



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

40th Session

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

(Prepared by the EWG led by New Zealand)

Codex members and Observers wishing to submit comments on this draft should do so as instructed in CL 2019/17-MAS available on the Codex webpage/Circular Letters: <http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>.

1. Revision of CXG 50: Process

1.1 This report

This report summarises the progress half-way through the agreed timeframe for presenting a proposed draft revised *Guidelines on sampling* (CXG 50 – 2004) to CCMAS 41.

The EWG have been very involved and constructive in their comments on the work to date. This paper summarises the main technical comments as well as some important questions. It also sets out the proposed process through to CCMAS 41.

1.2 CCMAS 39 Terms of Reference

The Committee agreed to start new work to revise the *Guidelines on sampling* (CXG 50 -2004) (hereafter referred to as GL50) and submit a revised project document to CCEXEC and CAC for approval as new work. CAC41 approved the new work.¹

CCMAS39 also agreed to:

- *The prioritisation of work (refer REP18/MAS Appendix VI);*
- *Establish an EWG chaired by New Zealand to develop the revised GL 50 based on the draft presented in CX/MAS 18/39/7 Appendix III.*

The new work set out the main aspects to be covered in the revision to result in a shorter document containing understandable and educational guidance along with links to the sampling plan tool. The document will cover:

- *Introduction;*
- *Concepts of sampling;*
- *Guidance on specification of sampling plans for foods;*
- *Sampling plan tool;*
- *Other technical information e.g. measurement error, sampling of bulk materials, sampling of in-homogeneous lots;*
- *Links to other sources of scientifically valid sampling plans.*

The revised GL 50 will align with established Codex principles for sampling plan set out in the Procedural Manual and in *Principles for the Use of Sampling and Testing in International Food Trade* (CXG 83-2013).

¹ REP18/CAC, para. 66 and Appendix VI

1.3 EWG process

We would like to take this opportunity to thank the EWG for considered, constructive and well-researched comment. An invitation to participate in the EWG was issued in July 2018. The list of participants is attached as [Appendix 3](#).

The first document sent to the EWG (October 2018) was the 'Proposed Draft Revised General Guidelines on Sampling' (CXG 50). This set out a proposed draft revised CXG 50 (draft revised guidelines) intended to provide understandable guidance on the design of sampling plans. A sampling plan tool was provided as part of this draft revised guidelines.

We provided a list of questions to guide responses. We also noted to the EWG that the sampling plan tool was a prototype version that will, in time, be replaced by a more general tool.

There were 9 responses provided. A summary of these responses is in [Appendix 1](#).

The second document sent to the EWG (February 2019) we described as a 'concept' document accessible online as an electronic book (e-book) at: <http://www.massey.ac.nz/~kgovinda/nzcodexdoc/>

This 'concept' document included sampling plan app links. It also included an explanation of the different types of sampling plans, how to use the apps, how to interpret the OC curves and some examples to demonstrate this.

We provided a list of questions to guide responses.

To date, 8 responses have been provided. A summary of these responses is in [Appendix 2](#).

EWG Chair's comment

Our intent was to provide the October 2018 'draft revised guidelines' as the 'master document' to respond to the Terms of Reference. The February 2019 'concept document' was to supplement the 'master document'. This concept document was intended to demonstrate how an e-book could be used to provide the sampling plan apps along with some information to support their use.

The EWG consultation advised us that the relationship between the master and concept documents was not clear.

The very useful commentary provided by EWG members also identified some important questions for consideration, as well as providing direction for the ongoing development of the revised draft guidelines and associated sampling plan apps.

This will include continued development of the draft revised guidelines to deliver the Terms of Reference. We will also develop the e-book to more closely link with the guidelines, to be user-friendly and to provide more background on the output of the apps compared to those plans currently in GL 50. We intend to include more apps to cater for those situations not currently included in GL50.

Key outcomes from the EWG consultation

- There was general support for the October 2018 draft revised guidelines.

A summary of these responses is in [Appendix 1](#).

- There was support for the February 2019 concept document including the apps in the e-book format. However, the content, structure and interpretation needs to be simplified and aligned with the draft revised guidelines to make a user-friendly document. A summary of these responses is in [Appendix 2](#)
- The EWG comments over both documents did raise some important and basic questions. We believe the following questions need to be answered and considered for introductory information in the draft revised guidelines. These include:

- In what context is it that Codex sampling plans are intended to be used?
- What do Codex sampling plans hope to achieve?
- How Codex sampling plans can be used by exporting and importing countries in real situations?
- Are Codex sampling plans intended for use in international trade disputes?
- What situations where Codex sampling plans are used, are covered or not covered?

