CODEX ALIMENTARIUS COMMISSION



Food and Agriculture Organization of the United Nations



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Agenda Item 7
CX/MAS 21/41/9 Add.1

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

REVISION OF THE GENERAL GUIDELINES ON SAMPLING (CXG 50 – 2004)

Comments at in reply to CL 2021/10/OCS-MAS

Comments of Australia, Canada, Cuba, Egypt, Iran, Iraq, Japan, Morocco, Paraguay, Peru, Philippines, Thailand, United Arab Emirates, United Kingdom, EURACHEM and IAEA,

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2021/10/OCS-MAS issued in March 2021. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the appendix

2. The comments submitted through the OCS are hereby attached as <u>Annex I</u> and are presented in table format.

ANNEX I

| GENERAL COMMENTS | | | | |
|--|----------------|--|--|--|
| Agree with proposed. | Iraq | | | |
| Clearly explained logic and terminology; Good theoretical and practical underpinning; Flexibility to deal with a range of scenarios; Explicit recognition of the needs of different key players: especially "producer" and "consumer" needs. Clear and accurate graphs and statistics; Useful pointers towards R apps to help implement the methods (although I did not explore these); One idea I particularly liked was that of "average noncompliance rates" (page 12). These are a pragmatic way to get things right overall (in the medium to longer term) while reducing sampling costs and aggravation from having to make separate decisions about each and every lot. This idea would not always be relevant, but where it is, it could be an enlightened approach. | United Kingdom | | | |
| The Philippines expresses appreciation for the work done by the eWG chaired by New Zealand and co-chaired by United States of America in revising the General Guidelines on Sampling The Philippines supports the revised CXG 50 package (the revised CXG 50 and its supporting documents) The Philippines agrees to advance the proposed draft revised CXG 50 (Appendix I) to Step 5. The Philippines agrees to re-establish the EWG to finalize CXG 50 and to further develop the documents in support of CXG 50 taking into account the comments received to CL2021/10-MAS with intention that they are part of the CXG 50 package Rationale : The revised guidelines will have a provision of a wider range of sampling plan options that enables different types of | Philippines | | | |
| sampling plans to be designed and evaluated, providing a wider consideration of cost and fairness as well as sampling, testing and a decision on acceptance or rejection of the food commodity. The revised guidelines is also much simpler and useful appended sections. | | | | |
| The Measurement Uncertainty (MU) arising from primary sampling (UfS) is excluded from the estimation of MU (e.g. 5.3.1.1). This is despite the fact that it has been quantified (as variance) in for four examples of aflatoxins in tree nuts given on Page 22 of this very document. Proposed change: Include UfS in the estimates of MU, or explain why it has been excluded. | EURACHEM | | | |
| Eurachem acknowledges that some of its comment raised on the previous version (20/41/9), have been addressed, but others comments require further revision (e.g. 5.1.2, see below). | | | | |
| Japan appreciates the efforts of EWG chaired by New Zealand and the United States of America preparing the draft revised Guidelines on Sampling. Since we understand that it is very important to consider the various option in developing a sampling plan, the proposed e-book including sampling Apps, as a separate information document, will be very helpful. We are of the view that the e-book should emphasize the importance to take into account sampling plans previously endorsed by CCMAS when Codex commodity committees and member countries would design a sampling plan. | Japan | | | |

