Agenda item 7

MAS/40 CRD/20

J
OINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON METHODS OF ANALYSIS SAMPLING
40th Session
Budapest, Hungary, 27 -31 May 2019

# General Guidelines on Sampling CXG 50 – 2004 update

# Outline

- Background and where the work is up to

- Activity between CCMAS39 (2018) and CCMAS40 (2019)

- Revised draft guidelines (October 2018)

- E-book concept (January 2019)

- Circular letter (April 2019)

- Presentation

- CCMAS40

# Background

- **CCMAS37 (2016)** provided for an eWG, chaired by New Zealand to review the current CXG 50 rationale and purpose, as well as identify any improvements.

- New Zealand presented the eWG report to CCMAS38 (2017). The report identified general and technical areas of improvement needed, along with eWG support to undertake new work on simplifying/updating CXG 50

- **CCMAS38 (2017)** agreed to continue the development of this work to prepare an outline of a new General Guidelines on Sampling (CXG 50-2004) along with prioritisation of technical and other improvements.

- the revision should provide simple and understandable guidance and avoid the overuse of statistical information; cross-referencing existing guidance on sampling; use of examples within the revised document should be avoided

- New Zealand offered to develop a template to provide guidance to committees for the development of sampling plans. This would lead to work to address all sampling plans in a comprehensive way to avoid inconsistencies in GL 50 or commodity standards

- **CCMAS39 (2018)** agreed to start new work and CCEXEC and CAC approved a revised project document to develop the revised CXG 50

- The approach will result in a shorter document containing understandable and educational guidance, along with links to sampling plan apps, to 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

- In addition, the revised CXG 50 is to align with established Codex principles for sampling plans as set out in the Procedural Manual and in Principles for the Use of Sampling and Testing in International Food Trade (CXG 83-2013)

- **CCMAS39 (2018)** agreed to a prioritisation list for the work

# REP18/MAS para 71: Prioritisation list

| Priority area and potential outcome |
|---|
| 1. An introduction to the revised document |
| Concepts of sampling<br>    o   Apps to demonstrate concepts of sampling, measurement error etc. |
| Step-by-step guidance on how to choose a sampling plan for foods |
| Attributes and variables sampling plans<br>    o   Tools to design and evaluate these plans |
| Explanation of ISO, GL50 sampling plans<br>    o   Lot size versus sample size<br>    o   Explanation of ISO, GL50 sampling plans<br>    o   Sampling schemes vs sampling plans<br>    o   Equivalent sampling plans(equivalent to sampling schemes)<br>    o   Re-inspection plans<br>    o   Tools |
| Bulk materials<br>    o   Introduction; what are they?<br>    o   Sampling plans, including plans based on the beta distribution<br>    o   Tools |
| Introduction to measurement error<br>    o   Nature of measurement error<br>    o   Design of sampling plans allowing for measurement error<br>    o   Tools |
| Other types of sampling plans and sampling plan tools<br>    o   For example, for microbiology (product quality, process hygiene, food safety) and histamine among other food safety parameters |
| Compliance of the average level<br>    o   Tools |
| Inhomogeneous lots |

# Where the work is up to

- The timeframe for the new work was set out in REP18/MAS App V:

| Time | Action |
|---|---|
| CCMAS39 (2018) | Agree to start new work |
| CAC 2020 | Approval of the new work |
| CAC 2021 | Adoption at Step Adoption at Step 8 |

- At the 41st session of the CAC, the Commission approved new work on the revision of the Guidelines on Sampling (CXG 50 – 2004)
- We are half-way through the CCMAS work to draft a revised CXG 50

# Activity between CCMAS39 and CCMAS40

- In October 2018, New Zealand sent the eWG a proposed draft revised CXG 50 to respond to the new work

- In January 2019, New Zealand send the eWG an electronic book (e-book) containing links to the sampling plan apps

- 'concept' for delivery of the apps

# Activity between CCMAS39 and CCMAS40 – draft revised CXG 50

- The proposed draft revised CXG 50 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

- It included a sampling plan tool prototype

- We provided questions for the EWG to consider in their response to this draft.