- Based on the EWG guidance we have set out our proposed way forward in [Table 1](#).

We have set out some of these important questions with some commentary in [Table 2](#).

The continuation of work on revision of CXG 50 (and sampling plan apps)

Recommendations

It is recommended that CCMAS 40:

1) approve continuing work on revision of CXG 50 by an EWG, covering the following topics: (Table 1 of Appendix 3 provides some EWG Chair's comments to guide discussion).

(i) Draft revised Guidelines

- Role of commodity committees
 - include information on awareness and acceptance of risks, already addressed in the *Principles for the use of sampling and testing in international food trade* (CXG 83 – 2013).
- Sampling plan apps
 - describe the theoretical basis of the apps
 - provide examples of how the output of the apps compared to currently-approved plans
 - describe the applicability of the apps to the wide variety of measurand/commodity combinations
- Inclusion of introductory material to answer a range of important questions (see Table 2 for examples of these)
- Continuation of prioritisation list, for example, sampling plans for bulk materials, measurement error

(ii) Linked electronic document containing sampling plan apps

- Continued development of the e-book:
 - improve user-friendliness
 - included text to align with the draft revised guidelines

2) consider the following questions to guide further work. (Table 1 of Appendix 3 provides some EWG Chair's comments to guide discussion).

- Is it practical to achieve a perfectly balanced producer/consumer risk, based on statistical theory will rarely ever be practically achieved, as there is not a single producer for a commodity, or a single consumer (importing country), or single testing authority who are importing and testing at the boarder all the producer product?
- Are Codex sampling plans intended for use in international trade disputes?
- When using Codex sampling plans, what are the situations that are covered or not covered?

Revised CXG 50

The draft revised guidelines were to provide understandable guidance on the design of sampling plans. A prototype sampling plan tool was part of these guidelines.

Structure

The document structure was set out under the following major headings:

- concepts of sampling: describing sampling principles including the probability approach and acceptance sampling;
- inputs to the design of the sampling plan: describing inputs to be considered including context on the commodity being sampled and provision being tested;
- design of the sampling plan: describing the key parameters for the actual design of the sampling plan (and re-inspection plan) using the sampling plan tool
- reviewing the sampling plan from the sampling plan tool to assess fitness for purpose and fairness as well as cost and practicality;
- evaluating alternative sampling plans using a similar approach;
- describing what is needed for endorsement of the sampling plan;
- documenting and communicating the sampling plan;
- dealing with sampling plan problems such as disputed lots; and
- other technical information and references.

Questions

The key question we asked was whether the format and content was understandable. We also asked a range of questions on the use of flow diagrams as an aid to understanding the development of sampling plans, the source of definitions, the use of 'information boxes' along with the guidelines and any missing content or areas that need to be developed.

Summary of responses

Comment	Chair's response, for EWG discussion
There was agreement to include definitions but a range of comments on the use of definitions from current Codex documents, ISO or other international sources, and the explanation of technical definitions provided a range of approaches.	<i>To include the Codex definition where a current one is available. Where this isn't, to use the ISO or other international standard where this is available. Then include an explanation for each definition with this explanation providing simpler language and where possible, a reference within the revised CXG 50.</i>
The EWG all supported the inclusion of a flow diagram. There was additional comment that the flow diagram should be developed at a later time once it is clear what the steps are for selecting a sampling plan for Codex purposes.	<i>A flow diagram is being developed in response to this EWG guidance.</i>
The EWG all commented that there were areas that need to be included that were not yet covered. These areas included guidance for sampling procedures and sampling when the commodity standard has a range of provisions and when different provisions will require different sampling schemes. Sampling procedures were not part of the agreed prioritisation list.	<i>To include a section on the principles of sampling procedures based on CXG50 as well as reference to international standards on sampling procedures (IDF). Different sampling plans may be required for different provisions in a standard.</i>
There was mixed support for the use of features such as hyperlinks within the document, noting while they are a part of other Codex documents they may be difficult to maintain.	<i>To include user-friendly features such as hyperlinks. However, confirmation on how these can be used in a published document to be asked of the Codex Secretariat. Definitions in relation to this work tend not to change often.</i>
There was general support for use of an 'information box' separately identified from the guidance. However, a note-worthy comment was that the document is intended to provide guidance and not information. In addition, a glossary was recommended.	<i>We included information in order to assist readers and provide the background to the guidance.</i>