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| Japan would like to recall that it was agreed that "the revised CXG 50 would provide guidance to developing / choosing appropriate sampling plans for use by all CAC subsidiary bodies, Codex members and other relevant stakeholders" (para. 71 of REP19/MAS), and "the aim of the revision is to provide a simpler more understandable guidance." (Appendix V, REP18/MAS). Considering above, there is still concern whether the draft is a simplified and understandable guidance. Japan suggests that, before starting further detailed discussion about contents of the draft revised CXG 50, CCMAS should ask commodity committees about framework of the draft revised CXG 50 and the sufficiency of the work from the viewpoint of understandability and user-friendliness. It should be noted that sampling plans in several standards, which had previously endorsed by the Committee, could require revision as a result of the revision of CXG 50 as noted in paragraph 69 of REP 18/MAS. It is therefore necessary to evaluate the impact of revision to standards. The draft includes statistical procedure that was not addressed in the current guidelines. We are of the view that the statistical procedure should be reviewed by experts, e.g. FAO/WHO expert consultation or expert panel, to ensure that it is valid for the Codex purposes. Regarding sampling Apps in the e-book, they should be debugged and validated. Since there are still a lot of points to be discussed as mentioned above, the draft should go back to Step 2 for further consideration by an EWG. | |
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| We also have comments on the e-book (Codex Sampling - Appendix III) as follows: | Thailand |
| Regarding Applications (Apps) recommended in e-book: 1) Footnotes describing links or URLs of the applications should be added for verification. 2) Codex standards cover various commodities including an agricultural commodity which has a wide variety and high variation, our observation is whether the proposed sampling plan tools are validated to prove that they are appropriate for designing sampling plans for the commodities | |
| We would like to express our appreciation to effort of the EWG (led by New Zealand and co-chaired by the United States of America) for the preparation of Proposed Draft Revised General Guidelines on Sampling (CXG 50-2004) (Appendix I). General comment: 1. The current CXG 50 should be the basis for the revision. The revised CXG 50 should be clear, simpler for understanding and practical. To avoid confusion, redundant description and information should not be added to the revised document. The structure of the draft revised CXG 50 should be based on the US proposal: "US proposed CXG50 revision Top-level Outline" (Appendix III, CX/MAS 20/41/9) that mostly follows the format of the current CXG50. It appears that our comments and several member countries recommend that the current CXG 50 should be the basis for the revision considering the outline proposed by USA which is entirely different from the Proposed Draft Revised Guidelines (Appendix I) prepared by EWG. It is needed that this crucial matter should be further discussed to reach an agreed approach for the revision and subsequently the draft revised CXG 50 will be finalized for requesting comments from member countries. | Thailand |

| 3. We support to re-establish the EWG to further discuss and develop the Proposed Draft Revised General Guidelines on Sampling (CXG50-2004) considering the US proposed CXG50 revision Top-level Outline. | |
|---|-------------------------|
| Morocco has no objection concerning the General Guidelines on Sampling. However we consider that the sampling plans should be further simplified with their terminologies used for different contaminants for easy implementation by various users, and we also consider that certain values / quantities should be indicated as a percentage. | Могоссо |
| Australia would like to thank New Zealand and the USA for their continued efforts and further development of the Proposed Draft Revised General Guidelines on Sampling (CXG 50) as provided in CX/MS 21/41/9. | Australia |
| Peru thanks the Electronic Working Group led by New Zealand for the effort undertaken in the revision of CXG 50-2004 and the drafting of the distributed Draft Revised Guidelines, which gives us the opportunity to present the following comments. | Peru |
| Peru, in response to circular letter CL 2020/27/OCS-MAS, presented comments on the orientation that the Draft Revised Guidelines should have, being in favor of including a support guide for the selection and design of sampling plans, recommending improving the layout/structure of the Draft to assist commodity committees, as well as regulatory bodies in Codex member countries and other users, to understand the principles of sampling, and that the Draft provides practical examples that could be added in each chapter of the document or in an annex to it; among other specific comments on key technical areas identified by New Zealand and the United States. | |
| In this sense, Peru is in favor of the information and guidance presented in the Draft Revised General Guidelines on Sampling (CXG 50-2004), and that the supporting documents continue to be developed (Guide for the selection and design | |
| of sampling plans and an information Document: e-book) with the intention of being part of the CXG 50 packages. | |
| of sampling plans and an Information Document: e-book) with the intention of being part of the CXG 50 packages. Likewise, we are in favor of the Draft Guidelines being moved forward to the next step. | |
| of sampling plans and an Information Document: e-book) with the intention of being part of the CXG 50 packages. Likewise, we are in favor of the Draft Guidelines being moved forward to the next step. Support for presenting the revised Guidelines as part of a package, i.e. the revised proposed draft Guidelines, and the documents: the guide to the selection and design of sampling plans and the e-book | ne 2 supporting |
| of sampling plans and an Information Document: e-book) with the intention of being part of the CXG 50 packages. Likewise, we are in favor of the Draft Guidelines being moved forward to the next step. Support for presenting the revised Guidelines as part of a package, i.e. the revised proposed draft Guidelines, and the documents: the guide to the selection and design of sampling plans and the e-book Cuba thanks the EWG created for the revision of document CXG-50, all the participating countries and especially the two countries that chaired (New Zealand) and co-chaired (USA) the GTE. A very complete document has been prepared that constitutes a very useful working tool for specialists working on the subject of sampling. The document is an excellent starting point in CCMAS's intention to update these guidelines. | ne 2 supporting Cuba |
| of sampling plans and an Information Document: e-book) with the intention of being part of the CXG 50 packages. Likewise, we are in favor of the Draft Guidelines being moved forward to the next step. Support for presenting the revised Guidelines as part of a package, i.e. the revised proposed draft Guidelines, and th documents: the guide to the selection and design of sampling plans and the e-book Cuba thanks the EWG created for the revision of document CXG-50, all the participating countries and especially the two countries that chaired (New Zealand) and co-chaired (USA) the GTE. A very complete document has been prepared that constitutes a very useful working tool for specialists working on the subject of sampling. The document is an excellent starting point in CCMAS's intention to update these guidelines. Appendix III, the e-book, in its final version, must be edited and must accompany the Guidelines, since the additional information, applications and evaluation of sampling plans that it provides constitute a very useful complement for users of this document. | ne 2 supporting Cuba |
| of sampling plans and an Information Document: e-book) with the intention of being part of the CXG 50 packages. Likewise, we are in favor of the Draft Guidelines being moved forward to the next step. Support for presenting the revised Guidelines as part of a package, i.e. the revised proposed draft Guidelines, and the documents: the guide to the selection and design of sampling plans and the e-book Cuba thanks the EWG created for the revision of document CXG-50, all the participating countries and especially the two countries that chaired (New Zealand) and co-chaired (USA) the GTE. A very complete document has been prepared that constitutes a very useful working tool for specialists working on the subject of sampling. The document is an excellent starting point in CCMAS's intention to update these guidelines. Appendix III, the e-book, in its final version, must be edited and must accompany the Guidelines, since the additional information, applications and evaluation of sampling plans that it provides constitute a very useful complement for users of this document. It is very significant, and at the same time positive, that users, when using the sampling plan applications included in the e-book, do not necessarily have to understand the statistical theory underlying the sampling tools, although, of course, they do need to understand the key concepts of it. It is a new contribution that will be used as reference material not only by the CODEX commodity committees, but also by the different countries. | ne 2 supporting Cuba |

