CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 7 **CX/MAS 18/39/7**
March 2018

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING
39th Session
Budapest, Hungary, 7 - 11 May 2018

PROPOSAL TO AMEND THE *GENERAL GUIDELINES ON SAMPLING (CXG 50-2004)*
(Prepared by the EWG led by New Zealand)

Introduction

1.1 TERMS OF REFERENCE

The specific terms of reference of the eWG as agreed at CCMAS38 are:

i. prepare a project document with a clear scope of the work to be undertaken, and

ii. an outline of a new *General Guidelines on Sampling* (CXG 50-2003); and

iii. prioritisation of technical and other improvements; and

iv. timeframes.

In addition, the Codex Secretariat considered the revision should aim at providing a 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.

There was also discussion on sampling plans that were not endorsed by CCMAS, since the plans did not correspond to those recommended in GL 50. 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.

1.2 EWG PARTICIPATION

New Zealand invited those members and observer organisations interested in participating in the eWG to advise the names and contact details of their representatives.

We provided a discussion paper along with a sampling plan tool in November 2017 and received detailed responses from colleagues in Norway, Iran, Uruguay, Canada, The Netherlands, Thailand, Japan and the United Kingdom. We provided an updated discussion paper and sampling plan tool to the eWG in January 2018 and received further detailed responses from Norway, Ecuador and Uruguay. A summary of the responses are in Appendix V: The list of the eWG participants is in Appendix IV.

1.3 LINKING OF THIS DOCUMENT TO THE TORS & OTHER REQUESTS

Terms of reference:	Linked to:
Project document with a clear scope of the work to be undertaken	Part 2: Project document
Outline of a new CAC/GL 50	Part 3: An outline of a new CAC/GL 50
Prioritisation of technical and other improvements	Part 2.9: Prioritisation
Timeframes	Part 2:10: Timeframes

For examples of guidance intended for inclusion in a new CAC/GL 50 refer to annexes 4, 5 and 6.

In addition to annex 6 in this document, a sampling evaluation tool has been developed to provide guidance to committees for the development of sampling plans.

RECOMMENDATIONS

The Committee is invited to:

- consider the proposal for new work on revision of GL 50 (project document attached as Appendix I) and agree on new work.
- agree on the proposed prioritization of work as presented in Appendix II.
- note the proposed outline of CAC/GL 50 as presented in Appendix III.

APPENDIX I

PROJECT DOCUMENT

THE PURPOSES AND THE SCOPE OF THE STANDARD

The purpose of this proposed new work is to produce a revision of the General Guidelines on Sampling (CXG 50-2004) (GL 50).

RELEVANCE AND TIMELINESS

The purpose of GL 50 is to help those responsible for sampling to select sampling plans that are appropriate for statistical inspections under specifications laid down by Codex standards.

The Guidelines are primarily aimed at Codex committees which select from the plans recommended. The Guidelines can also be used, if applicable, by governments in case of international trade disputes. The current Guidelines (69 pages) cover, firstly, general concepts of food sampling, applicable in any situations, and later sections cover certain situations of statistical food control, for which certain sampling plans have been selected. The Guidelines were adopted by the Commission in 2004 and there have been no subsequent amendments.

Some commodity committees and some members of CCMAS have expressed the view that the current Guidelines were difficult to understand and apply. The aim of the revision is to provide a simpler more understandable guidance.

MAIN ASPECTS TO BE COVERED IN THE PROPOSED REVISION

The proposed approach will result in a shorter document containing understandable and educational guidance, along with links to sampling plan apps. The proposed sections will cover:

- Introduction
- Concepts of sampling
- Guidance on specification of sampling plans for foods
- Sampling plan tools (containing links to apps of sampling plans tools, rather than the larger document full of tables, plots and formulae)
- Other identified technical information e.g. measurement error, sampling of bulk materials, sampling of non-homogeneous lots (refer Appendix: Prioritisation)
- Links to other sources of scientifically valid sampling plans.

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

AN ASSESSMENT AGAINST THE CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES

General criterion

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

The revision of the Guidelines is intended to give effect to the principles of sampling expressed in GL 83, in particular:

- fairness towards both the consumers and the producers, as well as importing and exporting countries;
- scientifically based, taking into account the existing Codex standards, appropriate to the commodity and lot or consignment to be sampled, and fit for intended purposes and applied consistently;
- commensurate with the potential loss posed to consumers from inappropriate acceptance of poor quality product and the potential loss posed to producers from inappropriate rejection of good quality product.

Clearer guidance, along with access to sampling plan apps and educational resources, will make the Guidelines more usable by all countries.

Criteria applicable to general subjects

(a) Diversification of national legislations and apparent resultant or potential impediments to international trade.

Countries take various approaches to sampling according to national circumstances. The improved Guidelines will enable development of more suitable sampling plans for Codex commodity standards, and assist national authorities to select appropriate sampling plans.

(b) Scope of work and establishment of priorities between the various sections of the work.

This project envisages a comprehensive revision of a major document. Accordingly the work will be conducted in stages with priorities as described below.

(c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body (ies).

Substantial work on sampling has been undertaken by other international organizations over many years. The revised Guidelines will make full use of this work, and will provide references and links to it.

(d) Amenability of the subject of the proposal to standardization.

The situations in which food must be sampled are very diverse. Nevertheless general guidance is needed to assist those responsible for selecting sampling plans to make an informed decision.

(e) Consideration of the global magnitude of the problem or issue.

Sampling plans are needed for any inspections that may be conducted against specifications laid down by Codex standards. Similarly national authorities need sampling plans for inspection of foods against national specifications.

RELEVANCE TO THE CODEX STRATEGIC OBJECTIVES

This proposal for new work is within the scope of the Codex Strategic Vision Statement 'To be the pre-eminent international food standards-setting body to protect the health of consumers and ensure fair practices in the food trade'.

