stated under Principle 5 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."

Appendix IV

PROPOSED DRAFT REVISED *GENERAL GUIDELINES ON SAMPLING* (CXG 50-2004)

(at Step 5)

1 Preamble

These Guidelines are intended primarily for use by Codex commodity committees responsible for developing sampling plans for provisions in Codex standards, and by governments responsible for import or export inspection of foods. They describe the design and evaluation of sampling plans for the international trade of food commodities.

Foods are frequently sampled, throughout the supply chain from producers to consumers, for the purposes of checking their safety and quality[1]. Clear definition of sampling plans is an integral part of specifications for the sampling and testing of foods. Sampling plans are included in Codex standards and may be used by governments in standards for foods.

Codex sampling plans, in conjunction with methods of analysis, are intended as a means of verifying that foods comply with provisions relating to composition, chemical or microbiological contaminants or pesticide residues contained in Codex standards.

Sampling therefore has an important role in achieving the Codex objectives of protecting consumers' health and ensuring fair practices in the food trade. Codex sampling plans also have an important role in avoiding or removing difficulties which may be created by diverging legal, administrative and technical approaches to sampling and by diverging interpretation of results of analysis in relation to lots or consignments of foods, in the light of the relevant provision(s) of the applicable Codex standard.

It is important that sampling is undertaken in a way that contributes to these objectives.

Specification of these quality objectives, the level of quality acceptable to the customer and the rate of acceptance of compliant product, in terms of allowable risks for the consumer and the producer, enable the development of sampling plans.

A Codex standard may set out a specific sampling plan for a particular context, or it may specify the outcome to be achieved by a sampling plan.

Although these Guidelines provide a generic approach to the design of sampling plans, Codex sampling plans are intended primarily for inspection of foods upon receipt, for example by importing country regulatory agencies, and might not be suitable for use by producers. However clear definition of sampling plans by Codex defines the quality objectives to be met and enables producers to devise appropriate control and inspection procedures to achieve them.

1.1 Scope

In Section 2, these Guidelines define general notions on food sampling, where applicable. In Sections 3 to 5 they cover certain situations of statistical food control, in which certain sampling plans have been selected. Section 6 covers other matters relating to sampling and includes physical sampling as well as general information.

Most of the material in these Guidelines relates to lots assumed to be homogenous. The following situations are covered:

- Sampling plans for the control of the percentage defective for homogeneous lots by attributes or by variables, for goods in bulk or individual items
- Sampling plans for the control of the mean content
- Adjustment for measurement error in cases where it is not negligible compared to sampling error.

Some general information is provided on sampling for inhomogeneous lots.

1.2 Definitions

For the terms commonly used in CXG 50, the following definitions are in addition to those in *Guidelines on Analytical Terminology* (CXG 72-2009).

1 The term 'quality' as used in these Guidelines covers 'food safety and quality'.

Acceptance Sampling

Sampling after which decisions are made to accept or not to accept a lot, or other grouping of products, materials, or services, based on sample results *(SOURCE: ISO 3534:2)*.

Note:

- Also referred to as "Acceptance Sampling Inspection"
- In CXG50 the term "Acceptance Sampling" and "Acceptance Sampling Inspection" are usually shortened to just "Sampling" or "Sampling Inspection"

Acceptance Sampling Plan

Plan which states the sample size (s) to be used and the associated criteria for lot acceptance.

(SOURCE: ISO 3534:2)

Information note

An **Acceptance Sampling Plan, referred to as a "Sampling Plan" in CXG50,** intended for determining the acceptance or the rejection of a lot. The plan specifies:

- the number of samples to be taken and how those samples are to be taken from a lot
- how those samples will be tested, and
- the decision rule, based on the test results obtained, used to determine whether the lot is accepted or rejected.

Acceptance Sampling Inspection by Attributes

Acceptance sampling inspection whereby the presence or absence of one or more specified characteristics of each item in a sample is observed to establish statistically the acceptability of a lot or process.

(SOURCE: ISO 3534:2)

Information note

Inspection by Attributes consists of examining an item, or characteristics of an item, and classifying the item as 'conforming' or 'nonconforming'. The action to be taken is decided by counting the number of nonconforming items or the number of nonconformities found in a random sample.

An inspection by attributes sampling plan specifies the number of samples (**n**) and the maximum number of nonconforming items, referred to as the acceptance constant (**c**), for the lot to be accepted.

The values of **n** and **c** are worked out from the specified levels of allowable risk.

Acceptance Sampling Inspection by Variables

Acceptance sampling inspection in which the acceptability of a process is determined statistically from measurements on specified quality characteristics of each item in a sample from a lot.

(SOURCE: ISO 3534:2)

Information note

Inspection by Variables starts with selecting a sample of a number of items and measuring dimensions or characteristics so that information is available not only on whether a dimension, for example, is within certain limits but on the actual value of the dimension. The decision whether or not to accept a lot is made on the basis of calculations of the average and the variability of the measurements.

An inspection by variables sampling plan specifies the number of samples (**n**) and an acceptability constant (**k**). A lot is accepted against an upper specification limit if the decision rule 'average result + **k** * the standard deviation of results' does not exceed the upper limit, and similarly for a lower limit. In other words, the decision rule is based on the average value x-bar and the standard deviation of the results from the testing.

The values of **n** and **k** are worked out from the specified levels of allowable risk.

[Confidence

The term 'confidence' is often used in conjunction with sampling plans. However, while it is a statistical term, in reality it has nothing to do with acceptance sampling. It is simpler to understand the correct approach to sampling to express risks in terms of probabilities of acceptance or rejection at specified levels of nonconforming product within a lot.

Confidence can be associated with consumer's risk, for instance 95% confidence (that the lot is of satisfactory quality). means there is only 5% chance of acceptance for a non-compliant lot.

However, confidence is not useful for describing producer's risk.**]**

Consumer and Producer

The terms 'producer' and 'consumer' are conventional and may apply to a range of different operators in the food chain, such as a grower, manufacturer, the manufacturer's own quality control system, supplier, exporting country, processor, on-seller, or importing country.

[Consumer's Risk (CR)

Probability of acceptance when the quality level of the process has a value stated by the acceptance sampling plan as unsatisfactory.

(SOURCE: ISO 3534:2)

Information note
Consumer's Risk is the probability of wrongly accepting a lot that is not of acceptable quality. It is a point on the OC curve corresponding to a predetermined and usually low probability of acceptance.]

Consumer's Risk Quality (CRQ)

Quality level of a lot or process which, in the acceptance sampling plan, corresponds to a specified consumer's risk.

(SOURCE: ISO 3534:2)

Information note
Consumer's Risk Quality (CRQ) is the level nonconforming in a lot, specified in the design of a sampling plan, corresponding to a specified Consumer's Risk of accepting a lot of poor quality

[Decision rule

A decision rule describes how measurement uncertainty is accounted for when stating conformity with a specified requirement**]**

(SOURCE: ISO 17025)

Lot

Definite part of a population (constituted under essentially the same conditions as the population with respect to the sampling purpose).

[Information note: "same condition"]

(SOURCE: ISO 3534:2)

[Measurement error

The 'measurement error' refers to a difference between an individual measurement value and the 'true' (or reference) value.

Measurement uncertainty

The measurement uncertainty is the range of values within which the value of the measurand (~ true value) lies**.]**

Operating Characteristic Curve

The Operating Characteristic Curve showing the relationship between probability of acceptance of product and the incoming quality level for given acceptance sampling plan.

(SOURCE: ISO 3534:2)

[Producer's Risk (PR)

Probability of non-acceptance when the quality level of the process has a value stated by the plan as acceptable.**]**

(SOURCE: ISO 3534:2)

Information note

Producer's Risk is the probability of wrongly rejecting a lot that is of acceptable quality. It is a point on the OC curve corresponding to a predetermined and usually high probability of acceptance.

Producer's Risk Quality (PRQ)

Quality level of a lot or process which, in the acceptance sampling plan, corresponds to a specified producer's risk

(SOURCE: ISO 3534:2)

Information note

Producer's Risk Quality is the level nonconforming in a lot, specified in the design of a sampling plan, corresponding to a specified Producer's Risk (PR).

Provision, Characteristic, Standard

A **provision** is a requirement for a commodity that must be met in order that the commodity conforms to the standard.

A **characteristic** is the attribute in the commodity to which the provision relates

[A **standard** is a set of provisions relating to a commodity, all of which must be met in order that the commodity conforms to the standard.**]**

Example

Fat in WMP must exceed 26%

Identified food or group of foods e.g. Milk powders and Cream Powders Codex Standard 207

The attribute is the 'characteristic' in the commodity to which the provision relates e.g. fat

Provision is the requirement that must be met e.g. must exceed 26%

Quality Level

Quality expressed as a rate of nonconforming units or rate of number of nonconformities.

(SOURCE: ISO 3534:2)

A **sampling scheme** defines what data will be obtained and how. Precision and systematic sampling error are two principles that guide the choice of sampling scheme.

2 Acceptance Sampling - General Principles

2.1 Reasons for sampling

While various measures such as Hazard Analysis and Critical Control Point (HACCP), Good Manufacturing Practice (GMP), process control and sampling are available to producers to provide assurance about the quality of products they supply, consumers usually rely on sampling if they wish to verify the quality of incoming products.

Acceptance sampling procedures are used when goods are transferred between two parties. The purpose of these procedures is to provide unambiguous rules for releasing a product after inspection of only a limited sample. Both parties are fully aware of the limitations and risks associated with using such a procedure and therefore most acceptance sampling procedures include provisions for dealing with non-conforming items found in lots that have been accepted by the sampling plan' .

Acceptance sampling is the process in which samples are taken from a lot and decisions are made concerning the disposition of that lot, whether the lot is accepted or rejected, based on the results from the testing or examination of those samples.

An acceptance sampling plan specifies the number of samples to be taken and how they are to be taken, the procedure used to test or examine those samples, and the decision rule, based on the results from the testing of those samples, used to decide whether a lot should be accepted.

In general acceptance sampling is used to:

- Reduce costs
- Allow product assessment when tests are destructive
- Enable faster decision making.

2.2 Approach to sampling

There are three possible approaches to sampling:

a. 100% inspection, involving inspection of all (i.e.100%) of the product

b. Sampling based on the principles of probability

c. Ad hoc inspection, that is, a sampling plan without a statistical basis.

The risks and costs associated with each of these three options can be considered:

For approach (a), it is clear that 100% sampling is usually not feasible due to the prohibitive cost of testing and in addition, there might not be any product left to sell if the inspection method necessitates destructive testing. In addition, the presence of measurement error means that it is still not possible to provide a 100% guarantee, even if all items in the lot are inspected.

Approach (b) has the disadvantage of higher risks as compared to approach (a), since some product will not be inspected. However, by using the probability approach the risks can be calculated and a sampling plan chosen that ensures these risks are controlled to desired levels. It also has the advantage of practicability and lower costs.

In the context of sampling, risk occurs when incorrect decisions are made about the status of the product.

There are two types of risks that can occur:

- Acceptance of product of unsatisfactory quality (consumer's risk) and
- Rejection of product of acceptable quality (producer's risk).

Sampling plans should be designed to control these risks to desired levels, i.e. they should take account of the principle of fitness for purpose. Such control provides assurance, over the longer term, across many lots (i.e. in terms of probability).