| In the text there are still some images that have not yet been translated into Spanish, which must be translated in the Spanish version of the document | |
|--|-------------|
| Australia supports the | Australia |
| revised CXG 50 package (the revised CXG 50 and its supporting documents) advancement of the proposed draft revised CXG 50 (Appendix I) to Step 5. re-establish the EWG to finalize CXG50 and to further develop the documents in support of CXG50 taking into account comments received to CL2021/10-MAS with intention that they are part of the CXG 50 package. | |
| Australia supports the, 1. revised CXG 50 package (the revised CXG 50 and its supporting documents) 2. advancement of the proposed draft revised CXG 50 (Appendix I) to Step 5. 3. re-establish the EWG to finalize CXG50 and to further develop the documents in support of CXG50 taking into account comments received to CL2021/10-MAS with intention that they are part of the CXG 50 package. Noting that we have itemized some minor amendments and comments in the 'Specific comments' section below which would help the packages progression. | |
| Egypt supports presenting the revised Guidelines as part of the above mentioned package with no added comments. | Egypt |
| General comments are requested on the readiness of the proposed draft revised General Guidelines on Sampling (C (Appendix I of CX/MAS 21/4/9) to be advanced to Step 5 | XG 50-2004) |
| Australia is of the view that the proposed draft revised General Guidelines on Sampling (CXG 50-2004) (Appendix I of CX/MAS 21/4/9) is ready to be advanced to Step 5. However, in considering this standard further, Australia would seek clarification on the implications of this guidance on the continued support by | Australia |
| CCMAS for Sampling plans from the Codex STAN 233 'Codex Sampling Plans for Prepackages Foods (AQL 6.5)', which was replaced by the General Guidelines on Sampling - GXG 50-2004 (see ALINORM 05/28/35 para.7). As while STAN 233 wasn't explicitly in conflict with the principles outlined in the revised CXG 50, it does conflict with the details in ISO 2859.1 Sampling procedures for inspection by attributes and continues to cause confusion, as the STAN 233 gives different: | |
| definitions for Inspection levels I & II Lot size to sample size ratios, so the Samples Size Code Letters are shifted to 2-3 letter lower in the alphabet The tabulated sample sizes, are similar but different for the AQL=6.5 Acceptance /rejections values. | |
| This confusion is likely to continue without a clear statement by CCMAS on the continued or discontinued use of the Codex STAN 233 sampling plans as the: | |
| revised CXG 50 Section 6.2 ISO Sampling Plans refers to ISO 2859 series Sampling procedures for inspection by attributes cites an example in section 6.2.2. of the lot size versus sample size relationship used in ISO 2859.1 and also | |

