CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 9 **MAS/38 CRD/19**

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

38th Session
Budapest, Hungary, 8 -12 May 2017

PROPOSAL TO AMEND THE *GUIDELINES ON SAMPLING* (CAC/GL 50-2004): DRAFT PROJECT DOCUMENT

(Prepared by New Zealand)[1]

1 Project document

This draft project document is set out in accordance with the Codex Procedural Manual project d ocument process.

2 The purposes and the scope of the standard

The purpose of this proposed new work is to produce a project document for the **revision** of the General Guidelines on Sampling (CAC/GL 50-2004).

3 Relevance and timeliness

At the CCMAS37 there was discussion of the usefulness of the General Guidelines on Sampling (CAC/GL 50-2004). Some members expressed the view that the current guidelines were difficult t o understand. An electronic working group (eWG) considered specific terms of reference as follo ws:

- Identify how CAC/GL 50-2004 is meeting the stated Rationale and Purpose (Preamble a nd Section 1 of the current Guidelines), and if required, update the Rationale and Purpose to en sure the revised Guidelines will be fit for purpose.

- Identify any improvements needed to meet the Rationale and Purpose, including conside ration of how the Guidelines should be structured to ensure coherence with other Codex docume nts dealing with sampling.

- Prepare a proposal for new work and an associated project document.

In addition, the eWG would take note of the discussion at the 37th session and the work on pra ctical examples on the selection of appropriate sampling plans as contained in the information do cument.

This document will meet the requirements for the third term of reference.

3.1 DEVELOPMENT AND ESTABLISHMENT OF GL 50

[1] Based on a review of the EWG responses

3.1.1 CCMAS19 (1995)

The Guide was intended to be a useful guide to governments (food inspectors), traders (importers and exporters) and food producers who wish to maintain the quality of their products. The document was intended for use by governments or organizations in developing their national or organizational policy guidelines on sampling. It was intended that it should be applicable to all commodities including pesticide residues, veterinary drug residues, aflatoxins and toxic elements.

3.1.2 Date of Establishment

CCMAS began work on the Guidelines in 1992 at the 18th session of CCMAS, following preliminary work dating back to the 15th session (1986) and discussion at intervals dating back to the 4th session in 1968.

The Guidelines were developed by several working groups, and specialist work was undertaken by three consultants, the FAO (Food Quality and Liaison Group of the Food Policy and Nutrition Division) and the Codex Secretariat. Part of the development work involved revision with an objective to make it easier, simpler and more user-friendly by using appropriate structure and wording in view of the general opinion that, at the time, it was very complicated and difficult to understand and therefore it required revision to make it easier for both government officials and Codex commodity committees.

Discussions also noted the possible need for a 'manual of sampling' for use by Codex commodity committees, and the need for worked practical examples.

The Guidelines were finalised at CCMAS25 and adopted by the Commission in 2004 as the Codex Guidelines on Sampling CAC/GL 50(GL 50, the guidelines).

There have been no subsequent amendments.

3.1.3 Associated Documents

The 'Principles for the Use of Sampling and Testing in International Food Trade' (CAC/GL 83-2013)(GL 83) is intended to provide assistance in assessing impacts of sampling and testing procedures on affected parties, specifically referencing GL 50 .

GL 83 advances GL 50 in certain ways including definitions, the need to understand GL 50 in order to use it effectively, principles on appropriate sampling procedures and other sampling references. GL 83 definitions include 'sampling procedure' , as well as linking to GL 50 and the Guidelines on Analytical Terminology (CAC/GL 72-2009)(GL 72) to ensure consistency of other key definitions (lot, consignment, sample, sampling plan).

GL 83 recognises the role of GL 50 ('the specification of the principles concerning acceptance or rejection of a lot or consignment e.g. General Guidelines on Sampling (CAC/GL 50-2004)') as well as the need to understand GL 50 ('full knowledge and understanding of the procedures and the inherent probabilities of wrongly accepting or wrongly rejecting a lot').

GL 83 provides additional explanation on the selection of sampling plans, and references the relevant parts of GL 50.

GL 83 also provides explanation on the scope of GL 50 and the considerable information available from elsewhere, e.g. international standards, such as ISO 2859 (Inspection by attributes), ISO 3951 (Inspection by variables) and ISO 10725 (Inspection of bulk materials), and published papers and textbooks, should be consulted when developing appropriate sampling plans.

4 Main aspects to be covered in the proposed revision

1. Update to the rationale and purpose to a proposed scope for the revision of GL 50 (refer Appendix 1)
2. A prioritised combination of general and technical improvements to deliver an updated GL 50 that is comprehensive, understood and used by Codex commodity committees, and implemented in the event of trade disputes
   - Prioritised general and technical improvements are in Appendix 2.