Approach (c) is not recommended. It may be used for practical reasons, such as limited resources, or for simplicity. However such plans might not provide the expected level of assurance of food quality and may inadvertently impose high costs, for instance through unwarranted acceptance of food that could lead to illness or unwarranted unjustified rejection that in turn, could lead to the imposition of fines, penalties or trade sanctions. The risks associated with such plans should be evaluated where possible. Decisions on acceptance or rejection should not be made solely on the basis of these plans except by mutual agreement of the consumer and producer based on an understanding of the risks.

In summary, the approach to sampling should be based on control of the levels of assurance provided and the costs to the parties involved in the transaction.

2.3 Sampling plan performance

2.3.1 Probability and what it means

Variation is present everywhere; raw materials vary in their composition, manufacturing process vary and, as a consequence, the products manufactured by those processes will also vary. Therefore, when we take a set of samples from a lot of product, we do not expect those samples to be of the same composition. Further, the presence of measurement error means that when those samples are tested, we will not get the same result, even if the same sample is retested. Similarly, we would not expect results from different sets of samples taken from the same lot or those taken from different lots to always be the same; there will be some variation of those results.

Variation causes uncertainty when we attempt to make decisions about the compliance of a lot to a specification limit; at any level nonconforming some lots might be accepted, and some might be rejected. However, if we describe the variation of the product and of the measurement process statistically, we can predict the expected outcome in any given situation, at any level nonconforming for any given sampling plan.

In acceptance sampling this expected outcome can be expressed as the average rate of acceptance (or success rate) over a long series of inspections of lots having the same level nonconforming. This average rate is more commonly known as the probability of acceptance and can lie between zero (lots with that level nonconforming are never accepted) and one (lots are always accepted).

In acceptance sampling the probability of acceptance for a particular plan depends on the level nonconforming in a lot, the decision rule for that sampling plan and possibly, in the case of significant measurement error, on the bias and variation inherent in the measurement process. In practice, the level nonconforming in a lot is not known beforehand but it is possible to calculate the probability of acceptance for any assumed level nonconforming in a lot.

The relationship between the probabilities of acceptance and the assumed levels nonconforming for a sampling plan is described by the Operating Characteristic curve.

3 Design of Sampling Plans

3.1 Inputs to sampling plans

3.1.1 Producer's Risk Quality and Consumer's Risk Quality

The Producer's Risk Quality (PRQ) and Consumer's Risk Quality (CRQ) , along with the allowable risks at those quality levels, are two fundamental inputs in the design of sampling plans; they define the stringency of the plan, the degree to which the sampling plan will control the producer's and consumer's risks.

Allowable risks are expressed in terms of the probabilities of acceptance or rejection at those quality levels, for example:

- Producer's Risk (PR) – the chance of rejection at the PRQ level (e.g. 5% chance of rejecting at PRQ of 1% nonconforming, or equivalently, 95% chance of acceptance at 1% nonconforming)
- Consumer's Risk (CR) – the chance of acceptance at the CRQ level (e.g. 10% chance of acceptance at a CRQ of 5% nonconforming.

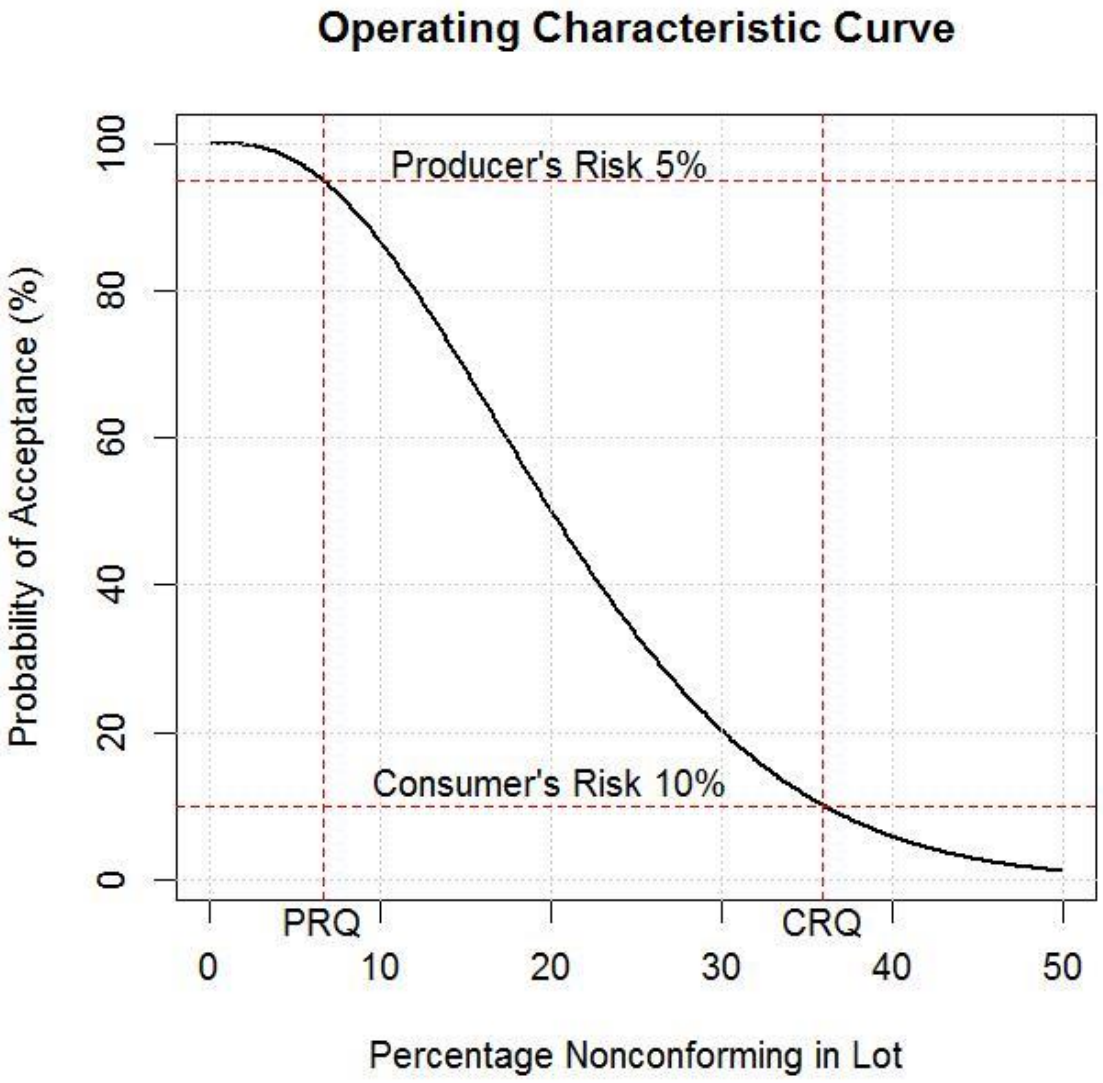
Once the PRQ and CRQ, along with their associated allowable probabilities of rejection (PR) and acceptance (CR) respectively are specified, a sampling plan, allowing no more than those levels of risk, can be developed. In some cases, such as where measurement error is significant, additional information may be required.

3.1.2 Operating Characteristic Curve (OC curve)

An Operating Characteristic curve (OC curve) for a sampling plan shows the probability of accepting (or rejecting) a lot in terms of the quality level (e.g. percentage nonconforming) in the lot. The OC curve is calculated using the principles of probability.

Note that the Operating Characteristic does not say anything about the quality of a lot; it serves only to show the probability of accepting the lot at a particular quality level.

3.1.2.1 Figure 1: Operating Characteristic Curve

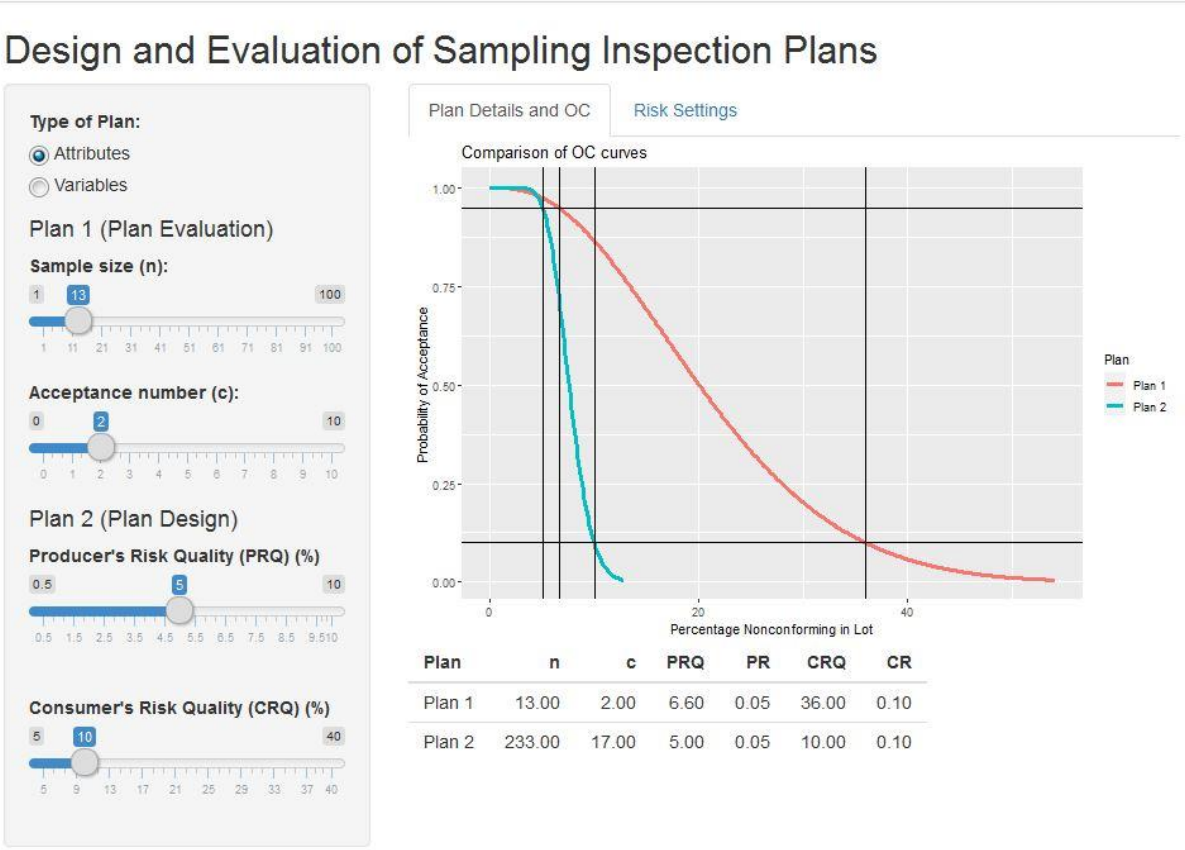


The diagram shows the points on the Operating Characteristic that are fundamental to the design of sampling plans.

3.1.3 Performance Criteria

Once the PRQ and CRQ, along with their associated probabilities of rejection (PR) and acceptance (CR) respectively are specified, a sampling plan, allowing no more than these levels of risk can be developed.

3.1.3.1 Figure 2: Design and Evaluation of Sampling Inspection Plans



3.1.4 Fitness for Purpose

Codex methods of sampling should be designed to ensure that 'fair and valid sampling procedures' are used when food is being tested for compliance with a particular Codex commodity standard. When commodity committees have included sampling plans in provisions in a Codex commodity standard, these should be referred to the Codex Committee of Methods of Analysis and Sampling (CCMAS) for endorsement along with relevant information relating to the sampling plan.

Sampling plans should also be designed to control the risks to desired levels, i.e. they should take account of the principle of fitness for purpose.