| Egypt supports to develop proposed draft of General Guidelines on sampling (CXG 50-2004) (Appendix I of CX/MAS 21/4/9) to be advanced to Step 5. | Egypt |
|--|----------|
| SPECIFIC COMMENT | 1 |
| Preamble | |
| Considering the current CXG 50 (section 1: Purpose of Codex Guidelines on Sampling), additional sub-sections should be inserted to this section to provide clear description of the purpose of guidelines, target audience and users of sampling plans. | Thailand |
| Foods are frequently sampled, throughout the supply chain from producers to consumers, for the purposes of checking their quality. 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. | IAEA |
| Recommend that the working "safety and quality" is used instead of "quality" through out the document | |
| Scope | |
| To be clear and avoid confusion, we recommended that "applicable in any situation" should be replaced with "where applicable". | Thailand |
| In Section 2, these Guidelines define general notions on food sampling, applicable in any situation 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. | Thailand |
| Most of the material in these Guidelines relates to homogenous lots. The following situations are covered: | EURACHEM |
| This statement needs revision as any food consignment/lot, etc. has a certain degree of inhomogeneity (i.e. heterogeneity). Proposed change: "Most of the material in these Guidelines relates to lots assumed to be homogenous" | |
| Adjustment for measurement error in cases where it is not negligible compared to sampling error. | Thailand |
| To comply with the scope of the current CXG50 that does not cover the control of non-homogeneous lots and homogeneous lots where measurement error is not negligible, we recommend that bullet 3 and the last sentence of this paragraph should be removed. | |
| Some general information is provided on sampling for inhomogeneous lots. | Thailand |
| Please see our comment above on the proposed deletion of the last sentence of this paragraph. | |
| Definitions | |
| For the terms commonly used in these Guidelines, the following definitions are in addition to those in <i>Guidelines on Analytical Terminology</i> (CXG 72-2009). | Iran |
| Decision rule need to be defined in definition clause as it is referred to in the text. | |

| "Measurement uncertainty and measurement error" need to be defined in definition clause as they are referred to in the text. | |
|---|-----------|
| Type I and type II error" need to be defined in definition clause as they are referred to in the text | |
| 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. | EURACHEM |
| Current meaning is unclear and misleading. Proposed change: means there is only 5% chance of acceptance for a non-compliant lot' | |
| Confidence | |
| 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. | Iran |
| The sentence:" there is 5% chance of acceptance" should alter to ":there is 5% chance of false acceptance | |
| However, confidence does not work well with producer's risk. | Iran |
| The sentence: "However, confidence does not work well with producer's risk" Need to be clarified | |
| Consumer and Producer | |
| The 'Information Note' under definition of 'Consumer and Producer' repeats the 'Confidence' definition text. We suggest the 'Information Note' is deleted. | Australia |
| 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. | lran " |
| should alter to:" there is only 5% chance of false acceptance" | |
| Acceptance Sampling Inspection by Variables | |
| 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 acceptance criterion 'average result + \mathbf{k} * the standard deviation of results' does not exceed the upper limit, and similarly for a lower limit. In other words, the acceptance criterion is based on the average value $\mathbf{x}_{\mathbf{a}}$ and the standard deviation of the results from the testing. | Canada |
| Average should have the - above the X | |
| Lot | |
| Definite part of a population (constituted under essentially the same conditions as the population with respect to the sampling purpose).a | Iran |
| An information box is recommended to be added in order to clarify the term "same conditions". Use of sublot could also be added. | |
| Approach to sampling | |

| requires a minor editorial change "In the context of sampling, risk occurs when incorrect decisions are made about the | Australia |
|--|-----------|
| status os of the product. | |