The specific nature of this proposed new work aligns with the Codex 2014–2019 Strategic Plan:

Strategic goal 1:	Establish international food standards that address current and emerging food issues
Objective 1.1:	Establish new and review existing Codex standards, based on priorities of the CAC.
Activities 1.1.1:	Consistently apply decision-making and priority setting criteria across Committees to ensure that the standards and work areas of highest priority are progressed in a timely manner.

Activities 1.1.2: Strengthen the critical review process to improve standards monitoring.

INFORMATION ON THE RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING CODEX DOCUMENTS AS WELL AS OTHER ONGOING WORK

A list of issued Codex documents that relate to this proposal are:

1. Principles for the Use of Sampling and Testing in International Food Trade (CXG 83-2013)
2. Guidelines for Food Import Control Systems (CXG 47-2003)
3. Working Principles for Risk Analysis for Food Safety for Application by Governments (CXG 62-2007).
4. Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLs (CXG 33-1999)
5. Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programme Associated with the Use of Veterinary Drugs in Food Producing Animals (CXG 71-2009)
6. General Standard for Contaminants and Toxins in Food and Feed (GSCTFF, CXS 193-1995)
7. Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods (CXG 21 – 1997)
8. Guidelines for Food Import Control Systems (CXG 47-2003)

9. Guidelines for Settling Disputes over Analytical (test) Results (CXG 70-2009)
10. Information Document on Practical Examples on the selection of appropriate sampling plans.
11. Guidelines on Measurement Uncertainty (CXG 54-2004).

There is no other ongoing work in this area in Codex.

IDENTIFICATION OF ANY REQUIREMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC ADVICE

Expert scientific advice will be needed to review the new sections (e.g. plans for inspection of bulk consignments) and the sampling plan apps that will be developed. CCMAS representatives may be asked to seek such advice from consultation with statistical experts in their own country.

In addition, the work developing apps consists of two parts, translating published material into apps and doing the research to develop and publish theory to fill identified gaps.

Some statistical expertise is needed for the first activity and a lot for the second. Work on these sections will be undertaken by the eWG. There will still however, be a need for involvement of experts who may be external to CCMAS, for some of these work items.

New Zealand is actively working on some of these items, including the introduction, the general guidance, sampling plan tools etc.

IDENTIFICATION OF ANY NEED FOR TECHNICAL INPUT TO THE STANDARD FROM EXTERNAL BODIES SO THAT THIS CAN BE PLANNED FOR

It is not envisaged that technical input will be sought from external bodies.

THE PROPOSED TIMEFRAME

Time	**Action**
CCMAS 39 (2018)	Agree to start new work
CAC 2018	Approval of the new work
CAC 2019	Adoption at Step 5
CAC 2021	Adoption at Step 8

APPENDIX II

PRIORITISATION

This list covers the areas for prioritisation. While the work on these sections may be undertaken by the eWG, there will still be a need for involvement of experts who may be external to CCMAS, for some of these work items.

New Zealand is actively working on some of these items, including the introduction, the general guidance, sampling plan tools etc.

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

APPENDIX III

AN OUTLINE OF A NEW CXG 50

1.1 SHORTER DOCUMENT

The proposed approach for a new General Guidelines on Sampling (CXG 50) (GL 50) will result in a shorter document containing understandable and educational guidance in sections, along with links to sampling plan apps. The sections will cover:

- Introduction
- Concepts of sampling
- Guidance on specification of sampling plans for foods
- Sampling plan tools (containing links to apps of sampling plans tools, rather than the larger document full of tables, plots and formulae)
- Other identified technical information e.g. measurement error, sampling of bulk materials, sampling of non-homogeneous lots (refer Appendix: Prioritisation)
- Links to other sources of scientifically valid sampling plans.

A table of the proposed changes, and how much of GL 50 will still be retained, is in Appendix: Table of proposed revision.

1.2 ALIGNMENT WITH CODEX PRINCIPLES

The revised GL 50 will align with the established Codex principles for sampling plans:

1.2.1 Codex procedural manual:

*Codex methods of sampling are designed to ensure that **fair and valid** sampling procedures are used when food is being tested for compliance with a particular Codex commodity standard'. The sampling methods are intended **for use as international methods** designed to avoid or remove difficulties which may be created by diverging legal, administrative and technical approaches to sampling …in lots or consignments of foods, in the light of the relevant provision of the applicable Codex standard*

1.2.2 Principles for the use of sampling and testing in international food trade CXG 83-2013:

*To ensure sampling…procedures are **valid**, they should be based upon scientifically and internationally accepted principles, and it is necessary to ensure they can be **applied fairly**.*

Principle 1: Transparency and agreements before initiating trade:

- *Having **full knowledge and understanding** of the procedures and the inherent probabilities of wrongly accepting or wrongly rejecting a lot leads to informed decision making.*

Principle 3: Probability of incorrect decisions:

- *Sampling plans are developed considering **probabilities of wrongly accepting or wrongly rejecting a lot or consignment**. The appropriate levels of the probabilities are set in conjunction with appropriate chose of AQL and LQ for characteristics in foods to be tested.*
- *The specification of acceptable probabilities of wrongly accepting or wrongly rejecting a lot or consignment should have regard to **principles of fairness towards both the consumers and the producers, as well as importing and exporting countries**. This means making sure that consumers are not exposed to an unduly high probability of accepting non-compliant product and that a compliant product is not exposed to an unduly high probability of rejection.*

Principle 4: Selecting appropriate sampling and testing procedures:

- *The sampling…procedures selected should be **scientifically based, taking into account the existing Codex standards, appropriate to the commodity and lot or consignment to be sampled, and fit for intended purposes and applied consistently.***

Principle 6: Fitness for purpose:

- *The number of samples and decision criterion are determined by the probabilities of wrongly accepting or wrongly rejecting a lot of consignment. **Fitness for purpose means that the [control of risks by the] sampling plan is commensurate with the potential loss posed to consumers from inappropriate acceptance of poor quality product and the potential loss posed to producers from inappropriate rejection of good quality product**.*

2 Appendix: Example of section: Introduction

The Codex Procedural Manual and the Principles for the Use of Sampling and Testing in International Food Trade' (CXG 83-2013) (GL 83) state that 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'*.