The Principles for the Use of Sampling and Testing in International Food Trade (CXG 83-2013) states that sampling and testing procedures selected should be fit for their intended purposes 'Sampling and testing procedures are fit for purpose in a given product assessment, if, when used in conjunction with appropriate decision criteria, they have acceptable probabilities of wrongly accepting or wrongly rejecting a lot or consignment'.

In the wider context, fitness for purpose should consider the implications relating to cost, practicality, and fairness in the design of sampling plans.

Sampling plans can also be designed to specifically control the costs associated with acceptance of nonconforming lots and the rejection of compliant lots, but costs associated with sampling and testing, which are usually smaller, and other costs can also be taken into account.

Other strategies could be used to develop sampling plans that are more economical in terms of sampling and testing:

- Managing average non-compliance rates over the medium to long term, rather than possibly paying a high premium in terms of testing costs for high levels of assurance on a lot-by-lot basis
- The use of 'indifference' plans that are designed around the 'Indifference Quality Level' (IQL), the level of defects at which there is 50% acceptance, rather than based on PRQ, CRQ. This leads to plans having more manageable sample sizes.

3.1.5 Fairness

Fairness must involve consideration of both consumer's and producer's risks, to avoid situations such as the following:

- Sampling plans having inappropriate stringency, not commensurate with the application, for example, plans for assessment of composition that are more stringent than those for food safety
- High producer's or consumer's risks that may arise due to use of plans not based on appropriate specifications of allowable producer's and consumer's risks
- Plans not based on statistically valid principles, for example, failure to allow for or properly allow for either sampling or measurement errors or inappropriate allowances made for these errors
- Use of single sampling plans, including those chosen from sampling schemes, might be unfair, even though producer's and consumer's risks have been specified in their design, for example:
    - there is always a chance that product of good quality may fail a consumer's inspection particularly when assessments are based on small sample numbers
    - use of the same sampling plan by the producer in situations of deteriorating quality could result in increased consumer's risk (even if only product that passed the producer's assessments was received by the consumer).

Fairness should also take account of the measures that the producer may have to take to ensure compliance, given that it is usually not suitable for the producer to use the same sampling plan as that used by the consumer. For example, designers of plans should ensure that producers are not exposed to unreasonable costs in terms of sampling and testing, loss of yields, or excessive rejection of their products in order to achieve compliance.

3.1.6 Stringency

In the interests of fairness, stringency should be in keeping with the perceived risks associated with failure and relativity among different characteristics. **[**The following example shows an approach that could be used to set allowable levels of consumer's risks across different characteristics.

Example: Stringency

Risk rating	**Severe**	**Serious**	**Moderate**	**Indicator**	**Utility**
Quality level nonconforming	1%	5%	8%	10%	20%
Consumer's risk (allowable probability of acceptance)	1%	1%	5%	5%	5%

Each characteristic would be ranked according to the rating scale above and then the levels of allowable risk and associated levels nonconforming would be assigned. The process could be extended to also include producer's risk**.]**

3.1.7 Nature of the Specification Limits

[Specification limits**]** may be expressed as a minimum or a maximum (or both) applied to either the overall distribution of the characteristic in the lot, e.g. the quality level, or to the average level; the Codex Procedural Manual states that the following should be specified when sampling plans are included in Codex standards:

- Whether the specification limit applies to every item in a lot, or to the average in a lot, or the proportion nonconforming (inferences to be made to lots or processes)
- The appropriate acceptable quality levels to be used (levels of risk to be accepted), noting that the 'quality level' is not the level of risk
- The acceptance conditions of a lot controlled, in relation to the qualitative/quantitative characteristic determined on a sample (decision rules).

In addition, Holst et al provides the following guidance 'It is sometimes seen that the measurement or sampling uncertainty has already been taken into account when formulating the specification limits. Such practice should, however, not be used. It is not good current practice to formulate specification limits in such a way that the values depend on a specific measurement and sampling procedure or technology'. As a consequence, unless specified

otherwise, specification limits should apply to the true values of the characteristics, not to the measurements themselves.

3.1.8 Nature of the Measurements

In some cases, such as where measurement error is significant, additional information may be required.

The options for sampling plans depend on whether the test results are measurements (variables data) or have nominal outcomes (attributes data), measured on a scale, including binary outcomes, for example, pass or fail, and measurements classified as binary outcomes. However, decisions on classifying measurements as binary outcomes should be made only after considering the sampling options available.

In the case of variables data, the assumed statistical distribution of the measurements must also be specified, whether the characteristic is normally distributed, a compositional proportion, or follows some other distribution or if it is not possible to define such a distribution. The nature of the measurements and their distribution will determine the choice of the plan.

However, it is not necessary that the characteristic follows the assumed distribution exactly (and in any case it is difficult to statistically verify conformance to a distribution using small samples), it is sufficient that the assumed distribution provides a satisfactory model for the behaviour of the characteristic in the lot.

3.1.9 Measurement and Inspection Errors

Measurement error refers to the difference between a measured value and the true value of what is being measured. On the other hand, inspection error refers to random errors of misclassifying conforming items as nonconforming and vice versa. The term ‘measurement error’ relates to variables data (measurements) whereas ‘inspection error’ relates to attributes data.

For attributes plans, details of the Type I and Type II error rates are needed. Refer to Section 5.2 for more details.

For variables plans, information about the measurement error, specifically the repeatability, reproducibility and possibly bias is required to enable the effect of measurement errors on the performance of sampling plans to be investigated and adjustments to be made if required. Refer to Section 5.3.

Information on the statistical distribution of the measurement errors is also needed when measurement error is significant, although it is common to assume measurement errors are normally (or log-normally) distributed.

3.1.10 **[**Lot Homogeneity

Sampling inspection plans usually assume that the lots to which they are applied are ‘homogeneous’, having the same quality throughout, and indeed, the international definition of a lot is ‘a quantity of product produced under conditions presumed uniform’. Applying sampling inspection plans to a lot of varying quality can result in unjustified rejection of the lot as a whole, or the acceptance of the lot on an average basis, with parts of the lot containing product of possibly unsatisfactory quality.

In the statistical literature, heterogeneity usually refers to ‘non-constant variation’ with no reference to specification limits. However in sampling inspection, lot heterogeneity, such as short term process trends, is not particularly important and need not cause nonconformance provided there is an adequate offset between the average level of a lot and the specification limits to allow for the variation present. Hence it follows that in sampling inspection homogeneity must consider the proximity of results (or the potential result distribution) to the specification limits.

A lot (or essentially parts of a lot, which are termed as [sublots]) is called homogeneous when the quality within it is the same i.e. having the same probability nonconforming throughout with no particular part differing from any other part. This is equivalent to saying that a lot can be called homogeneous with respect to given specification limits, if the probability distributions of all sublots have the same fraction nonconforming. However, sublots should not be defined by test results from the lot.

The definition of any lot might differ according the characteristic inspected.

Section 4.4 discusses some of the issues concerning the inspection of inhomogeneous lots.**]**

3.1.11 Lot Size

Lot size is not normally an input required for the design of sampling plans intended to control the consumer’s and producer’s risks in acceptance sampling. However, specification of the lot size is needed for attributes plans applied to small lots.

3.1.12 Other Inputs

For the purpose of the Guidelines, the context for the sampling plan should include consideration of the following points:

Inputs	Description
The identified food or group of foods	The sampling plan should relate to an identified food or group of foods.
Identified characteristic	The characteristic in the commodity to which the provision relates.
Provision in a Codex Standard	A requirement that a characteristic must meet, in order that the commodity conforms to the standard. The provision may specify a minimum or maximum limit relating to either the overall distribution or to the average level of the lot.
Use of food	Whether the food is intended for direct consumption or used as an ingredient, its content in the final food and the nature of any further processing steps.
Codex Procedural Manual	Information relating to the scope or field of application and the type of sampling (e.g. bulk or unit)

4 Sampling Plans

4.1 Selection of Sampling Plans

The following table provides references within these Guidelines.

4.1.1.1[Table 1: References to the selection of sampling plans in these Guidelines

Homogeneous lots				
Data Type	**Nature of Provision**	**Distribution**	**Negligible Measurement Error**	**Significant Measurement Error**
Attributes	Minimum or Maximum	Not applicable	Inspection by Attributes Plans	Retesting
			(Section 4.2)	(Section 5.2.1)
				Known Inspection Errors
				(Section 5.2.2)
Variables	Minimum or Maximum	Normal	Inspection by Variables Plans	Repeatability Error (1)
			(Section 4.3)	(Section 5.3.1)
				General Measurement Error (1)
				ISO3951-6
				Fractional Nonconformance Plans
				(Section 5.3.4)
	Minimum or Maximum	Non-normal	Classification to Attributes	Fractional Nonconformance Plans
			(Section 4.2.6)	(Section 5.3.4)
Variables	Minimum or Maximum	Compositional Proportions	Plans for Compositional Proportions	Not included
			(Section 4.3.4)	
	Average Level	Not applicable	Plans for Average Level	
			(Section 4.3.5)	
Inhomogeneous Lots (Bulk Materials)				
Attributes	Minimum or Maximum	(blank)	Attributes Plans	
			(Section 4.4.3)	
Variables	Minimum or Maximum	(blank)	Variables Plans	
			(Section 4.4.4)	
	Average Level	Not applicable	Plans for Average Level (Section 4.4.5)	

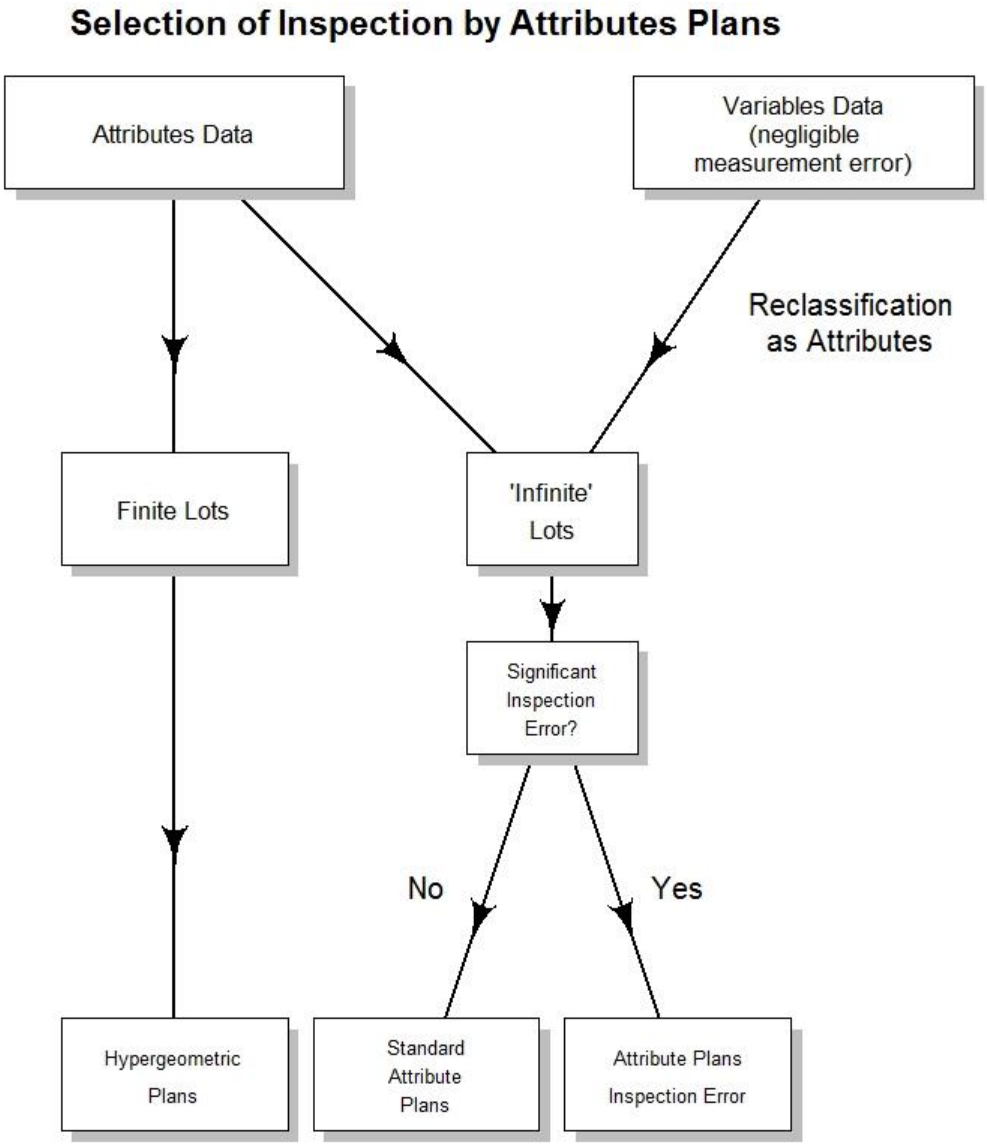
Note (1): In these cases measurement error is also assumed to be normally distributed**]**