	<p><i>To include 'information boxes' only where needed. A glossary or similar list of terms, acronyms and references used in the document to be developed.</i></p>
<p>Some technical questions were raised. These included whether codex sampling plans applied to re-inspection plans, further consideration of 'Indifference plans', clarity as to why 'measurement error' is used rather than the more widely used concept of 'measurement uncertainty' (MU), the assumption that ME is negligible which is frequently not the case, the need for sampling plan examples and for those examples to be linked to other codex areas where this may be needed for example, pesticides.</p>	<p><i>Re-inspection plans are an alternative to switching rules that are seen impractical in international trade.</i></p> <p><i>Re-inspection is necessary to maintain fairness, due the relatively high chance of making incorrect decisions when small sample numbers are used.</i></p> <p><i>MU relates only to the random components of measurement error; we prefer to use the general term at this stage.</i></p> <p><i>The assumption that ME is negligible relates only to plans in GL 50 and most of those discussed so far in the e-book.</i></p>

Concept document including sampling plan apps

The 'concept document' was to demonstrate how sampling plan apps could be part of an electronic document intended to contain enough information to support the use of the sampling plan apps.

Questions

The key question we asked was '*Is this simplified version of the Guidelines helpful to understand the development and evaluation of sampling plans?*' We also asked a range of questions on the use of the sampling plan apps and whether the examples were helpful.

Summary of responses

Comment	Chair's response, for EWG discussion
Improve user-friendliness of the content and format and align the text with the draft revised guidelines	<i>This was a common view expressed by the EWG respondents.</i>
Could CCMAS could make use of a guidance document and apps to set an appropriate 'default' Acceptance Sampling Plan for inspection of attributes or inspection by variables (in accordance with ISO 2859 and ISO 3951 respectively) and potentially ISO 10725 in the case of inspection of bulk materials? Users assessing which is the most appropriate 'default' inspection for the commodity/lots in question.	<i>ISO2859 and ISO3951 do not cater for significant measurement error in general, although a special case is presented in ISO3951. ISO10725 deals with bulk materials but only in respect of the average level. There is a need to enhance CXG 50 to include material for:</i> <ul style="list-style-type: none"> - <i>plans where there is significant measurement error</i> - <i>assessment of bulk materials against minimum or maximum limits.</i>
What data are used to construct the OC curves?	<i>The OC curve for a sampling plan shows the probability of acceptance of a lot in terms of the percentage non-conforming in the lot overall. The construction of OC curves is a theoretical exercise based on statistical theory. Usually OC curves are calculated for percentages non-conforming from 0% to 100%. The formulae to calculate the probabilities of acceptance are in the current version of GL50, in sections 3.2.1 and 4.2.1 for plans based on inspection by attributes and sections 4.3.2.1 and 4.3.3.1 for plans based on inspection by variables, for unknown standard deviations (the s-method) and known standard deviations (the sigma-method) respectively.</i> <p><i>With the exception of the sigma method for inspection by variables where one must specify a standard deviation representing the variation with the lot, when there is negligible measurement error it is not necessary to specify any parameters relating to the lot to be able to derive the Operating Characteristic.</i></p>
It's not clear how the apps can generate relevant OC curves for probabilities of inaccurately (or accurately) classifying lots as "acceptable" for vastly different measurands (e.g. the length of stems in canned button mushroom as well as concentrations of ultra-trace contaminants that can be very heterogeneous in a bulk commodity).	<i>Different sampling plans would be possibly required for the different measurands, depending on the nature of the measurements (i.e. attributes having pass/fail or equivalent binary outcomes, or variables being measured concentrations etc.) and on the choice of Acceptance Quality Level (AQL) and Limiting Quality Level (LQ/LQL) considered appropriate for that inspection, and possibly other factors such as the measurement error.</i>
How does the output of these tools compare to the current sampling plans that are associated with Codex provisions (e.g. total aflatoxins in peanuts)?	<i>The procedure describes the formation of a composite sample for testing, No acceptance criterion is mentioned unless 15 µg/kg is intended as the maximum level. However a single test result from the testing of a composite sample is an estimate of the average level so that comparison with the maximum level might not provide the intended levels of consumer protection.</i>