Fairness can only be established by consideration of both consumer's and producer's risks. This revised GL 50 contains sections covering:

- Concepts of sampling
- Guidance on specification of sampling plans for foods
- Sampling plan tools (containing links to apps of sampling plans tools, rather than the larger document full of tables, plots and formulae)
- Other identified technical information e.g. measurement error, sampling of bulk materials, sampling of non-homogeneous lots (refer Appendix: Prioritisation)
- Links to other sources of scientifically valid sampling plans.

The sampling plan tool allows **for control of *both* consumer's and producer's risks** as part of the choice of sampling plan. This tool will also produce an Operating Characteristic (OC) curve. The OC curve is an important component of sampling plan choice. The Codex Procedural Manual says '*a commodity committee should, whenever possible, provide information to CCMAS for each sampling plan relating to the scope or field of application, the type of sampling (e.g. bulk or unit), sample sizes, decision rules, details of plans (e.g. Operating Characteristic curves), inferences to be made to lots or processes, levels of risk to be accepted and pertinent supportive data'*.

Commodity committees can use the sampling plan tool, and the resulting OC curve, to understand the important components of sampling plan design including the levels of consumer's and producer's risks.

Codex commodity committees are responsible for developing Codex provisions – the need to be aware of how a sampling plan will perform in regard to Codex provisions. The sampling plan tool can be used to demonstrate the OC curve that comes from selection of a combination of Acceptance Quality Limit (AQL), Limiting Quality (LQ or LQL), the number of samples 'n', the acceptance number 'c' or the acceptability constant 'k', and the resulting consumer's and producer's risks.

3 Appendix: Example of section: General introduction – Concepts of sampling

3.1 THE PURPOSE OF SAMPLING

The main aim of sampling inspection is to ensure that the customer receives product of the required quality and to ensure that products are safe, while remembering that financial resources are limited and the cost of the product must also reflect any costs associated with sampling and testing.

The choice of sampling plan depends on the level of protection against poor quality products to be provided to the consumer, whilst also ensuring suitable fairness to producers, in recognition of fair practices in food trade and the nature of measurements associated with the testing for the provision.

3.1.1 What are the ways that sampling inspection can be carried out?

There are three possible ways that sampling inspection can be carried out:

a. 100% inspection
b. Sampling design and choice of as sampling plan based on probability, application on statistics
c. *Ad hoc* inspection, that is, a sampling plan without a statistical basis.

For Approach (a), it is clear that 100% sampling is not feasible due to the prohibitive cost of testing and in addition, there might not be any product left to sell. Also, 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), some product might not be inspected. However by using the probability approach the risks can be calculated and a sampling plan chosen ensures these risks are controlled to desired levels. It also has the advantage of practicability and lower costs.

Approach (c) is often used for practical reasons, such as limited resources, or for simplicity. However such a plan might not provide the expected level of assurance of food quality and may inadvertently impose high costs, for instance through unwarranted food acceptance or rejection. The probabilities associated with such a plan should be evaluated where possible. Decisions on acceptance or rejection should not be made solely on the basis of such a plan.

The use of ad hoc sampling plans can lead to unjustified rejection of product that in turn could lead to the imposition of fines or penalties, trade sanctions or loss of access to markets.
Unjustified rejection might occur because assessments were inappropriately stringent, proper allowance for measurement error has not been made or that there was insufficient evidence that the lot overall fails to comply.

Approach (b) - the probability approach

There are two types of risks that can occur:

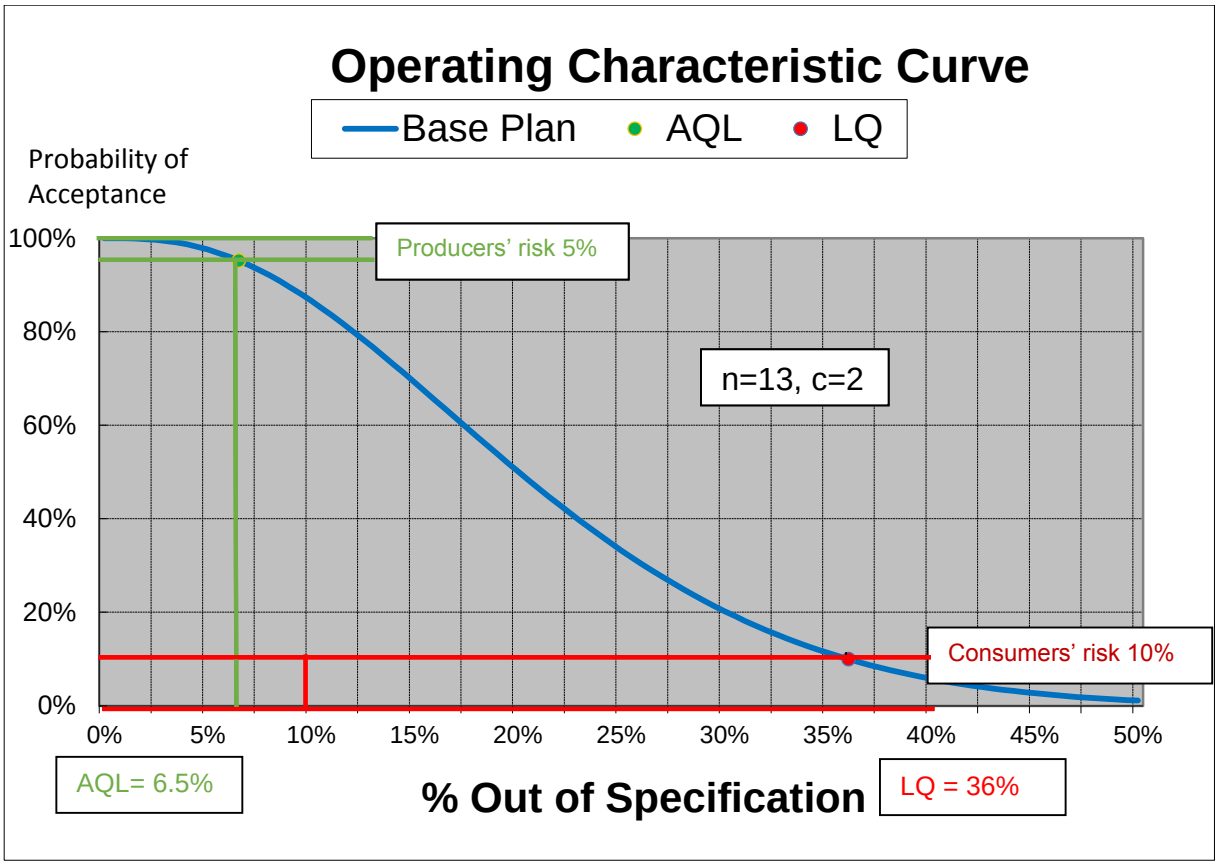
- The risk that product of unsatisfactory quality will be accepted (Consumer's Risk)
- The risk that good quality product will be rejected (Producer's Risk).