| Design of Sampling Plans Inputs to sampling plans | |
|---|-----------|
| 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) | Iran |
| The sentence "Producer's Risk (PR) – the chance of rejection at the PRQ level" should alter to ""Producer's Risk (PR) – the chance of false rejection at the PRQ level | |
| Consumer's Risk (CR) – the chance of acceptance at the CRQ level (e.g. 10% chance of acceptance at a CRQ of 5% nonconforming. | Iran |
| The sentence "Consumer's Risk (CR) – the chance of acceptance at the CRQ level" should alter to ""Consumer's Risk (CR) – the chance of false acceptance at the CRQ level" | |
| Figure 1: Operating Characteristic Curve | |
| Editorial / Technical: The apps use LQL instead of CRQ and AQL is used in place of PRQ. These acronyms should be made consistent with those used in this document | Canada |
| Stringency | |
| replace the word 'below' with 'above' as the position of the Stringency table in the document seems to have moved, i.e. 'Each characteristic would be ranked according to the rating scale below above and then the levels of allowable risk and associated levels nonconforming would be assigned.' | Australia |
| Measurement and Inspection Errors | |
| 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 distributed. | EURACHEM |
| Log-normal distributions are common in mycotoxin contamination of foods (e.g. aflatoxins) such as in Table 1 on page 22 of this document. | |
| Let Hemographic | |
| | |
| the proximity of results (or potential result distribution), i.e. 'Hence it follows that in sampling inspection homogeneity must consider the proximity of results (or potential result distribution) to the specification limits. | Australia |
| Sampling Plans | Γ |
| The revised draft CXG50 should include only homogeneous lots, excluding inhomogeneous lots, so we recommend that: (1) Table 1: References to the selection of sampling plans in these Guidelines Information regarding inhomogeneous lots should be removed from the table. (2) The explanation related to inhomogeneous lots should be removed from this section or relocated to e-book to be additional information for users. | Thailand |
| Sampling Plans Selection of Sampling Plans | |

| Table 1: References to the selection of sampling plans in these Guidelines | | | | | | | | |
|--|---|---------------|--------------------------|-----------------------------|--|-------------|--|--|
| 5. Section 4 | 4.1.1.1 Table | 1: reference | to the selection of sa | mpling plans in these gu | uidelines - a number of the references | Australia | | |
| need to be updated with this latest revision. The ones I could identify for updating are provided below in blue. This should | | | | | | | | |
| also he refle | also be reflected in e-book 1.1. Peterence table | | | | | | | |
| | | | | | | | | |
| [| | Homog | eneous lots | | | | | |
| Data Type | Nature of | Distribution | Negligible | Significant | | | | |
| | Provision | | Measurement Error | Measurement Error | | | | |
| | Minimum or | Not | Inspection by Attributes | + | | | | |
| Attributes | Maximum | applicable | Plans | Retesting | | | | |
| | | | (Section 4.2) | (Section 5.2.1) | | | | |
| | | | | Known Inspection | | | | |
| | | | | Errors | | | | |
| | | | | (Section 5.2.2) | | | | |
| Variables | Minimum or | Normal | Inspection by Variables | | | | | |
| | Maximum | | Plans | Repeatability Error (1) | _ | | | |
| | | | (Section 4.2 4.3) | (Section 5.3.1) | _ | | | |
| | | | | (1) | | | | |
| | | | + | ISO 3951-6 | - | | | |
| | | | | Fractional | - | | | |
| | | | | Nonconformance Plans | | | | |
| | | | | (Section 5.3.2 5.3.4) | | | | |
| | Minimum or | Non-normal | Classification to | Fractional | | | | |
| | Maximum | | Attributes | Nonconformance Plans | - | | | |
| | | Composition | (Section 4.2.6) | (Section 3.3.4) | - | | | |
| | Minimum or | al | Plans for Compositional | | | | | |
| Variables | Maximum | Proportions | Proportions | Not included | | | | |
| | | | (Section 4.3.1 4.3.4) | | | | | |
| | Average | Not | | | | | | |
| | Level | applicable | Plans for Average Level | | _ | | | |
| | | Inhomonoo | (Section 4.3.2 4.3.3) | _ | - | | | |
| Attributes | Minimum or | (blank) | IS LOIS (BUIK Materials) | | - | | | |
| Aunouces | Maximum | (biank) | Attribute | es Plans | | | | |
| | | | (Section | n 4.4.3) | 7 | | | |
| Variables | Minimum or Maximum | (blank) | Variable | es Plans | 1 | | | |
| | | | (Section | n 4.4.4) | - | | | |
| | Average | Not | Plans for / | Average Level | 1 | | | |
| | Level | applicable | (Sect | ion 4.4.5) | | | | |
| 4.2.1.1 Figu | ure 3: Desig | n of Attribut | e Plans | | | | | |
| Attribute pla | an and descr | iption is men | tioned as variables pla | ans | | United Arab | | |
| | | | | | Emirates | | | |
| the figure 3 | the figure 3 appears to be a replicate of 4.3.2.1 Figure 4 for Variable Plans, thus needs to be replaced or be removed. | | | | | Australia | | |
| 2 | | | <u> </u> | · | | | | |