4.2 Inspection by Attributes Plans

4.2.1 Introduction

These plans are usually referred to as attributes sampling plans. They are the simplest type of single sampling plan because the inspection results are classified into two possible outcomes - conforming or nonconforming. Because they are applicable to all sampling situations, they have become the benchmark that all other sampling plans can be compared against.

4.2.1.1 Figure 3: Design of Attribute Plans



4.2.2 Two-class Attributes Plans

Two-class attributes plans are defined by two numbers, the sample size ***n***, the number of items to be taken from the lot under inspection and the acceptance number ***c***, the maximum number of nonconforming items allowed in the sample for acceptance of the lot. If the number of nonconforming items in the sample is less than or equal to ***c*** then the lot can be accepted. If the number of nonconforming items found is greater than ***c*** then the lot is rejected.

4.2.3 **[**ISO 2859 Sampling Plans

In these plans the number of samples is determined by the lot size. This means that the plans explicitly control either the Producer's Risk for plans indexed by the PRQ or the Consumer's Risk for plans indexed by CRQ, but not both as in the case of the general plans. The acceptance numbers © for these plans are determined by the chosen PRQ or CRQ respectively, and the lot size.

The AQL plans are used for the inspection of a continuing series of lots, often in relation to a contractual arrangement between a supplier and a customer. On the other hand, the LQL plans are used for the inspection of isolated lots.

Refer to Section 6.2 for more details.**]**

4.2.4 Plans for Small Lots (based on the hypergeometric distribution)

If the sample size is large in relation to the lot size, some economy in the number of samples may be possible. As a rule, such economies are possible if the number of samples, calculated assuming an infinite lot size, exceeds 10% of the lot size. For conceptually infinite lots, sampling plans based on the hypergeometric distribution are the same as the general two-class plans based on the binomial distribution.

4.2.5 Zero-Acceptance Number Plans (including hypergeometric)

Zero-acceptance number plans (ZAN) are a special case of two-class plans in which the acceptance numbers are set to c=0. They are used in more critical situations such as for pathogens or for foreign matter where only consumer's risk is considered directly and acceptance of lots demands that nonconforming items are not found in the inspection.

However, it should be noted that just because nonconforming items have not been found does not mean that they are not present in lots that have passed inspection. One disadvantage of ZAN plans is that they have poor discrimination between good and poor quality lots, so they may not be generally applicable. The low sample numbers generally employed for microbiological applications enable high levels of consumer protection to be provided because of the offsets between the limits used in those plans and levels of contamination at which food might become unsafe.

4.2.6 Three-class Attribute Plans

In these plans inspection results are classified into three classes, usually referred to as 'good', 'marginal' and 'poor' or 'unacceptable'. This type of plan is frequently used in microbiological assessments. They have an advantage, relative to two-class plans, of providing better discrimination between good and poor quality i.e. they have 'steeper' OC curves than two-class plans for the same number of samples.

Three-class plans are defined by four numbers (***n, c, m, M***) where:

- ***n*** is the number of samples to be taken
- ***c*** is the maximum number of 'marginal' samples allowed for acceptance of the lot
- ***m*** is the maximum limit for 'good' samples
- ***M*** is the microbiological limit above which samples are classified as 'poor'
- Samples with results lying between the numbers ***m*** and ***M*** are classified as marginal.

Lots are accepted provided:

- None of the n samples is poor, with levels exceeding ***M***
- Most c of the samples are marginal, with levels between ***m*** and ***M***.

If ***m***=***M*** a three-class plan becomes a two-class plan.

Evaluation of these plans generally requires an assumption about the underlying distribution of the identified characteristic, such as the log-normal distribution for microbiological parameters. This might also apply to two-class plans, especially for microbiological plans.

Three class plans for finite lots can also be designed based on the hypergeometric distribution.

4.2.7 Variables Plans (where an appropriate distribution is unknown)

If the underlying distribution of a measured characteristic within a lot is not known and we are not prepared to assume that the characteristic can be adequately described by the normal or any other distribution, then the only recourse available is to classify the results as conforming or nonconforming with respect to the specification limit and to use attributes plans. Note that this approach should be used only when measurement error is negligible.

4.2.8 Attribute Plans for Multiple Characteristics

Attributes plans can be easily applied to multiple characteristics by classifying inspected items as nonconforming if any of the individual characteristics are nonconforming. Obviously, it makes sense to apply a plan to multiple characteristics only if the individual characteristics are of similar 'stringency', i.e. if the same or similar plans would be used if the characteristics were inspected individually. These plans have the advantage, compared to the use of individual plans, of allowing better control of producer's risk, of incorrectly rejecting product of good quality

4.3 Inspection by Variables Plans

4.3.1 Introduction

If the underlying distribution of a measured characteristic is known, acceptance sampling can be performed directly on the measurements themselves. This often allows a considerable saving in sample size, but we need to know the probability distribution of the characteristic within the lot; the Gaussian or normal distribution is commonly adopted. For compositional proportions in bulk materials, the beta distribution is more appropriate, but the normal distribution can serve as an approximation.

4.3.2 Advantages and Disadvantages of Plans

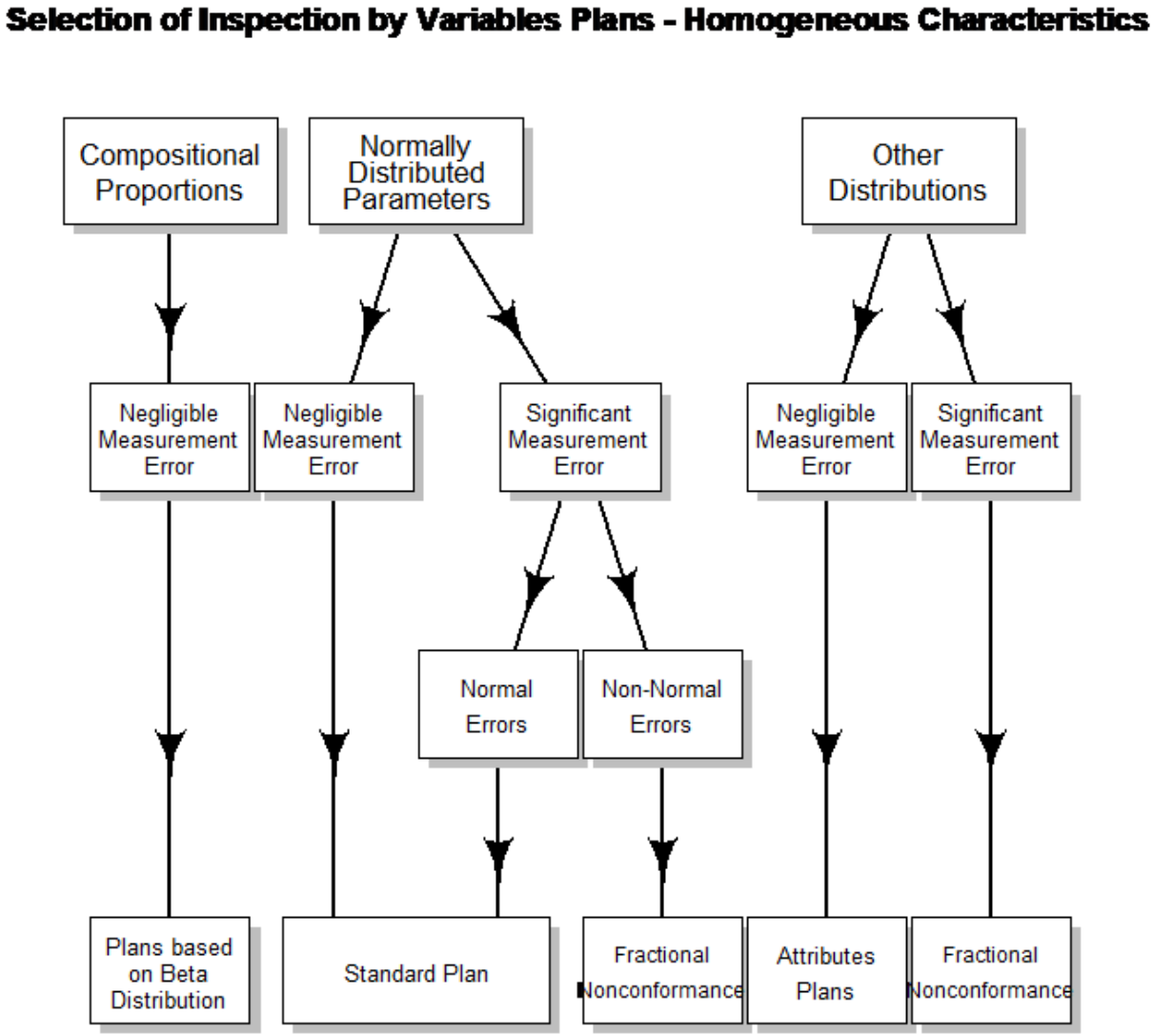
The advantages of variable sampling plans are:

- They offer the same protection with a smaller sample size than that required for attributes plans
- There is feedback of data on the process which produced the units
- There is more information available in waiver situations
- The extent of conformity of each unit is taken into account in the application of the plan
- There is an increased likelihood that any errors in measurement will be detected.

The disadvantages are:

- The outcome is dependent on the appropriateness of the underlying distribution, that the assumed statistical distribution provides a satisfactory description for the behaviour of the characteristic within the lot
- Variables sampling plans are only applicable to one characteristic at a time
- There may be a higher inspection cost per unit
- There may be higher clerical cost per unit due to the calculations involved
- A lot with no nonconforming units may be rejected by a variables plan, which can occur when the average level lies too close to the specification limit relative to the variation (standard deviation) present
- There is a possibility that no nonconforming units are found to show to the producer after rejection.

4.3.2.1 **Figure 4: Selection of Inspection by Variables Plans**



4.3.3 General Variables Plans

In variables plans, the mean ($\bar{X}$), is compared with the acceptance limit in a similar way to the attributes plans but, in order to allow for the variability in the lot, the sample standard deviation ***S*** is computed.