5 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 f ood trade and taking into account the identified needs of developing countries.

Criteria applicable to general subjects

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

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

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

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

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

6 Relevance to the Codex strategic objectives

This proposal for new work is within the scope of the Codex Strategic Vision Statement 'To be th e preeminent international food standards-setting body to protect the health of consumers and en sure 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 is sues

Objective 1.1: Establish new and review existing Codex standards, based on prioriti es of the CAC.

Activities 1.1.1: Consistently apply decision-making and priority setting criteria across Committe es to ensure that the standards and work areas of highest priority are progressed in a timely ma nner.

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

7 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 (CAC/GL 83-2013)
2. Guidelines for Food Import Control Systems (CAC/GL 47-2003)
3. Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007).
4. Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLs (CAC/GL 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 (CAC/GL 71-2009)
6. General Standard for Contaminants and Toxins in Food and Feed (GSCTF, CODEX STAN 193-1995)
7. Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods (CAC/GL 21 - 1997)
8. Guidelines for Food Import Control Systems (CAC/GL 47-2003)

9. Guidelines for Settling Disputes over Analytical (test) Results (CAC/GL 70-2009)[2]

Documents under development:

10. [Under CCMAS review] Information Document on Practical Examples on the selection of appropriate sampling plans

8 Identification of any requirement for and availability of expert scientific advice

9 Identification of any need for technical input to the standard from external bodies so that this can be planned for

Expert scientific advice will be needed to provide for the prioritised improvements so it is technic ally complete and understandable. Technical input from external bodies may also be needed. In a ddition, external technical drafting and editing resourcing will be needed.

[Consider other examples within Codex eg CCFH work]

Also there are other important and relevant factors that an updated GL 50 needs to cover, includi ng the relationship between GL 50 and other international sources of sampling guidance.

The amount of work to address agreed improvements will be significant. A structure to prioritise t he work, both resourcing as well as a timeline will need to be considered once there is agreeme nt on the improvements.; a method of achieving it should be explained, and the impact of the inf ormation document on practical examples should be considered.

In order to quantify what may be required, New Zealand suggests identifying some priority areas to be worked on during the intersessional time when the proposal for new work is being worked on by the eWG. These priority areas will be used to gauge the amount and extent of expert advi ce needed and the best way to achieve this. The work on these priority areas will then be used as a basis for the document wide process. Refer Appendix 3.

10 The proposed time-line for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years.

Time	Action	Process to deliver this
CCMAS 38 May 2017	Agreement to proceed with recommendati ons for the proposed 'revision' of GL 50	
Between CCMAS 38 and CC MAS 39	eWG produce a project document as set out in the CPM including prioritisation, re sourcing, timeline and plan for provision of expert advice	
	Identification of some priority areas and progress these as examples for the deve	

[2] 3 Possible reasons for disagreement may include one or several causes such as: the existence, appropriateness and statistical validity of the sampling plan used to assess the product; the allowances made for normal measurement error and within-lot product variation; differences in physical sampling procedures; differences in composition of the samples tested due to product in homogeneity or changes occurring during storage and/or transport of the product.

Time	Action	Process to deliver this
	lopment of the 'revised' GL 50	
CCMAS 39	Agreement to project document proposal, and process, resourcing, timeline and co ntent presented in examples, and provide recommendation to CAC to proceed wit h the revision of GL 50	
CAC 2018	Agreement to approve the proposal for the revision of GL 50 as new work and the approved n ew work will be referred for consideration to CCMAS	
Refer CPM: Section II: Elaboration of Codex texts Part 4. Uniform Accelerated Procedure for the Elaboration of Codex Standards and Related Texts		
Between CCMAS 39 and CC MAS 40	EWG prepare, with expert advice prepara tion of the agreed parts of the the revise d GL 50.	
CCMAS 40 2019	Agreement to the agreed parts of the rev ised GL 50.	
Continue this process until the agreed updates have been completed. The expected timeline wi ll be set out in the project document. The Steps for the agreed Revision will be followed with t he intended outcome being adoption by the Commission.		