| 4.3.4 Sampling Plans for Compositional Proportions(measurement error negligible) | | | | | | |
|--|----------------------|--|--|--|--|--|
| replace "strictly speaking 'dimensionless' numbers lying between 0 and 1." with "strictly speaking 'dimensionless' numbers (or ratios) lying between 0 and 1." | | | | | | |
| 4.4.2 Theory of Sampling (TOS) | | | | | | |
| TOS reference is not mentioned in references section | United Arab Emirates | | | | | |
| 4.4.4 Illustration of Terms [reference NMKL] | | | | | | |
| Figure should be numbered | United Arab Emirates | | | | | |
| 4.4.7 Variables Plans for Bulk Materials | | | | | | |
| Suggest adding a sentence at end of last paragraph. A disadvantage of large sample composite testing is the information lost 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. | Australia | | | | | |
| Example Codex Standard 193 | -1 | | | | | |
| Table 1 (on p 22) gives estimates of what amounts to measurement uncertainty (MU, but expressed as variance) arising from three of its components (i.e. primary sampling, sample prep and chemical analysis. The sampling component is clearly dominant in most cases. Proposed change: Include the other components of measurement uncertainty (mainly called measurement error in this document), rather than restricting consideration to just the analytical source. If not, explain why this decision has been made. | EURACHEM | | | | | |
| 5. Inspection and Measurement Errors | | | | | | |
| The description and information in this section should be replaced by Section 2.4 Estimation errors of the current CXG50 which provide clear description and can be used as guidance for the consideration of measurement error. The description and information in this section of the current draft guideline should be relocated to e-book to be additional information for users. | Thailand | | | | | |
| 5.1.2 Measurement Uncertainty and Measurement Error | | | | | | |
| The term 'measurement error', defined as 'error' in the <i>Guidelines on Analytical Terminology</i> (CXG 72-009) as 'Measured quantity value minus a reference quantity value', is more conceptual, and reflects the effect of both bias and random errors. On the other hand, while also used conceptually, 'measurement uncertainty' refers specifically to a parameter characterizing the dispersion of values attributed to the measurand. | EURACHEM | | | | | |
| You have not explained clearly that ME refers to a difference between an individual measurement value and the 'true' (or reference) value, but the MU is (informally) the range of values within which the value of the measurand (~ true value) lies. Proposed change: Improve explanation of difference between the terms Measurement Uncertainty (MU) and Measurement Error (ME). | | | | | | |
| 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. | EURACHEM | | | | | |

| However, conformity assessment can equally focus on decisions about a lot, and not just on the samples that were taken. Proposed change: Revise the wording to make clear that conformity assessment is also applied to decisions about a lot, and not just on the samples that were taken (with the objective of representing that lot). (Ellison SLR and Williams A, EURACHEM /CITAC Guide: Use of uncertainty information in compliance assessment, First edition 2007 https://www.eurachem.org/ | |
|--|-----------|
| 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. | Canada |
| if we are discussing bias, we should call it "expected" outcomes | |
| 5.2.1 Retesting | |
| Australia believes that this section requires additional explanation: a. The statement that inspection errors increase producer's risk more than they increase consumer's risk – is based on an underlying assumption that the producer has a higher probability of producing a conforming product. b. Based on this assumption of inspection errors increase producer's risk more than they increase consumer's risks, it is stated that its more important to control Type I errors (conforming items classified as nonconforming). Then extends the assumption to state that, "therefore, it makes more sense to retest only the items that are apparently nonconforming". This appear to be contrary to the concept of Fairness and could lead to 'bias'. c. In accordance with CAC/GL 70-2009 'Guidelines for Settling Disputes on Analytical (Test) Results' the analysis of reserve sample(s) could be considered as 'retesting' and we suggest this should be explained in this section of the revised proposed draft Guidelines. Further, if other 'retesting' is to be allowed further explanation is required on how many tests are required before the initial test is considered an 'outlier' or how large the 'maximum of m' of retests can be. The current guidance for retesting could be interpreted as 'Testing into compliance' without clear and justified decision processes. | Australia |
| Figure 5: Effect of Measurement Error | |
| For clarity it should be explained that in the diagram under 'With Measurement Error' is actually exhibiting both 'Random error(s)' and 'Systematic error(s)'. To remedy for this an amended figure is provided below. | Australia |