Variables sampling plans are defined by two numbers, the sample size ***n***, the number of items to be taken from the lot under inspection and the acceptability constant ***k***, the multiplier of the standard deviation in the decision rule.

A lot is accepted if $\bar{X} + kS \leq U$ for an upper specification limit ***U*** or if $\bar{X} - kS \geq L$ for a lower limit ***L***.

The numbers ***n*** and ***k*** can be found from a specification of two points on the intended OC curve, usually by a Producer's Risk Quality (PRQ) and a Consumer's Risk Quality (CRQ) and their associated probabilities of rejection and acceptance respectively.

4.3.4 **[**ISO 3951 Sampling Plans

In these plans the number of samples is determined by the lot size. This means that the plans explicitly control either the Producer's Risk for plans indexed by the PRQ or the Consumer's Risk for plans indexed by CRQ, but not both as in the case of the general plans. The acceptability numbers (k) for these plans are determined by the chosen PRQ or CRQ respectively, and the lot size.

The AQL plans are used for the inspection of a continuing series of lots, often in relation to a contractual arrangement between a supplier and a customer. On the other hand the LQL plans are used for the inspection of isolated lots.

Refer to Section 6.2 for more details.**]**

4.3.5 Sampling Plans for Compositional Proportions (measurement error negligible)

Compositional characteristics are often quality measures for bulk materials. For example, the percentage fat with a minimum limit of 26% is a primary quality measure for milk powders. Compositional proportions, also referred to as mass fractions, are characterized by units of measure such as percentages (by mass), mg/kg, µg/100g and the like, which are, strictly speaking 'dimensionless' numbers (or compositional ratios[2]) lying between 0 and 1.

Compositional fractions can be modelled using the beta distribution. Variables sampling plans based on the normal distribution can only be approximate for compositional proportions and can lead to higher consumer's risks than desired.

Sampling plans for compositional proportions are defined by two parameters, ***m***, the number of samples to be taken from the lot and ***k***, the acceptability constant defined in the same way as for the usual variables sampling plans. In addition to the PRQ, CRQ etc. to design these plans we also need an estimate of the 'precision parameter' for the beta distribution, denoted by ***ϑ***, which can be obtained from the analysis of historical data.

When using these plans, the ***m*** samples are taken from the lot and can be tested individually or combined (and blended, well mixed etc.) to form a composite sample that needs to be tested only once.

The average level ***P*** is taken as either the average of the ***m*** results from the testing of the individual samples or the single result from the testing of the composite sample.

A feature of the beta distribution is that its standard deviation depends on the average level, enabling an assessment to be conducted using a single test of a composite sample taken from the lot. The standard deviation is calculated using the formula:

$$s = \sqrt{P(1-P)/\theta}$$

where ***ϑ*** is the precision parameter for the beta distribution, estimated from historical data (see below).

The lot is accepted against an upper limit ***U*** provided $P + k \times s \leq U$ and similarly for a lower limit.

4.3.6 Plans for the Average in the Lot

In some cases, such as the net weight of packages, a limit is set on the average level, with the intention that the average level in the batch should not be less than the limit. In Codex, although an example of sampling plans for bulk materials, the plans for aflatoxins are also based on compliance of the average level, to ensure that there is a small chance that the average level in a lot exceeds the maximum limit.

It is usually assumed that the quality characteristic is normally distributed; the appropriateness of the distribution is less critical when compliance of the average level is being assessed. It is also usually assumed that there is a single specification limit, either a lower specification limit, ***L*** or an upper specification limit, ***U***.

When the lot standard deviation **σ** is known based on historical process data, the inspection plan for compliance of the average level to a minimum limit ***L*** is operated as follows:

1. Take a random sample of size n and obtain the sample mean
2. Calculate $A = L + k \times \sigma$
3. If the sample mean $\bar{x} > A$ accept the lot; otherwise reject the lot.

The parameters of the plan are ***n*** and ***k***, although the values of ***n*** and ***k*** are not the same as the those in the usual variables plans. When the lot standard deviation **σ** is unknown, it is replaced with the sample standard deviation ***s***. The OC curve for this plan is less discriminatory than the plan when the standard deviation **σ** is known, and a greater sample size will be required to provide equivalent discrimination to that provided when the standard deviation is known.

[2] Note however, that while the fat content can be considered a compositional ratio, it might not be appropriate to use these plans for the protein-solids-non-fat ratio (a provision for milk powders) or other, similar ratios appearing in Codex standards.

4.4 [Sampling of Bulk Materials]

4.4.1 Introduction

Bulk materials are continuous, consisting for example of particles of different densities and sizes. It is impossible to consider a lot of a bulk material as a set of discrete items because there is no way of selecting the items in a way that is not biased when using simple random sampling. This is where a different methodology is introduced, which brings with it sampling bias and non-representativeness. Some general objectives of bulk sampling are:

- Acceptance on a lot-to-lot basis
- Characterise the material as to grade, any need for further processing, and its destination
- Control during processing
- Determination of weight or content for purposes of payment
- Determination of properties that must be known so that the end use will be appropriate
- Experimentation and analysis to determine further sampling procedures and uses of the material.

Sampling units are created at the time of sampling by means of some kind of sampling device. The sampling units change depending on different factors such as how the device is employed, and the conditions that the device is used under.

In bulk sampling, the lots of bulk material are seen as being composed of mutually exclusive segments. Sometimes the segments are obvious, such as when the material comes in boxes or bags.

Other times the segments are not obvious, and so they have to be artificially created. One way of doing this, is by superimposing imaginary grids over the material.

4.4.2 Theory of Sampling (TOS)

The Theory of Sampling[3] (TOS) provides a comprehensive approach to the design of representative sampling, the aim of which is to obtain a sample for laboratory analysis whose composition is an unbiased estimate of the average level of a lot. However, this sample would not, by itself, be useful for assessing conformance of a lot to minimum or maximum specification limits as an additional allowance is required to compensate for variation in the lot to enable such assessments to be made.

4.4.3 **[**Terminology

The special nature of sampling for bulk materials has led to the use of specific terminology, although this terminology varies between different fields, and between authors. Some of the commonly used terms are:]

Term	Meaning
Lot	An identifiable quantity of a food commodity delivered at one time and determined to have common characteristics, such as origin, variety, type of packing, packer, consignor, or markings.
Segment	A portion of the lot to which inference will be made.
Increments	Randomly selected samples that represent the segment and may be used to form a composite sample.
Blending	The mixing or agglomerating of increments to form the composite sample.
Composite sample	A sample formed by blending a certain number of increments from specified segments of the lot.
Sub-sample	A portion of the composite sample that is sent to the laboratory.
Laboratory sample	A portion of the sub-sample that is measured.

4.4.4 Illustration of Terms [reference NMKL]

This diagram, from NMKL Procedure 12, shows how these definitions relate to the different aspects of the overall sampling process, from the sampling of the bulk material to obtaining laboratory samples for testing.

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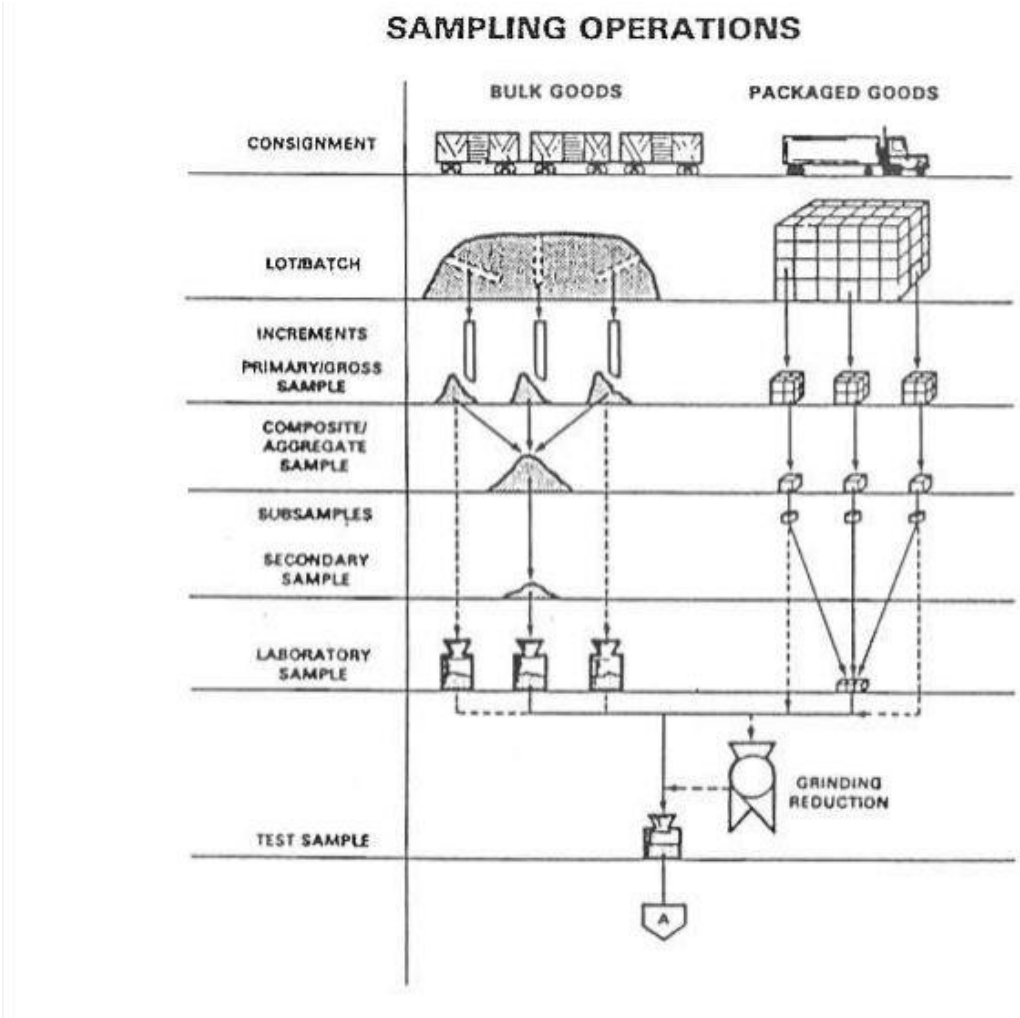
[3] Esbensen, Kim & Wagner, Cooper. (2015). Theory of sampling (TOS) - Fundamental definitions and concepts. 27. 22-25

4.4.4.1 [Figure 5: Sampling and preparation of lab samples]



4.4.5 Design of General Sampling Plans for Bulk Materials

In the simplest case, such as the inspection of bulk materials of manufactured products, lots can often be considered homogeneous allowing the standard attributes or variables plans to be used, with adjustment for measurement error where appropriate.

On the other hand, some bulk materials, such as shipments of grains or other raw materials, cannot be considered homogeneous - the variation of a characteristic within a lot can often not be satisfactorily described by a single distribution. Special techniques are required for this situation, but the statistical methods are complex and only an overview is provided in these Guidelines – see Sections 4.4.6 and 4.4.7.

Lot homogeneity is difficult to verify for bulk materials, generally requiring large numbers of samples, and it is difficult to take proper random samples from an entire lot of a bulk material. As a precaution lots should be treated as inhomogeneous as insurance against such possible heterogeneity.

The general approach to sampling inhomogeneous lots of bulk materials is that a lot is considered as a set of smaller segments (strata) each of which is more homogeneous than the entire lot. This allows the usual sampling procedures based on random sampling to be applied within each segment as heterogeneity within each segment will have less effect. The basic sampling and inspection procedure can be described as follows:

- Segments are chosen at random using simple random sampling
- Several increments are chosen at random from each segment
- The increments from each segment can sometime be combined to form a composite sample, which is thoroughly mixed
- One or more sub-samples are taken from each composite sample
- These sub-samples are tested
- Acceptability of the lot is decided based on a decision rule.