# The proposed draft revised CXG 50

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

| Comment | Chair's response |
|---|---|
| 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. | *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.* |
| 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. | *A flow diagram is being developed in response to this EWG guidance.* |
| 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. | *To include a section on the principles of sampling procedures based on CXG50 as well as reference to international standards on sampling procedures (IDF).*<br><br>*Different sampling plans may be required for different provisions in a standard.* |
| 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. | *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.*<br><br>*Definitions in relation to this work tend not to change often.* |
| 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. | *We included information in order to assist readers and provide the background to the guidance.*<br><br>*To include 'information boxes' only where needed. A glossary or similar list of terms, acronyms and references used in the document to be developed.* |
| 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. | *Re-inspection plans are an alternative to switching rules that are seen impractical in international trade.*<br><br>*Re-inspection is necessary to maintain fairness, due the relatively high chance of making incorrect decisions when small sample numbers are used.*<br><br>*MU relates only to the random components of measurement error; we prefer to use the general term at this stage.*<br><br>*The assumption that ME is negligible relates only to plans in GL 50 and most of those discussed so far in the e-book.* |

# Activity between CCMAS39 and CCMAS40 – e-book concept

- The 'concept' document was available on-line at http://www.massey.ac.nz/~kgovinda/nzcodexdoc/ and included:

- guidance on sampling

- sampling plan app links

- how to use the apps

- how to interpret the OC curves

- some examples to demonstrate this.

- We provided questions for the EWG to consider in their response to this draft.

### 2.3.1   Apps to demonstrate acceptance sampling

There are 14 apps available in the newly developed `R` package called `nzcodex`. This R package can be launched in RStudio environment.

The `nzcodex` `R` package containing all the apps and sampling inspection tool documentation can be downloaded at the following link.
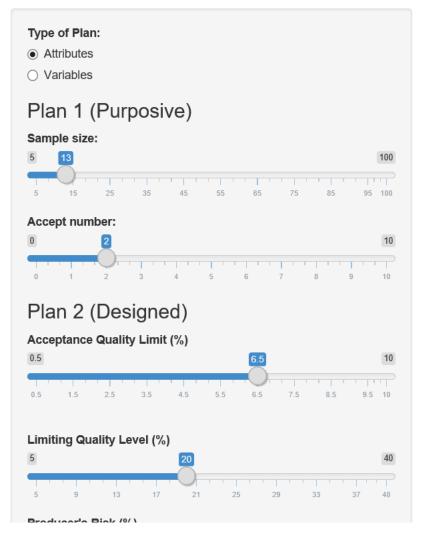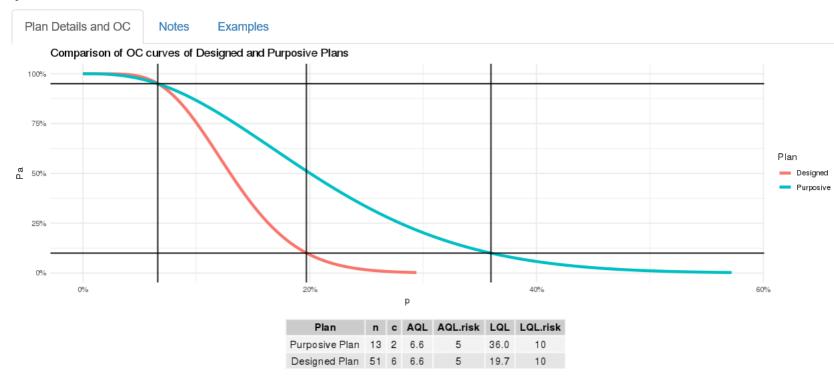
**nzcodex**

The package will launch shiny applications (apps) or tools. Some apps are intended for demonstrating risk assessment principles while other apps are to design sampling inspection plans on statistical risk assessment principles.

**App1** is about design and evaluation of sampling plans. This app can be used to examine the OC curves before creating and using a sampling plan as the different curves can be compared. It compares attributes and variables sampling 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 AQL, LQL, producer's risk, and consumer's risk are all to be entered. Once the parameters are chosen, the two OC curves can be compared. It is similar for the variables sampling plan also, except there is a k-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.