APPENDIX 3**Table 1**

Draft Revised Guidelines	
Topic	Chair comment
Role of commodity committees <ul style="list-style-type: none"> - include information on awareness and acceptance of risks, already addressed in CXG 83-2013. 	<i>Understanding of consumers and producers risk is key to developing sampling plans</i>
Sampling plan apps <ul style="list-style-type: none"> - describe the theoretical basis of the apps - provide examples of how the output of the apps compared to currently-approved plans - describe the applicability of the apps to the wide variety of measurand/commodity combinations 	<i>Raised by the EWG</i>
Inclusion of introductory material to answer a range of important questions (see Table 2 for examples of these)	<i>Raised by the EWG</i>
Continuation of prioritisation list, for example, sampling plans for bulk materials, measurement error	<i>Reference CCMAS 39 Prioritization list (REP18/MAS, Appendix VI)</i>
Linked electronic document containing sampling plan apps	
Topic	Chair comment
Continued development of the e-book: <ul style="list-style-type: none"> - improve user-friendliness - included text to align with the draft revised guidelines 	<i>We intend to add other sampling plan apps and supporting text to the e-book to cover those situations not covered in the current version of GL 50.</i>

Table 2

Question	Chair's response, for EWG discussion
Is it practical to achieve a perfectly balanced producer/consumer risk, based on statistical theory will rarely ever be practically achieved, as there is not a single producer for a commodity, or a single consumer (importing country), or single testing authority who are importing and testing at the boarder all the producer product?	<p><i>We envisage that Commodity Committees (and possibly governments) will specify "minimum" requirements for sampling plans applicable for each provision, in much the same way as has been done in International Recommendation OIML R87 relating to the Average Quantity System for Weights.</i></p> <p><i>For example, a Commodity Committee might recommend that for a particular provision in a Codex standard, a sampling plan should have:</i></p> <ul style="list-style-type: none"> - <i>an Acceptance Quality Level (AQL) of 2.5%, with a producer's risk not exceeding 5%</i> - <i>a Limiting Quality Level (LQL) of 5%, with a consumers risks not exceeding 10%</i> <p><i>Following this:</i></p> <ul style="list-style-type: none"> - <i>each consumer would design a plan taking account of the measurement error and bias present in its own laboratory, if measurement error is significant</i> - <i>producers would design plans to ensure that product meets consumer requirements, in particular that it would pass inspection by consumers using their sampling plans. Producers would also allow for their own measurement error and bias, if significant</i> <p><i>In this model it is assumed that sampling plans assess the compliance of lots net of measurement error, taking account of bias and random measurement error.</i></p>

Question	Chair's response, for EWG discussion
Are Codex sampling plans intended for use in international trade disputes?	<p><i>Codex sampling plans are intended for use routinely and in trade disputes.</i></p> <p><i>The Codex Procedural Manual identifies the need for harmonisation in the interpretation of measurement results in relation to product assessment:</i></p> <p><i>At present there is no official guidance on how to interpret analytical results in the framework of Codex. Significantly different decisions may be taken after analysis of the "same sample". For example some countries use an "every-item-must-comply" sampling regime, others use an "average of a lot" regime, some deduct the measurement uncertainty associated with the result, others do not, some countries correct analytical results for recovery, others do not. This interpretation may also be affected by the number of significant figures included in any commodity specification.</i></p> <p><i>It is essential that analytical results be interpreted in the same way if there is to be harmonization in the framework of Codex.</i></p>
When using Codex sampling plans, what are the situations that are covered or not covered?	<p><i>App1 covers most of the plans in the current GL50. Areas not currently covered are:</i></p> <ul style="list-style-type: none"> <i>- Where there is significant measurement error</i> <i>- Assessment of bulk materials against minimum or maximum limits.</i> <p><i>The aim is that the revised CXG 50 will cover these areas</i></p>

List of EWG registrants

Member / observer organisation	Title/Name
Argentina	Codex Contact Point
Australia	Mr Tom Black
Australia	Mr Richard Coghlan
Brazil	Ligia Lindner Schreiner
Brazil	Carolina Araujo Vieira
Brazil	Simone de Oliveira Reis Rodero
Canada	Dr Thea Rawn
China	Stephen Chung
Croatia	Ranka Simic
Croatia	Iva Mraovic
Colombia	Myriam Rivera Rico
Ecuador	Victor Hugo Almeida Arteaga
Egypt	Mariam Barsoum Onsy
EU	Mr Franz Ulberth
France	Mrs Clara Pacheco
France	Mr Jean-Luc Deborde
Germany	Dr Katrin Franks
Hungary	Zsuzsa Farkas
Hungary	Attila Nagy
Hungary	Aron Hamow Kamiran
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