A disadvantage of composite testing is the loss of information on variation compared to individual sample testing or small composite sample testing, e.g. if an individual or multiple segment is the cause of a non-conformance.

4.4.6 Attributes Plans for Bulk Materials

The following points need to be considered in the design of attributes plans for bulk materials:

- Heterogeneity will be present and hence the standard attribute sampling plans for homogeneous lots will not be suitable as they do not provide adequate protection for consumers
- Heterogeneity can be overcome either by allowing for the correlation within the batch in the design of the sampling plan or, alternatively, by splitting the lot into more homogeneous segments, and using stratified sampling techniques. Either way, a preliminary study is needed to estimate the correlation and the variation between segments
- The proposed plans should be validated using different statistical models for the behaviour of the level nonconforming within the lot, to ensure robustness against different levels of correlation
- Measurement error can be allowed for by performing multiple tests on each laboratory sample, with an initial recommendation that each sample should be tested at least three times. Under this scheme a sample would be declared 'conforming' if the majority of results (i.e. at least two out of three test results complying with the limit) passed rather than requiring 'no test samples failing'.
- Lot resubmission and repeat testing should be allowed to guard against measurement system failures that might also include errors incurred by taking primary samples as grab samples.

4.4.7 Variables Plans for Bulk Materials

Typically, the total observed variation within a lot of bulk materials consists of several components due, for example, to variation between and within segments, due to sample preparation (e.g. including sub-sampling), testing and other causes.

Sampling plans for bulk materials, especially cost-optimal sampling plans, can be designed most effectively with prior knowledge of the different components of variation that exist within lots; it is desirable that a preliminary investigation of the variation is carried out prior to the development of any plans.

A minimum of ten (10) lots and ten individual subsamples per segment is needed to estimate the within segment variation to allow design of a sampling plan. Laboratory samples must be tested at least in duplicate to allow estimation of the component of variation due to measurement error, unless estimates are available from other sources such as test method validation.

Example
Codex Standard 193 shows the breakdown of the total variation for aflatoxins in tree-nuts, with a focus on the sample preparation and testing; the variation due to sampling includes both between and within segment variation. It is noted that provisions for aflatoxins are expressed in terms of the average levels in a lot.

Table 1. Variances[a] associated with the aflatoxin test procedure for each treenut

Test procedure	Almonds	Hazelnuts	Pistachios	Shelled Brazil nuts
Sampling[b,c]	$S^2_s = (7\,730/ns)\ 5.759C^{1.561}$	$S^2_s = (10\,000/ns)\ 4.291C^{1.609}$	$S^2_s = 8\,000/ns)\ 7.913C^{1.475}$	$s_s^2 = (1\,850/ns)\ 4.8616C^{1.889}$
Sample Prep[d]	$S^2_{sp} = (100/nss)\ 0.170C^{1.646}$	$S^2_{sp} = (50/nss)\ 0.021C^{1.545}$	$S^2_{sp} = (25/nss)\ 2.334C^{1.522}$	$s_{ss}^2 = (50/nss)\ 0.0306C^{0.632}$
Analytical[e]	$S^2_a = (1/na)\ 0.0484C^{2.0}$	$S^2_a = (1/na)\ 0.0484C^{2.0}$	$S^2_a = (1/na)\ 0.0484C^{2.0}$	experimental $s_a^2 = (1/n)\ 0.0164C^{1.117}$ or FAPAS $s_a^2 = (1/n)\ 0.0484C^{2.0}$
Total variance	$S^2_s + S^2_{sp} + S^2_a$	$S^2_s + S^2_{sp} + S^2_a$	$S^2_s + S^2_{sp} + S^2_a$	$S^2_s + S^2_{sp} + S^2_a$

A sampling plan is defined in terms of the numbers 'ns', the number of samples, 'nss', the number of subsamples taken from each sample and 'na', the number of analytical samples taken from each subsample. The information in this table can be used to design an optimal sampling plan, optimal in terms of total cost for a specified consumer's risk at any given concentration 'C'. Obviously, the costs associated with each step need to be known to derive a cost optimal plan.

Any sampling plan derived from the design process should be validated against a range of statistical models for the behaviour of the characteristic within the lot.

Since bulk materials are continuous, parts of each sample can be mixed together to form a composite. This composite is then tested only once, rather than having to perform many tests on the individual samples. This is a physical way of creating a composite sample representing the average content of lot or segment. This averaging causes a reduction in the apparent variation meaning that adjustment of the decision rule may be required for assessments against minimum or maximum limits.

Note however, that the use of composite sampling adds complexity to the design of a general sampling strategy due to the statistical complexity of modelling the mixing process; assuming that composites made up from many individual portions can be thoroughly mixed is unrealistic.

4.4.8 Variables Plans for the Average Level

Many sampling plans for bulk materials are used to assess compliance of the average level of a characteristic, as in the sampling plans for aflatoxins. Other procedures for the inspection of the average level of a lot are available that consider costs to derive plans that are economical to apply, although these plans might not be suitable in cases where more precise determination of the average level is required.

Plans for the average level might also be applicable where product is homogenized through blending or further processing.

4.4.9 Variables Plans for Percentage Nonconforming (Minimum or Maximum limits)

The strategy is similar to the design of variables plans for the average level except that an additional allowance must be made for variation within the lot, obtainable from the statistical analysis described above. A simpler approach is to estimate within lot variation as the variation among the segments by taking one sample from each segment and testing those samples in duplicate to allow adjustment for measurement error, although this will not provide any information on other components of variation:

- The decision rule has the same form as a conventional inspection by variables plan applied to homogeneous lots
- The number of samples ***n*** and the acceptability constant ***k*** can be found by a trial and error process, assessing the probabilities of acceptance against various alternative models for the behaviour of the characteristic in the lot. This exercise should recognises that the formation of the segments might not reflect the disposition of nonconforming product within the lot.

5 Inspection and Measurement Errors

5.1.1 Introduction

Measurement error refers to the difference between a measured value and the true value of what is being measured (the measurand). On the other hand, **inspection error** refers to random errors of misclassifying conforming items as nonconforming and vice versa. The term 'measurement error' relates to variables data (measurements) whereas 'inspection error' relates to attributes data.

Significant measurement and inspection errors have the potential to affect the probabilities of acceptance of a sampling plan. It has been shown that measurement and inspection errors affect producer's risk more than they affect consumer's risk i.e. the increase in producer's risk, of incorrectly rejecting product of good quality, exceeds the increase in consumer's risk, of accepting product of poor quality. On this basis it might be unfair not to allow for measurement error in sampling inspection.

Sampling inspection plans can be designed to allow for measurement and random misclassification errors.

Sampling is also cost-optimal in the presence of significant measurement error.

5.1.2 **[**Measurement Uncertainty and Measurement Error

The aim of acceptance sampling inspection is to make good decisions about a lot given when measurement errors are present whereas the purpose of conformity assessment is to say something about the true values of the samples tested, allowing for measurement uncertainty.

The design and evaluation of sampling inspection plans requires that separate allowances are made for biases and random errors as they affect the operating characteristic differently. In addition, the construction of an OC curve demands that random errors are described in terms of the variation about the true values of measurands, i.e. that they are Type A components in measurement uncertainty terms.

In the estimation of 'measurement uncertainty', biases are treated as Type B components, i.e. as the outcomes of random variables following assumed distributions around their observed values, to allow their inclusion in the overall measurement uncertainty. The overall uncertainty might also include other Type B components based on the 'degree of belief' that the possible values of a component follow an assumed distribution.**]**

5.2 Attributes Plans

In the context of attributes plans, 'inspection error' refers to random errors of misclassifying conforming items as nonconforming and vice versa.

Inspection errors occur when testing a unit for conformance and can be caused by human error, instrument error, or any other measurement related errors:

- Type I errors (***e₁***) occur when true conforming units are classified as apparently nonconforming
- Type II errors (***e₂***) are when true nonconforming units are placed as apparently conforming.

When inspection errors are present, they generally cause a greater increase in producer's risk than consumer's risk. For a single sampling plan, Type I errors (e_1) have a greater effect on the OC curve than Type II errors (e_2).

The true fraction nonconforming ***p*** and the observed fraction nonconforming ***pₑ*** are related through the following equation:

$$p_e = e_1(1-p) + (1-e_2)p$$

where

e₁ is the probability of classifying a conforming item as nonconforming and

e₂ is the probability of classifying a nonconforming item as conforming.

The impact of inspection error is particularly marked for zero acceptance number plans.

5.2.1 [Retesting

Retesting can be used to mitigate the impact of inspection errors. It can be used with either attributes or variables plans. If an item is found to be nonconforming, it can be tested again. Since a smaller proportion of nonconforming units is expected, retesting will be required only occasionally. Retesting conforming units is often not beneficial for economic reasons.

In addition, because inspection errors increase producer's risk more than they increase consumer's risks, it is more

important to control Type I errors (conforming items classified as nonconforming). Therefore, it makes more sense to retest only the items that are apparently nonconforming.

Retesting of an item can be done up to a maximum of ***m*** times, with the value of ***m*** to be decided. This means that each sampled item will have a maximum of ***m*** chances to achieve conformance. Retesting relies on the assumption that testing will not degrade the quality of the item. If a sample is of a non-discrete type physical material such as powder, then it is assumed that ***m*** homogeneous sub-samples can be made for every unit of the sample.

If misclassification errors are large, retesting of nonconforming items is necessary to reduce the adverse impact on the producer's risk. Inspection errors do affect the consumer's risks, but the effect is small compared to the effect of producer's risks and it can be compensated for by adjusting the sample size. Such adjustments are likely to be small.]

5.2.2 Known Inspection Errors

If the misclassification errors are known, i.e. if precise estimates of the misclassification errors are available, for example from a method validation study, the estimates of the Type I and Type II errors can be used to design a sampling plan to control producer's and consumer's risks to specified levels. This will inevitably lead to increased sample sizes.