However, if we specify how we want to control these risks, we can choose a sampling plan that ensures these risks are not exceeded.

In practice, the producer's and consumer's risks are specified in terms of the Acceptance Quality Limit (AQL) and the Limiting Quality level (LQ or LQL) respectively. Once these are specified, along with their associated probabilities of rejection and acceptance respectively, a sampling plan, allowing no more than these levels of risk can be developed.

3.1.2 Key definitions

The **Operating Characteristic (OC) curve** is a curve showing, for a given sampling plan, the probability of acceptance of a lot as a function of its actual quality.



Producer's Risk is the probability of wrongly rejecting a compliant lot, with level of non-conformance at or below the acceptance quality limit (or proportion of non-conforming units for lots consisting of discrete items).

Generally the tolerable limit for the level of non-conformance in an acceptable lot is expressed as the Acceptance Quality Limit. It is a point on the OC curve corresponding to some predetermined and usually low probability of rejection. This probability of rejection is called the 'producer's risk'.

Consumers' 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. This probability is then called the 'consumer's risk' and the corresponding lot quality is called the Limiting Quality (LQ or LQL).

The **Acceptance Quality Limit (AQL)** (previously called Acceptable Quality Level) is the level of proportion of nonconforming items at which lots are accepted most of the time, usually expressed as the level non-conforming associated with 95% acceptance.

The **Limiting Quality (LQ or LQL)** is the proportion of nonconforming items at which lots are rejected most of the time, usually expressed as the level non-conforming associated with 10% acceptance

A **Sampling Plan** is one according to which one or more samples are taken from a lot in order to obtain information about or possibly reach a decision about that lot.

An **Acceptance Sampling Plan** is one intended for determining the acceptance or the rejection of a lot.

The **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 non-conforming items, referred to as the **acceptance constant 'c'**, for the lot to be accepted.

The **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 acceptance criterion "average result + k * the standard deviation of results" does not exceed the upper limit, and similarly for a lower limit.

3.2 DIFFERENT SAMPLING PLAN CHOICE APPROACHES

Commodity committees need to understand that there are different approaches to the choice of suitable sampling plans. When sampling plans are presented to CCMAS, the basis for these sampling plans needs to be clear. The key parameters behind, and required for the approval of a sampling plan include the producer's and consumer's risks. Approval might also involve consideration of practicality, fitness for purpose and potential unfairness to one of the parties.

There is no one-size-fits-all sampling plan choice that applies. What is important is that the approach used is science-based, with sound statistical backing. In practice, sampling plans may be based on industry practice. However, the choice of plans should still be made with knowledge of the associated risks, bearing in mind that the main purpose of sampling is to ensure that the customer receives product of satisfactory quality.

3.3 ENDORSEMENT BY CCMAS OF SAMPLING PLANS

The Codex Procedural Manual 'General Instructions for the Selection of Methods of Sampling' says that sampling methods described in GL 50 or elaborated by suitable international organisations are preferred, and provides as guidance, different types of sampling plans and procedures.

The Codex Procedural Manual also says '*a commodity committee should, whenever possible, provide information to CCMAS for each sampling plan relating to the scope or field of application, the type of sampling (e.g. bulk or unit), sample sizes, decision rules, details of plans (e.g. Operating Characteristic curves), inferences to be made to lots or processes, levels of risk to be accepted and pertinent supportive data'*.

CCMAS endorsement of sampling plans is based on the information provided, and expertise to judge the validity of the plan. Commodity committee choice of a sampling plan is also based on criteria, as well as expertise to apply the criteria to a suitable sampling plan to demonstrate *'fair and valid sampling procedures are used when food is being tested for compliance with a particular Codex commodity standard'*.

To aid the choice of a sampling plan by the commodity committee, and to help with the provision of the basis for the sampling plan, the OC curve should be used. The sampling plan tool we are developing will provide the opportunity for commodity committees to evaluate and compare different sampling plan criteria, based on what is needed in the commodity standard.