| 6.2 ISO S | Sampling | Plans | | | | | | |
|--|---|---|---|--|--|--|---|----------------------|
| 481 (1 | SO 2859) | is not m | entioned in refe | rences sec | tion | | | United Arab Emirates |
| 6.2.2 Lot | Size vs S | ample S | ize | | | | | |
| The follow PRQ of 2. the lot siz TABLE AI | ving table .5% (Leve e. ND FIGUF | and grap I II Gener RE should | h shows the OC al Inspection). d be numbered | Curves of t The consur | the single samp ner's risks diffe | pling plans fo er significantl | or normal inspection from ISO 2859, for a ly for these plans and varies according to | United Arab Emirates |
| to be cons first row, t sampling and Samp | sistent wit to have the plan of the ple Code) | h ISO 289 e first inso e existing with the s | 59.1 Table 1 an erted row to cor Sample C row sampling plan o | d Table 2-A respond (in and the sec f the existin | , two additiona all respects ex cond inserted ro g Sample Code | al rows shoul cept Lot size ow to corresp e F row. | d be inserted for 'Lot size range' after the e range and Sample Code) with the pond (in all respects except Lot size range | Australia |
| Lot size range | Sample Code | (n , c) | Level nonconforming (PRQ) | Probability of Rejection | Level nonconforming (CRQ) | Probability of Acceptance | | |
| 26 - 50 | D | (5,0) | 2.5% | 0.119 | 36.9% | 0.10 | | |
| 51 - 90 | Е | (20,1) | 2.5% | 0.088 | 18.1% | 0.10 | | |
| <u> </u> | 1 | 1 | 4 | I | 4 | 1 | - | |
| 6.4 Inhon | nogeneou | is Lots | | | | | | |
| First sente and this s | ence refer ection wit | ence sho h how to | uld be amende handle isolated | d - Section heterogene | 3.1.8 3.1.10 on | Lot Homogecur. | eneity deals with homogeneity in general, | Australia |
| | | | e-book | (Codex Sa | mpling) for Ge | eneral Guide | elines on Sampling (CXG 50-2004) | |
| Acceptar | nce Samp | ling Insp | ection by Vari | ables | | | | |
| An inspect accepted does not of average v | ction by va against ar exceed the value x ar e above X | riables sa n upper s e upper li nd the sta | ampling plan sp pecification limi mit, and similar ndard deviatior | ecifies the r t if the acce ly for a lowe of the resu | number of samp ptance criterior ar limit. In othe llts from the tes | ples (n) and n 'average re r words, the sting. | an acceptability constant (\mathbf{k}). A lot is esult + \mathbf{k} * the standard deviation of result acceptance criterion is based on the | Canada 5' - |
| Apps to c | demonstr | ate acce | ptance sampli | ng | | | | |
| App1 is a | bout desig | an and ev | aluation of san | pling plans | . This app can | be used to e | examine the OC curves before creating a | d Canada |
| using a sampling plan as the different curves can be compared. The app can be used to examine the OC curves before creating and plans or variables plans. In the attributes sampling plan, there is the option to change the sample size and the acceptance number for plan 1 (the purposive plan). For plan 2 (the designed plan), the PRQ, CRQ, producer's risk, and consumer's risk | | | | | | | | |