**App2** is about the effect of batch size. This app allows you to see the impact that sample size and batch

# Design and Evaluation of Sampling Inspection Plans

## Type of Plan:
- ◉ Attributes
- ○ Variables

## Plan 1 (Purposive)

**Sample size:**

| 5 | 13 | 100 |
|---|---|---|

5  15  25  35  45  55  65  75  85  95 100

**Accept number:**

| 0 | 2 | 10 |
|---|---|---|

0  1  2  3  4  5  6  7  8  9  10

## Plan 2 (Designed)

**Acceptance Quality Limit (%)**

| 0.5 | 6.5 | 10 |
|---|---|---|

0.5  1.5  2.5  3.5  4.5  5.5  6.5  7.5  8.5  9.5  10

**Limiting Quality Level (%)**

| 5 | 20 | 40 |
|---|---|---|

5  9  13  17  21  25  29  33  37  40

**Producer's Risk (%)**

---

### Plan Details and OC | Notes | Examples

**Comparison of OC curves of Designed and Purposive Plans**



| Plan | n | c | AQL | AQL.risk | LQL | LQL.risk |
|---|---|---|---|---|---|---|
| Purposive Plan | 13 | 2 | 6.6 | 5 | 36.0 | 10 |
| Designed Plan | 51 | 6 | 6.6 | 5 | 19.7 | 10 |

# Apps

- Some apps are intended for demonstrating risk assessment principles while other apps are to design sampling inspection plans on statistical risk assessment principles.

- Supplementary technical notes and examples are also given in the apps.

- App1 is about design and evaluation of sampling plans.

- App2 is about the effect of batch size.

- App3 is created to demonstrate variables plan for averages.

- App4 is about exploring repeat testing.

- App5 is about exploring the effect of lot heterogeneity.

- App6 is about re-sampling.

- App7 is about the effect of inspection errors on risks.

- App8 facilitates the implementation of the fractional non-conformance plans.

- App9 is about conformity testing.

- App10 is about sampling plans for compositional proportions.

- App11 is about compressed limit sampling inspection plans.

- App12 demonstrates optimum guard-banding analytics for a user dataset that can be uploaded.

- App13 is a tool that matches single and two-stage microbiological sampling plans based on compressed limits.

- App14 is about trace compositional components such as vitamin sampling plans.

# The e-book (concept)

| Comment | Chair's response, |
|---|---|
| Improve user-friendliness of the content and format and align the text with the draft revised guidelines | *This was a common view expressed by the EWG respondents.* |
| 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. | *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:*<br>*- plans where there is significant measurement error*<br>*- assessment of bulk materials against minimum or maximum limits.* |
| What data are used to construct the OC curves? | *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.*<br><br>*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.* |
| 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). | *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.* |
| 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)? | *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.* |

# Key outcomes from eWG activity

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

- 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

- There was strong support for a presentation at CCMAS40 to review the process, key questions and use of the sampling plan tool

- The EWG comments over both documents did raise some important questions and these were covered in the CL2019/17-MAS

- 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?

# CCMAS40

- Update on the work to date

- Presentation

- Continuing this work to revise the draft guidelines and e-book

| Draft revised guidelines | **Role of commodity committees**<br>- **include information on awareness and acceptance of risks, already addressed in CXG 83-2013.** |
| --- | --- |
| | Sampling plan apps<br>- describe the theoretical basis of the apps<br>- provide examples of how the output of the apps compared to currently-approved plans<br>- 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 |
| | Continuation of prioritisation list, for example, sampling plans for bulk materials, measurement error |
| **Linked electronic document containing sampling plan apps** | Continued development of the e-book:<br>- improve user-friendliness<br>- included text to align with the draft revised guidelines |

# Proposed timeframe for continuation of this work

- 2 rounds of consultation on the draft revised guidelines and sampling plan apps
- Circulation of a final draft well in advance of CCMAS41

| Time | Action |
|---|---|
| Mid-late 2019 | Update #2 of the revised guidelines and sampling plan apps |
| Late 2019/early 2020 | Update #3 of the revised guidelines and sampling plan apps |
| February/March 2020 | Revised guidelines and sampling plan apps to CCMAS 41 |

# Thank you

# Questions raised by WG Consultation

1. What do Codex sampling plans hope to achieve?

2. In what context is it that Codex sampling plans are intended to be used?

3. How can Codex sampling plans be used by exporting and importing countries in real situations?

4. Are Codex sampling plans intended for use in international trade disputes?

5. What situations where Codex sampling plans are used, are covered or not covered?