CCMAS will be in a position to endorse the sampling plan presented, whether the plan is sourced from GL 50, ISO or another source, so long as the key parameters are statistically supportable, and deliver a sampling plan that will meet the requirements of the commodity committee to demonstrate *'fair and valid sampling procedures are used when food is being tested for compliance with a particular Codex commodity standard*'.

4 Appendix: Example of section: Sampling plan tool information and links to the tool/app

4.1 WHAT INFORMATION IS NEEDED TO CHOOSE THE SAMPLING PLAN

A sampling plan design and evaluation tool has been developed in Microsoft Excel. This tool covers both inspection by attributes and inspection by variables sampling plans. The tool can be developed further to assist commodity committees with the choice of a sampling plan to ensure fair practices in food trade. The tool can be enhanced for example, to allow for measurement error.

The guidance for the choice of suitable sampling plans is science-based, and soundly based in statistical theory. This tool allows the statistics to sit in the background.

The tool will help guide the choice of an appropriate sampling plan by using the operating characteristic (OC) curve to demonstrate the details of the plan. The tool also allows for the preferred approach, where the plan is chosen from the Acceptance Quality Limit (AQL) and Limiting Quality (LQ or LQL). The OC curve plots the probabilities of accepting a lot versus the fraction nonconforming for a given sample size and acceptance number.

The tool can be used by specifying both the AQL & LQ, from which it will work out the 'number of samples 'n' and the acceptance number 'c' from this for attribute plans, or for variables plans, the 'n' and the acceptability constant 'k'. This means the LQ is specified at the start of the design.

This tool provides the option to move away from either the AQL or the LQ approach to choose plans that control both consumer's and producer's risks. In general for the measurement-error free situation [and possibly more generally] you need to specify any two points on the operating characteristic, two levels non-conforming and their associated probabilities of acceptance or rejection, to determine n and c (or k). Usually these points are chosen as a level non-conforming at which the product should be accepted most of the time, the AQL, and a level at which it will be rejected most of the time, the LQ. It is usual to associate the AQL with 95% probability of acceptance and the LQL with 10% acceptance, but other probabilities can be used.

The input parameters in this tool allow the probabilities of acceptance, or levels out of specification corresponding to specified levels of acceptance, to be calculated.

4.2 SAMPLING PLAN TOOLS

4.2.1 Version

The current version is:

Sampling plan design and evaluation tool V2

The sampling plan tool is in Microsoft Excel. *New Zealand is developing an interactive Shiny app (R package) in addition to the Microsoft Excel version.*

This tool can be used to determine (attributes - n, c)/ (variables – n, k) sampling plans from specifications of AQL, LQ and their associated risks.

Each worksheet allows evaluation of the OC for a specified sampling plan from the selection of (n, c)/ (n, k) at the top left.

The button at the lower left sets the maximum value displayed on the horizontal axis (x-axis).

The buttons at right allow selection of the AQL and LQ, the associated risks can be set manually.

Any cell highlighted in yellow is an input.

In the Variables worksheet, the OC curves for the unknown standard deviation case are based on an approximation, as the statistical function to calculate the OC for normally distributed data, is not available in Microsoft Excel. This accounts for why some of the points on the OC, i.e. those used in the design specification, might not correspond to the values specified.

Also, there are buttons for the known/unknown standard deviation. These of course correspond with the sigma method and the s-method in GL50. The s-method be used if the standard deviation is not known and the sigma method is to be used if the standard deviation is well known.

The s-method is used when the true value of the standard deviation is not known; in this case the standard deviation is estimated from the test results obtained from the testing of the lot currently under inspection.

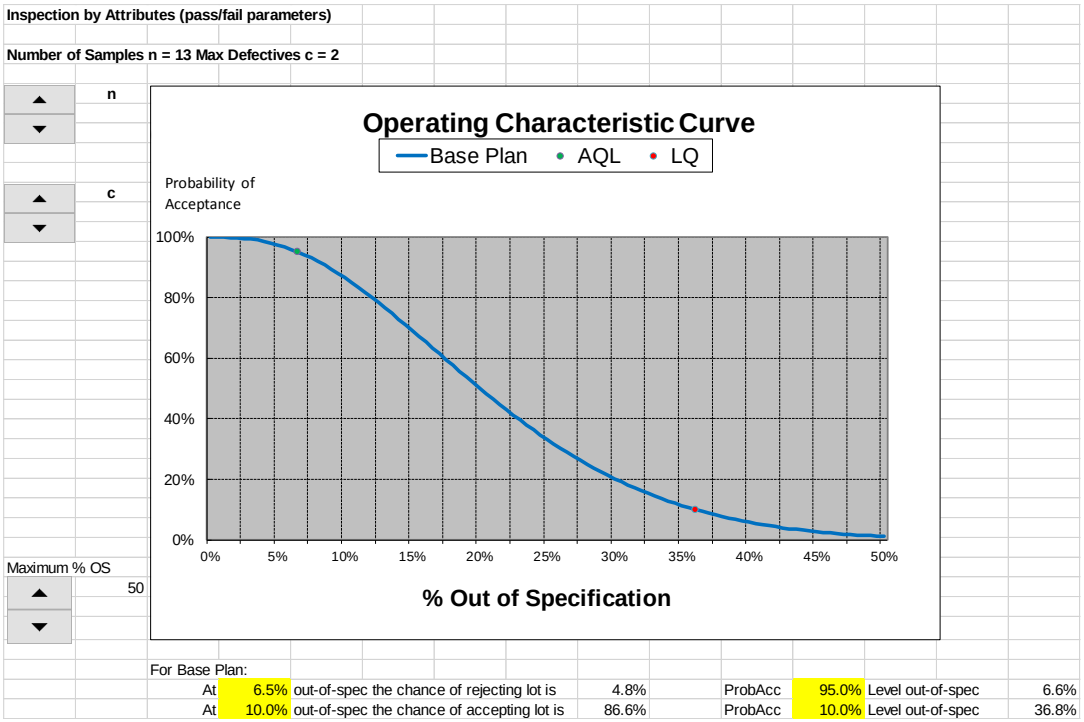
The sigma method is used when the standard deviation is known, i.e. its value represents longer term variation of a stable manufacturing process.