5.3 Variables Plans

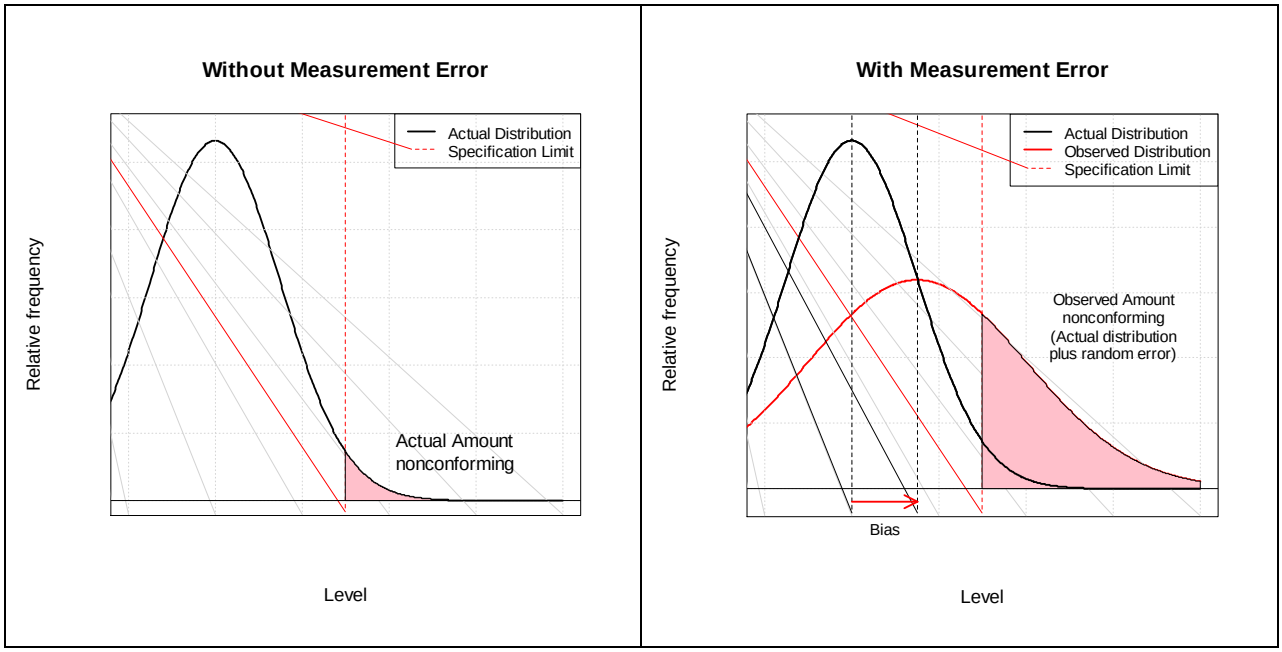
Measurement error is the difference between a measured value and the true value of what is being measured (the 'measurand'). Measurement errors can be either random or systematic.

'Random errors' are uncorrelated, but they affect the results of repeated measurements. Random errors are characterised by measures such as the repeatability, reproducibility, and stability.

'Systematic errors' such as biases affect all measurements in the same way and can be identified when the random errors are small. Systematic errors can be described in terms of accuracy, bias, and drift. In general, adjustment for biases can be made by subtracting the bias from the actual measurements and then applying the variables plan as usual. Any uncertainty arising from the estimation of the bias would need to be allowed for as an additional random error.

The following diagrams show the effect of measurement error on the observed level nonconforming in a lot and unless suitably accounted for, on its probability of acceptance.

5.3.1.1Figure 6: [Effect of Measurement Error



The terms 'significant' and 'negligible' are often used as the basis to decide whether allowances should be made for analytical measurement uncertainty in sampling. 'Significant' means that the measurement uncertainty is large in relation to the sampling uncertainty It is assessed using the 'error-variance' ratio, the ratio of the measurement uncertainty variance[4] to the sampling uncertainty variance. Adjustment for measurement uncertainty is usually deemed necessary if the error-variance ratio exceeds 10%. However, this rule is subjective and the only definitive way to assess whether adjustment for measurement uncertainty is required is to examine the OC curves for the proposed sampling plan in the presence of the measurement uncertainty.**]**

5.3.2 Significant Repeatability Measurement Error (no bias)

If the characteristic follows a normal distribution in the lot under inspection and the measurement error is also normally distributed, a variables plan allowing for repeatability error will have the same acceptability constant (k-value) as the 'error free' plan, but a larger sample size will be required to provide the same control of producer's and consumer's risks. The number of samples depends on the 'erro-variance ratio', described above. However, in other respects these plans are the same as those for error free variables plans, with the acceptance of lots based on decision rules such as $\bar{X} + kS \leq U$ for an upper specification limit ***U*** where, in this case, $\bar{X}$ is the average of the measurements and S is their standard deviation.

5.3.2.1 Hahn's Approach[5]

Hahn suggested a simple method of adjusting data to adjust for the effect of measurement error in the observed data. This involves adjusting the observed standard deviation by 'subtracting' the standard deviation representing the repeatability component of measurement error.

This adjustment is made by subtracting the repeatability variance from the observed variance (the variance is the square of the standard deviation):

$$s_{adj}^2 = s_{obs}^2 - s_r^2$$

where $\boldsymbol{s_{adj}, s_{obs}}$ *and* $\boldsymbol{s_r}$ are the adjusted, observed and repeatability standard deviations respectively. It is possible that the repeatability standard deviation is greater than the observed standard deviation, in which case the adjusted standard deviation is assumed to be zero. In general, the acceptability constant will be smaller for plans based on adjusted standard deviations.

5.3.3 Significant General Measurement Error

In this context, measurement error refers to reproducibility. This situation is dealt with in ISO3951-6. It is assumed that repeatability and reproducibility, as well as the identified characteristic, are normally distributed. While the decision

4 In statistics, the variance is the square of the standard deviation

5 Hahn, G. J. 1982. Removing Measurement Error in Assessing Conformance to Specifications'. Journal of Quality Technology 14: 117–21.

rule is of exactly the same form as the other variables plans, in some circumstances it might not be possible to find a sampling plan (the number of samples ***n*** and the acceptability constant ***k***) that controls producer's and consumer's risk in the manner intended

5.3.4 Fractional Nonconformance

If the characteristic does not follow a normal distribution in the lot [i.e. it is not appropriate to assume that the characteristic follows a normal distribution, refer to Section 3.1.6], plans based on Fractional Nonconformance (FNC) can be used for measurement error adjustment (FNC plans can also be used if the characteristic is normally distributed).

The FNC for a sample can be thought of as the probability that the true value of the sample exceeds the specification limit, allowing for any measurement error present.

A sampling plan based on the FNC adjustment principle is defined by two numbers, ***n***, the number of samples to be taken and ***Ac***, the maximum acceptance limit for acceptance of the lot. These two numbers are determined in the same manner as other types of plan, by considering the allowable risks at the producer's and consumer's quality levels. Additional information on the 'error-variance' ratio is also required for the design of these plans.

A lot is accepted provided the sum of the individual sample FNC values does not exceed the maximum acceptance limit.

$$\sum_{i=1}^{n} FNC_i \leq Ac$$

Where $\boldsymbol{FNC_i}$ is the FNC value for the i^{th} sample (i = 1…n).

The main advantage of FNC inspection plans is that they can be used even when the underlying quality characteristic is not normally distributed, unlike variables plans they do not require the underlying assumptions about the distribution of the characteristic to be met.

The use of FNC adjustment is preferred over approaches based on measurement uncertainty in which samples are classified as conforming or non-conforming using the 'beyond reasonable doubt' principle. This approach will be less economical in terms of sample numbers and might not be optimal in terms of controlling producer's and consumer's risks; Individual samples are classified non-compliant only under a reasonable worst case measurement scenario. As measurement uncertainty has the potential to affect both producer's and consumer's risks it is necessary to consider both measurement and sampling uncertainty in the design of sampling plans.

6 Other Matters Relating to Sampling

6.1 Physical Sampling

Physical sampling, including sample handling, is a significant area in itself.

A single sample taken from the product is a minimum amount to allow the laboratory testing in accordance with the requirements of the test method noting there could be more than one test applied to a single, larger sample.

In some cases, a larger sample might be taken from a lot and one or more sub-samples taken from that sample after it has been thoroughly mixed.

The Theory of Sampling (TOS) (Section 4.4.2) relies on procedures due to Gy[6] that represent best practice for physical sampling from a lot in an unbiased manner. These sampling procedures should be observed with respect to each individual sample taken from a lot, and for any subsequent mixing and sub-sampling etc., noting that usually more than a single sample is required in sampling inspection plans. Reference should be made to product specific ISO or other standards for details of sampling procedures for different commodities. Adherence to specified sampling procedures might be a legislative or regulatory requirement for some commodities in some jurisdictions.

6.1.1 Random Sampling

For lots consisting of discrete items, random sampling means that each item has an equal chance of being selected in the sample. The assumption of random sampling allows the Operating

Characteristic to be calculated; deviating from random sampling might mean that the plan does not control the producer's or consumer's risks as might have been intended. In many cases systematic sampling, taking samples at regularly spaced intervals throughout a lot, will suffice as a substitute for true random sampling.

It is common for lots to be 'layered', individual items might (say) be packed in cartons, there might be several (but the same number) of these smaller cartons packed into a larger carton, and several (but the same number) of the larger

6 P.M. Gy, Sampling of Particulate Material, Theory and Practise, Elsevier, Amsterdam, 1992.

cartons packed on a pallet. Selecting a random sample of size ***n*** items would proceed as follows:

- Select ***n*** pallets from the number of pallets in the lot (the same pallet can be selected more than once)
- Select a random larger carton from the cartons on each side of the selected pallets
- Select a smaller carton from each of the larger cartons that have been selected
- Finally, select an individual item from each of these smaller cartons – these constitute the sample which will be tested or examined.

For bulk materials taking a random sample is more difficult. Many lots of bulk materials can be considered as a collection of segments; stratified random sampling is used in which, in the simplest case, segments are selected at random from the total number of segments, then within each segment that has been chosen a random sample of increments is taken.

This is discussed in more detail in Section 4.4

In principle there is no need for random sampling for well-mixed fluids or bulk products; however random sampling might still be used as a precaution against heterogeneity or for procedural reasons.

6.1.2 Convenience Sampling

Convenience sampling is often referred to as pragmatic sampling.

It involves taking samples and sometimes only a single sample from a part of a population that is nearby and convenient to sample. It is a non-probability sampling and sometimes used in pilot testing.

It is an *ad hoc* method of sampling that is readily available, and often used due to low cost.

There are usually more disadvantages than advantages with convenience sampling. There is a possibility of sampling error and lack of adequate representation of the population, and furthermore, use of convenience sampling might lead to disputes as it is neither a fair nor a valid procedure.

6.2 [ISO Sampling Plans]

6.2.1 Introduction

The two standards ISO 2859 Sampling procedures for inspection by attributes and ISO 3951 Sampling procedures for inspection by variables are the two principal ISO standards dealing with sampling inspection. These standards are based on the following principles and assumptions:

- The plans are applicable to lots consisting of discrete items, so they are not directly applicable to lots consisting of bulk materials, noting that for these applications the lot size is not, for instance, the number of packages in the lot. The sample size is determined according to the lot size
- The standards describe sampling schemes, i.e. sets for sampling plans, for normal, tightened, and reduced inspection, with switching rules based on recent quality history to swap between those inspection levels
- The sampling schemes are designed to specifically control either the producer's risk, or the consumer's risk, but not both
- It is assumed that measurement error is negligible in the construction of most of these schemes although ISO3951 does contain some information relating to adjustment for measurement error.

6.2.2 Lot Size vs Sample Size

[Statistically, the lot size itself does not have an important role in determining protection to consumer and producer whereas changes in sample size do affect on the protection afforded by any plan.

However, despite this, a lot size versus sample size relationship has been built into the design of the sampling plans appearing in the ISO standards. This relationship is arbitrary, and has been changed over time, although it has the general effect of reducing the risks of making incorrect decisions for larger lots, where the costs incurred from incorrect decisions will be greater.