| are all to be entered. Once the parameters are chosen, the two OC curves can be compared. Variables sampling plans are similar except there is a <i>k</i> -constant instead of an acceptance number. There is also an additional parameter, which is whether the standard deviation is known or unknown. The two OC curves can again be compared for the variables sampling plan. | |
|---|----------|
| Editorial/Technical: AQL.risk should be PR in the App; LQL.risk should be CR in App | |
| App2 demonstrates the effect of lot size. This app allows you to see the impact that lot size and sample size have on the OC curves. There are two curves, for finite and infinite lots. The OC curve for the infinite lot does not change, but the finite lot OC curve changes depending on the plan parameters. The sample size, acceptance number, lot size and producer's and consumer's risks can be altered to see what effect the changes have on the OC curves. | Canada |
| Batch and lot size are sometimes used and the term should be consistent | |
| Look at the measurement error | |
| Needs to explain why these two sources of uncertainty in the measured concentration are not treated equally, and why the 'sampling error' is not included in the estimate of measurement uncertainty. Proposed change: Explain why these two sources of measurement uncertainty are not treated equally, and the 'sampling error' is not included in the estimate of measurement uncertainty (often called 'measurement error' in this document) | EURACHEM |
| Example | |
| Perhaps a clear explanation of the goal of this section should be added | Canada |
| The following is a screenshot of the OC curve produced by the tool for $n=80$, $L=80$, $k=0$ for the true SD $\sigma=0.6$. | |
| L=80 a typo? Should it be 97? | |
| Average Quantity System | |
| If Q_{nom} is the nominal prepackage quantity, q_i is the actual quantity of the ith prepackage, then the error for the ith prepackage $e_i = Q_{nom} - q_i$. In a random sample of size <i>n</i> drawn from the lot whose prepackage quantity is normally distributed with mean and standard deviation σ , it is ensured that the lot is rejected when $e_{avg} < c$ where c is a constant found satisfying: | Canada |
| Please provide symbol for normally distributed mean | |
| In other words, the <i>c</i> constant is a parameter for the test of average requirement which mainly protects the interest of the producer. The producer's risk of rejecting the lot, whose true mean is at the nominal value, is controlled. | Canada |
| Symbol for true mean is missing | |
| $\frac{n(N-1)}{N-n} \ge \frac{t_{0.9,n-1} - t_{0.005,n-1}}{0.74}$ | Canada |
| t is from t-distribution? | |
| Define N for readers | |

| T2 error control. Individual prepackages with errors less than -2T are called T2 error prepackages, which are extremely short compared to the nominal Q_{nom} . The lot is rejected in the event of a T2 error. In other words, a zero acceptance number attributes plan is employed to control the proportion of prepackages not conforming to the T2 error criterion. | Canada | |
|--|----------|--|
| Please clarify the intent and concerns addressed in this section | | |
| Sampling Inspection Plans for Compositional Proportions | | |
| The SD is estimated as $=\hat{\sigma} = \sqrt{\hat{\mu}(1-\hat{\mu})/\theta} = \sqrt{0.332(1-0.332)/10000} = 0.00471$. For L=32.4% and <i>k</i> =1.3, $\hat{\mu} - k\hat{\sigma} = 0.332 - 1.3 * 0.0015 = 32.6\%$ which is greater than the lower limit L=32.4%. The lot is therefore accepted. | Canada | |
| Suggest this 0.0015 should be 0.00471 | | |
| Where did 32.4 come from? Perhaps it should be 34 based on the introductory information in 7.2? | | |
| App for the design of beta sampling plan (graphics) | Canada | |
| This example has different values of Theta and L from above, may not be clear | | |
| App for the design of beta sampling plan | | |
| As an example, consider five numerical measurements of a weight characteristic (100.5, 100.7, 100.2, 100.6, 100.4). If the measurement error distribution is known to be normally distributed with mean zero and standard deviation 0.25, i.e. N(0, 0.25), the probabilities of these five measurements falling below the lower specification limit of $L=100$ are (0.023, 0.003, 0.212, 0.008, 0.055). The sum of all the FNC values, $\sum \hat{p}_{iu}$ is given by 0.3. This sum can be compared with a fractional acceptance number such as 0.5. This approach is similar to comparing the number of nonconforming units <i>d</i> with the acceptance number <i>c</i> in the attribute plan. The plan can also be implemented using the mean FNC which can be compared with the maximum allowable fraction nonconforming. | Canada | |
| In following example fractional acceptance number is 1.7, should be matched up for clarity | | |
| Conformity Testing | | |
| Conformity testing, also known as evaluation of conformity or compliance testing, is used to assure that an 'entity' meets a specific requirement and/or regulatory standard. In this context entity refers to the sample actually tested. | EURACHEM | |
| However, conformity assessment can equally focus on decisions about a lot, and not just on the samples that were taken. Proposed change: Revise the wording to make clear that conformity assessment can also be applied decisions about a lot, and not just on the samples that were taken with the objective of representing that lot. (Ellison SLR and Williams A, EURACHEM /CITAC Guide: Use of uncertainty information in compliance assessment, First edition 2007 https://www.eurachem.org/ | | |
| Assurance of conformity: The uncertainty interval is included within the region of allowed values; | Paraguay | |
| Standardize expression with the following bullet. | | |