For both the attributes and the variables sampling plan, the input parameters allow the probabilities of acceptance, or levels out of specification corresponding to specified levels of acceptance, to be calculated. This is also set out in the messages on the worksheet.

4.2.2 Example of use of the sampling plan design and evaluation tool

Attributes worksheet: the base plan

1. This is produced after specifying ‘n’ and ‘c’ and the intended level of acceptance or rejection. An acceptance of 95% is usually associated with good quality and 10% acceptance with poor quality so it seems easier to specify levels representing what is good quality that should be accepted most of the time and what is poor quality, rejected most of the time.

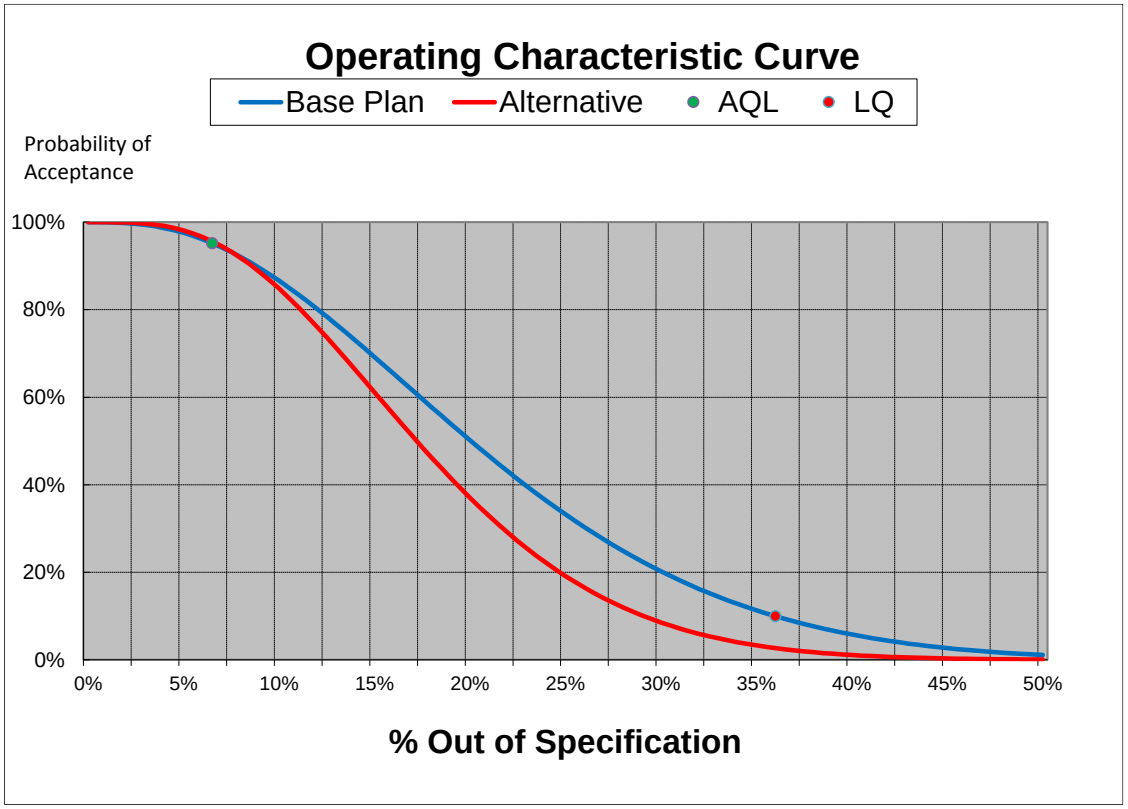


2. The Consumers’ Risk is the probability of wrongly accepting a lot that is not of acceptable quality.

3. Generally it is expressed as the LQ which corresponds to the proportion of nonconforming items in the lot accepted in 10% of the cases, in this case 36.8%.
4. The commodity committee can ask the question - is this acceptable? If not, consider an alternative plan.

Attributes worksheet: the alternative plan

5. This is produced after specifying the AQL and LQ the intended level of acceptance or rejection at this level, to determine 'n' and 'c'. An acceptance of 95% is usually associated with good quality, and 10% acceptance with poor quality so it seems easier to specify levels representing what is good quality that should be accepted most of the time and what is poor quality, rejected most of the time.



Number of Samples n = 21 Max Defectives c = 3										
	AQL	**6.5%**	**AQLRisk**	**5%**						
	LQ	**30.0%**	**LQRisk**	**10%**						
For Alternative Plan:										
At	6.50%	out-of-spec the chance of rejecting lot is			4.4%	ProbAcc	95.00%	Level out-of-spec		6.8%
At	10.00%	out-of-spec the chance of accepting lot is			84.8%	ProbAcc	10.00%	Level out-of-spec		29.1%

6. The alternative plan set a lower LQ of 30% (meaning the proportion of nonconforming items in the lot accepted in 10% of the cases, would be 30%).
7. As a result, the plan calculation determined 'n=21' and 'c=3' to achieve this LQ of 29.1%.