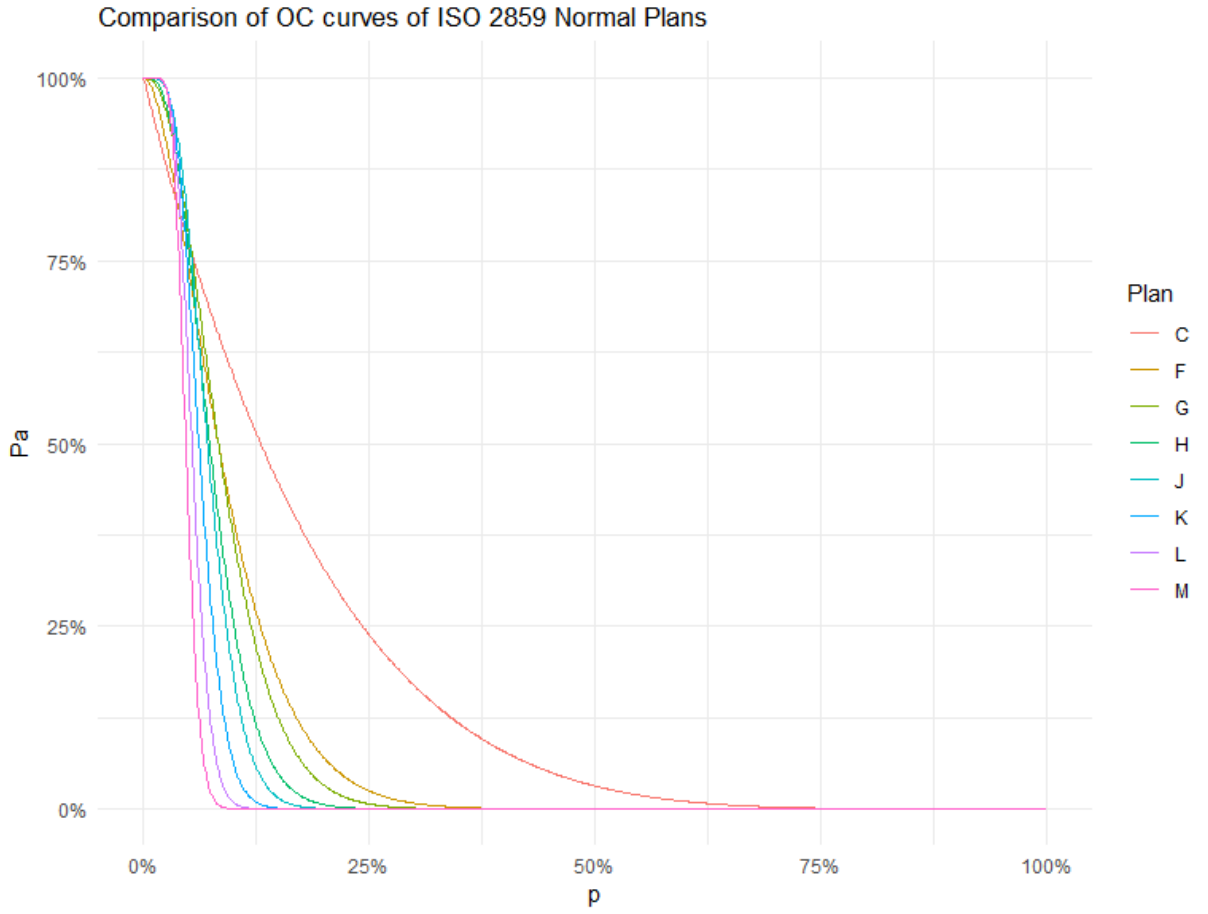
To achieve this, the designers of the ISO plans have chosen not to explicitly control both the producer's or consumer's risks in the design of these plans, plans are based either on control of producer's risk or control of the consumer's risk; sampling plans indexed by PRQ do not fix the consumer's risk at a constant level such as 5% and the consumer's risk will decrease only for large lot sizes.

The following table and graph shows the OC curves of the single sampling plans for normal inspection from ISO 2859, for a PRQ of 2.5% (Level II General Inspection). The consumer's risks differ significantly for these plans and varies

according to the lot size.

Lot size range	Sample Code	(*n* , *c*)	Producer's Risk		Consumer's Risk	
			Level nonconforming (PRQ)	Probability of Rejection	Level nonconforming (CRQ)	Probability of Acceptance
1690	B,C,D,E	(5,0)	2.5%	0.119	36.9%	0.10
91-150	F	(20,1)	2.5%	0.088	18.1%	0.10
151-280	G	(32,2)	2.5%	0.045	15.8%	0.10
281-500	H	(50,3)	2.5%	0.036	12.9%	0.10
501-1200	J	(80,5)	2.5%	0.015	11.3%	0.10
1201-3200	K	(125, 7)	2.5%	0.014	9.2%	0.10
3201-10000	L	(200, 10)	2.5%	0.013	7.6%	0.10
10001-35000	M	(315, 14)	2.5%	0.014	6.3%	0.10

]



As a consequence of employing the sample size versus lot size relationship, ISO has designated that sampling plans indexed by PRQ, explicitly controlling the producer's risk, are intended for the inspection of a continuing series of lots

and plans indexed by CRQ, explicitly controlling consumer's risk, as being suitable for the inspection of isolated lots. However, this distinction is no longer relevant if both types of risk are considered in the design of plans.

6.2.3 Sampling Schemes

ISO standards employ sampling schemes, sets of sampling plans with different levels of inspection to ensure quality is effectively controlled. Sampling schemes also contain switching rules for changing between inspection levels based on recent quality history. Typically, and in ISO standards, switching occurs between normal, tightened, and reduced inspection plans within each sampling scheme.

Sampling schemes provide more comprehensive assurance compared to sampling plans.

Normal inspection is used when the process is considered to be operating at, or slightly better than, the PRQ.

Tightened inspection uses stricter decision rules than those used in normal inspection. The main objective of using tightened inspection is to exert pressure on the producer when the quality is poorer than the PRQ by introducing a higher rate of rejection.

Reduced inspection permits smaller sample sizes than those used in normal inspection. When the level of the submitted quality is sufficiently good, reduced inspection offers sampling economy.

Switching rules are considered too complex to apply in international trade, and from a consumer's point of view in general, although it is possible to design an equivalent [single] sampling plan that controls the producer's and consumer's risks to the same levels as an overall sampling scheme.

6.3 [Reinspection

Sampling inspection plans usually assume that a random sample is taken from the lot. When random sampling of prepackaged commodities from large containers is difficult, physical sampling may be done poorly. Hence it is natural for the producers or consumers to occasionally suspect or dispute the sampling done. The use of sampling plans based on relatively small sample sizes can result in high risks of making incorrect decisions, so reinspection plans should be used in the interests of fairness.

When the original inspection is considered suspect due to sampling or measurement issues, lot reinspection can be carried out, in which the lot is resubmitted for inspection with a new sample taken to make a decision. This process can be repeated; the design of the sampling plan used for each reinspection depends on the number of reinspections allowed.

Reinspection schemes are particularly useful for zero acceptance number sampling plans. It is well known that the zero-acceptance number plans generally involve a higher risks to producers. Hence use of reinspection allows producers to opt for reinspection of a lot when there is good process history to believe that the quality of the lot is indeed good but the lot may have been rejected due to poor sampling or problems with measurement. Variables sampling plans employing small sample sizes and large k values such as $k = 2$ can also be harsh on producers.**]**

6.4 Inhomogeneous Lots

Section 3.1.10 on Lot Homogeneity deals with homogeneity in general, and this section with how to handle isolated heterogeneity should it occur. Section 4.4 discussed issues concerning fundamental heterogeneity of lots in the context of plans for the inspection of bulk materials.

Acceptance inspection often necessitates levels of protection for both the consumer and the producer that require large sample sizes relative to the lot size. A given sample size can, however, apply to several lots jointly if the lots can be shown to be homogeneous. This reduces the economic impact of a necessarily large sample size. If the lots are not homogeneous, then this is unable to occur.

Most sampling plans are based on the assumption that the lots are homogeneous. Use of these plans in the presence of lot heterogeneity will usually increase producer's and consumer's risks, so that consumer protection may be compromised when an inspection lot is not homogeneous.

If a lot is fundamentally inhomogeneous, as in lots consisting of bulk materials, those plans should be used.

Inhomogeneous lots might occur because inspection lots differ from manufacturing lots or for other reasons; one approach may be to split that lot into sublots in line with production lots or other standardised manufacturing processes. Each of the sublots might then be sufficiently homogeneous to be inspected using standard attributes or variables sampling plans, inspecting each sublot with the same plan that would be used for the entire lot, if that lot was homogeneous. However, lots should not be split into sublots on the basis of results obtained from earlier testing.

Appendix V

Rules to select Type II methods from multiple Type III methods

(for comments)

Introduction

It is not uncommon that several analytical methods are proposed for a single commodity – provision combination. However, only one of these can be designated as the reference method (Type II method). The following paragraphs give guidance on the selection of a Type II method from multiple Type III methods.

Codex Methods of Analysis

According to the Procedural Manual, the Codex analytical methods are primarily intended as international methods for the verification of provisions in Codex standards. They should be used for reference, in calibration of methods in use or introduced for routine testing and control purposes.

Purpose of Reference Methods (Type II)

Definition as per the Procedural Manual: 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.

Purpose of Alternative Approved Methods (Type III)

As per description in the Procedural Manual, a Type III method is one which meets the criteria required by the Committee on Methods of Analysis and Sampling for methods and may be used for control, inspection or regulatory purposes.

In the event of multiple Type III methods for the same provision-commodity combination, it is expected that these methods, although they might use different approaches, should result in equivalent decisions (compliant vs. non-compliant).

Current situation

Currently only general guidance (as per the Procedural Manual) is available for the classification of analytical methods as Type II or III. For this reason, we propose to apply the following rules[1]:

Prerequisites for inclusion in Codex standards for Type III chemical or physical Methods

i. The method is validated according to an internationally recognized protocol and the validation data published

ii. The method should fulfil the general method performance criteria in the Procedural Manual

iii. The method is easily accessible, e.g. from SDO websites

iv. Codex (commodity) committees, country delegations or NGO's submitting methods of analysis to CCMAS for consideration need to provide technical information using the template MAS/40 CRD 28 (cf. CCMAS40 CRD05)

v. The validation covers the analytical range for the provision (e.g. MRL).

Additional considerations in cases where results from several Type III methods for the same commodity-provision combination are compared and the Criteria Approach is not an option:

i. All methods should measure the same analyte (specific chemical entity to be determined), especially if the methods contain differing analysis steps or sample preparation (e.g. Vitamin B6 with or without enzymatic digestion). If available, the assumption can be confirmed by an equivalence study.

ii. The methods are preferably validated on the same matrices. In absence of methods covering the commodity of the provision, a potential suitable method validated on matrices of similar composition (in terms of fat, protein and carbohydrate content) can be considered.

iii. Check availability of results of proficiency tests[2] in order to detect systematic differences between methods.

[1] In some situations, CCMAS may decide not to apply these selection rules, e.g. for ethical, economic or safety reasons. This decision must be duly justified.

[2] e.g. NIST https://nvlpubs.nist.gov/nistpubs/ir/2019/NIST.IR.8266.pdf

Decision rules for choosing the best method (=Type II) among multiple Type III methods[3]

i. As the scope of methods of analysis include various groups of commodities (Codex Procedural Manual, *General Criteria for the Selection of Methods of Analysis*), the method explicitly validated for the commodity stated in the Codex provision should be preferred: e.g. if a method for copper in infant formula is required, a method specifically validated for this commodity should be preferred to a method validated for milk powder.

ii. The method validated for the larger panel[4] of matrices should be preferred. For example. a method validated for milk-based and soy protein-based infant formulae should be preferred to a method validated only for milk-based infant formula.

iii. The method with the best selectivity should be preferred.

iv. The method with the best precision data (if this precision difference is relevant to the question asked) should be preferred.

v. The method where a certified reference material, preferably from a matrix similar to that used in the scope of the method, was included in the validation should be preferred.

[3] The decision rules should be considered in the order presented.

[4] Larger panel means different types of one matrix. For example, infant formula includes milk-based, soy-based, hydrolyzed protein based.