5 Appendix: Table of proposed revision

<table>
<tr><th>Current GL 50</th><th>New GL 50</th></tr>
<tr><td>Preamble</td><td rowspan="2">Replace with:
- Introduction
- Concepts of sampling
- Guidance on specification of sampling plans for foods</td></tr>
<tr><td>Section 1: Purpose
- Purpose
- Target audience
- Users of sampling plans recommended by the guidelines
- Scope
- Relationship with ISO</td></tr>
<tr><td>Section 2: Main Notions
- Introduction
- Common terms
- Sampling procedures
- Estimation errors
- Types of single sampling plans
- Cost of sampling</td><td>Revise and replace:
- Definitions
Revise other parts, and replace as needed (not including the physical taking of the samples from the lot under examination, currently covered in GL50, section 2.3).</td></tr>
<tr><td>Section 3: Selection of sampling plans for single or isolated lots in international trade
- Sampling procedures for inspection by attributes indexed by LQ
- Two and three class attributes plans
- Sampling plans for average control</td><td rowspan="3">Replace with:
- Sampling plan tools (containing links to apps of sampling plans tools, rather than the larger document full of tables, plots and formulae)
- Other technical guidance e.g. sampling of bulk materials, sampling of non-homogeneous lots, measurement error (refer Appendix: Prioritisation)</td></tr>
<tr><td>Section 4: Selection of sampling plans for a continuous series of lots from a single source
- Single sampling plans for inspection of defective percentage by attributes
- Single sampling plans for inspection by variables for % nonconforming
- Variable sampling plans with unknown standard deviation
- Variable sampling plans with known standard deviation
- Single sampling plans for average control</td></tr>
<tr><td>Section 5: Selection of sampling plans for variables in bulk materials
- General
- Sampling procedures for inspection of individual lots</td></tr>
<tr><td>Section 6: References</td><td>Revise and replace:
- Links to other sources of scientifically valid sampling plans</td></tr>
</table>

APPENDIX IV

LIST OF PARTICIPANTS

Member / Observer		**Organisation**
New Zealand	Dianne Foley	Ministry for Primary Industries
Australia	Kate Slater	Department of Agriculture and Water Resources
Argentina	Gabriela Catalani	Agroindustry Ministry
Japan		Ministry of Health, Labour and Welfare
Dominican Republic	Fatima del Rosario Cabrera	Ministerio de Salud Publica v Asistencia Social
IDF	Aurelie Dubois	International Dairy Federation
India	Suni Bakshi	
Poland	Magdalena Kowalska	
Brazil	Ligia Lindner Schreiner	
Norway	Norwegian Food Safety Authority	
Egypt	Mariam Barsoum Onsy	Egyptian Organisation for Standardisation & Qyuali
South Africa	Malose Matiala	Department of Health
Germany	Katrin Franks	BVL
IDF	Jaap Evers	New Zealand
IDF	Robert Crawford	New Zealand
Australia	Richard Coghlan	NMI
USA	Greg Noonan	FDA
Australia	Karina Budd	Department of Agriculture and Water Resources
Japan	Takahiro Watanabe	National Institute of Health Sciences
Japan	Hidetaka Kobayashi	Ministry of Agriculture, Forestry and Fisheries
Japan	Yukiko Yamada	Ministry of Agriculture, Forestry and Fisheries
Canada	Barbara Lee	Health Canada
The Netherlands	Henk van der Schee	NVWA
Canada	Thea Rawn	Health Canada
Iran	Samaneh Eghtedari	Isiri
Switzerland	Gerard Gremaud	Swiss Federal Food Safety and Veterinary Office
Uruguay	Pedro Friedrich	Laboratorio Technologico del Uruguay
Norway	Stig Valdersnes	Institute of Marine Research
India	Anoop A Krishnan	Export Inspection Agency - Kochi Laboratory
India	Surender Singh Raghav	Food Research & Standardisation Laboratory (FSSAI)
India	Manish Paradkar	ITC Limited
The Netherlands	Yannick Weesepoel	RIKILT - Wageningen University and Research
India	Dr Akanksha	OmniActive Health Technologies Ltd
Ecuador	Victor Hugo Almeida Arteaga	Ministerio de Salud Publica del Ecuador
United Kingdom	Chelvi Leonard	Food Standards Agency
Iran	Arasteh Alimardani	Novin Saffron Co.
Uruguay	Laura Flores	LATU

Member / Observer		**Organisation**
Republic of Korea	Chaehyung Kim	Ministry of Food and Drug Safety
South Africa	Ephraim Moruke	Department of Agriculture, Forestry and Fisheries
Nigeria	Gbemenou Joselin Benoit gnonionfin	Ecowas Commission
Thailand	Rungrassamee Mahakhaphong	ACFS
Thailand	Chanchai Jaengsawang	Department of Medical Sciences
Turkey	Sinan Arslan	Republic of Turkey Ministry of Food, Agriculture
American Oil Chemists Society	Scott Bloomer	
Kazakhstan	Zhanar Tolysbayeva	The Ministry of Healthcare

APPENDIX V

SUMMARY OF RESPONSES – FIRST ROUND

	Key questions	***Summary of comments***
1	GL 50 is not used often by commodity committees. It has been referred to as 'too difficult and confusing'. There is confusion about the 'compliance of the result' versus 'compliance of the product or lot'. There are some key areas not covered, including sampling plans for bulk materials as well as measurement error.	
	Will this approach of an outline of guidance and the sampling plan tools help commodity committees understand the purpose of sampling and the sampling, and the key points needed to design suitable sampling plans?	*There was strong support for the approach presented (guidance and sampling plan tools). There was general support to include bulk sampling and measurement error in the sampling plan tools. One participant noted that these additions were very important - but the work to make the GL simpler and more understandable and user-friendly shall be given the highest priority. All participants expressed interest in a workshop to discuss the sampling plan tool.*
2	We have described a new approach of guidance and tools.	
	Should it be part of a new GL 50?	*There was agreement that the proposed workshop would be useful to understand the tool. Most participants agreed that this new approach of guidance and tools should be a part of the revised GL 50. One participant commented that the guidance document may be better as an accompanying document to GL 50, and linking it to the new GL 50.*
	Would it be helpful for a workshop to be held prior to CCMAS 39 to explain the principles behind sampling and to demonstrate the use of this tool?	*There was strong support for the workshop to be held at CCMAS 39.*
Questions that will help guide direction of the new GL 50		
3	Lots referred to by Codex may be bulk materials, or they may consist of discrete objects e.g. shipments of pre-packaged foods, fruits and vegetables. The sample size versus lot size relationship is applicable only for lots consisting of discrete objects: the GL 50 tables are not relevant to bulk materials.	
	Should GL 50 include written information on sampling plans for bulk materials? Or should a sampling plan tool be available for use? Or uplift plans or the basis for plans from reputable literature?	*There was general support for the inclusion of bulk materials. One participant suggested to define the number of sampling plans for bulk materials. One other participant noted that inclusion of bulk materials is out of scope, but may need to be considered in the future. There was support for the development of the sampling plan tool in R. One participant suggested include ways to decide the optimal mass of the primary sample (e.g. mass required to give optimal measurement uncertainty). There was also support for also including sampling plans from reputable literature.*
4	The lot size versus sample size relationship is not mathematical, it is essentially arbitrary with the general intention that there will be less chance of making an incorrect decision for larger lots where the costs of making an incorrect decision are greater.	
	Should GL 50 include sampling plans that do not reference lot size?	*There was agreement to include sampling plans that do and do not reference lot size.*

	Key questions	***Summary of comments***
	Or should a sampling plan tool be available for use?	*One participant suggested to also explain that theoretically this parameter is not relevant. There was strong support for the use of a sampling plan tool to develop the appropriate sampling plans. One participant also commented that mostly, sampling plans are on a basis of probability (application on statistics), meanwhile sampling plans without a statistical basis should not be included in the revised GL 50, as it will cause confusion. However, when it is needed, sampling plans without a statistical basis could be used on a case by case basis. There was support for the availability of the sampling plan tool.*
5	AQL based plans, as set out in GL 50, may be better intended for use in supplier-customer relationships quite possibly for situations where the product is further processed. · In these situations there might be less need for higher levels of consumer protection. Otherwise, for product intended more for direct consumption, we are interested in ensuring consumers receive product of acceptable quality, i.e. protecting consumer's risk.	
	Should GL 50 include alternative approaches to the design of sampling plans?	*There was support for alternative approaches based on current standards for sampling. One participant suggested GL 50 should contain recommendations for sampling plans to protect consumers, and another member commented that GL 50 are for the sampling to check the compliance with the Codex Standards. This participant also noted that the decision on the acceptable level of the "probability of incorrect decisions" (ref. the reports of the 33rd and 34th CCMAS)..*
	Or should a sampling plan tool be available for use?	*There was strong support for the sampling plan tool*
	Or uplift plans or the basis for plans from reputable literature?	*There was also support for tools as an R based app or excel sheet with examples of sampling plans and tables of sampling standards are recommended, while remaining readable.*
6	We have developed tools for the design of sampling plans by using the OC curve. This approach specifies the AQL & LQ, and works out the 'n' and the acceptance number 'c' from this for attribute plans, or for variables plans, the 'n' and the acceptability constant 'k'. The tools allow the probabilities of acceptance or levels out of specification corresponding to specified levels of acceptance to be calculated.	
	Are these tools, along with the guidance, able to make the design of sampling plans understandable? Are the tools useful to enter information from different references, and see the resulting OC curves?	*There was support for the sampling plan tool making the design of sampling plans understandable. One participant commented that being able to test the impact as one changes the parameters will aid groups in developing appropriate sampling plans, with knowlede of the impact of changing different aspects eg sample numbers etc. There was also agreement that allowing commodity committees to use the sampling plan development tool, once guidance is provide relating to the AQL or LQ would be helpful. The role of measurement uncertainty was raised with a request to explain how*
7	As an alternative to selecting specific sampling plans, should the guidance allow for commodity committees to prescribe AQLs	*There were different views on this – that the guidance allows for commodity committees to select for AQL and or LQs, versus this will*

	Key questions	*Summary of comments*
	and (and/or?) LQs and then leaving it to users to determine a suitable plan from whatever resources they have available, including GL50?	*lead to inconsistency between sampling There was acknowledgement that the sampling plan tool makes it easier to select an appropriate tool, but recognition that some codex standards specify an AQL outcome.*

SUMMARY OF RESPONSES – SECOND ROUND

	Key questions	*Summary of comments*
1	*Do you agree with the proposed outline of a new CAC/GL 50?*	*There was agreement with the proposed outline, noting that it provides a 'simpler document' and retains much of the current structure of GL 50*
	Are the appended examples of sections that may be part of a revised GL 50 useful?	*The participants commented that the appended sections are useful and contain definitions needed to understand the concepts of sampling and the sampling tool. Replacing the examples, formulas and calculations by applications is supported. One participant suggested not to put these same examples including formulas and calculations in the new GL 50 unless it is necessary. One participant suggested they could go into an Information Document.*
2	*Is the project document realistic, especially noting the timeframes?*	*There was agreement that the project document timeframes seem reasonable.*
3	*Is the prioritisation list suitable?*	*There was generally agreement with the proposed prioritisation list from some participants. However, some participants suggested that the prioritisation list also needs to include information about sampling for microbiology and two- and three-class sampling plans, along with inclusion or references to any relevant sampling plan tools, for example the WHO/FAO sampling tools for microbiology and histamine. One participant suggested the prioritisation list should also include sampling techniques for sampling plans.*
	Are there any other items to be included, or changes to the priority that should be done?	*There was agreement with the priority list.*
4	*Comments*	*There was a number of comments recommending some minor amendments (for clarity) were put forward. Some comments could not be actioned, for example a suggestion to change wording when the statement in question was from an issued Codex guideline.*