11 Appendix 1: Proposed scope for the revision of GL 50

The Guidelines for Sampling are intended to provide **guidance** so that the **principles for the use of sampling in international food trade, including fair and valid sampling procedures,** are **understood**. This, along with **knowledge of the commodity characteristics including how the commodity is traded internationally**, will provide a **basis for certain sampling plans** intended to be adopted by Codex, for **use when food is being tested for conformance with the relevant parameter of a particular Codex commodity standard.**

- **Guidance** for when statistical food control is needed, or alternatives to this
- Referring to **the principles for use of sampling in international food trade** in GL 83.
- **Understood** so that the information in GL 50 is clear, and set out so that Codex commodity committees or governments can determine risk, as well as what the sampling plan will deliver, to manage allowable risk.
- **Knowledge of the commodity characteristics including how the commodity is traded internationally** so that GL50 will provide for a detailed and succinct sampling plan, based on knowledge of the commodity characteristics, including characteristic distribution within the commodity, and how the commodity is traded internationally is required.
- **Used as a basis for certain sampling plans** developed by Codex commodity committees, where GL 50 may be the primary source of information, noting that in some situations, alternate sources of guidance on sampling plans may be used

  Used when food is being tested for conformance with the relevant parameter of a Codex commodity standard, such as in international trade disputes

12 Appendix 2: Improvement of GL50: categorisation of topics

(Key words in each topic highlighted.)

12.1 **FORMAT**

1. Reviewing how information in GL 50 is set out, in relation to how user-friendly this is. This includes recognising the key audience ranges from non-scientists through to statisticians, and include separate parts to cover principles, general technical explanations, and specific statistical guidance
2. Review the options for presenting this information to the audience, for example, alternative approaches taken by other Codex Committees such as the use of external expertise to develop such material
3. Limiting this guidance to only the scope of CCMAS

12.2 **CONSIDERATION OF OTHER CODEX DOCUMENTS**

GL 50 should consider, and not overlap with other Codex guidance on sampling. A future objective may be that all Codex guidance on sampling should appear in a single document. [Note Principles, Pesticides, Vet Drugs, Food Import, Measurement Uncertainty, Settling Disputes.]

4. In the interim, this improvement needs to include Clarity on the sampling guidance and other related documents such as the Information Document on Practical Examples, and how they relate to each other
5. Seek input to practical examples from other Codex committees (as requested by CCMAS36), as well as examples from within their field of competence for which they would like to use, or should use, GL 50
6. Updating GL 50 to reference GL 83, and incorporate the key principles and explanatory notes
7. Additionally, how this aligns with the GL 47 (Guidelines for Food Import Control Systems)
8. the relationship to the document on the use of analytical results: sampling, relationship between the analytical result, the measurement uncertainty, recovery factors and the specification in Codex standards
9. Review the sampling information in the Codex Procedural Manual, to ensure alignment

12.3 **REVIEW**

10. Review and update section 1.5 ISO Standards of GL 50,
11. Review the work on practical examples on the selection of appropriate sampling plans as contained in the information document (CCMAS37)
12. Review of the criteria for judging when measurement error is negligible
13. A review of the sample sizes involved as these have an important impact on the costs of sampling, testing and administration. These numbers come from the specification of producers' and consumers' risk, although there are statistical methods to achieve the same risk outcomes with economical levels of testing (in some/many situations)
14. Review of GL 50 to correct any errors, and correction of these. Suggested amendments to date are: … *[list of required editing]*
15. Reviewing the role of sampling uncertainty when assessing conformance (already taken into account in the existing GL50 and will be in any future work based on a statistical approach)

12.4 **NEW GUIDANCE**

16. Targeting basic sampling guidance 'generally applicable to a number of foods' which can be built upon in more complex situations and make it practical so the reader derives a detailed sampling plan to meet their needs.
17. An initial section discussing the principles of acceptance sampling and how it works, and how to determine a sampling plan for a particular application
18. A focus on the information needed by Codex commodity committees that own various Codex standards, and how to consider 'consumers' risk' and 'producers' risk' when selecting sampling

plans include guidance on re-inspection, and on selection of appropriate AQL and LQ, along with specific examples.

19. Provide more useable or simplified advice on the practical implementation, i.e. GL 50 provides guidance on what sampling plan might be applied under what circumstance; the step from that to practical implementation is not always understood by Codex commodity committees

20. Provide information on other sources of sampling procedure guidance, and clarifying the relationship to GL 50, and relevance to the sampling of foods for international trade, for example, methods of physical sampling may be commodity specific

21. Review of the situation regarding 'lots viewed in isolation' and 'continuous series' of lots. In particular whether the current focus on Limiting Quality and producers' risk is in general appropriate for isolated lots, and whether an update should consider the producers' side of the equation in these cases.

22. A section describing how Codex commodity committees decide on the appropriate 'consumers' risk' and 'producers' risk', and the implications in term of quality of product they are standardising, as well as how to develop a sampling plan to achieve these desired levels of risk (there would be tables, programmes or tools)

23. Guidance on how the parties (in an ideal situation, the customer and supplier, but often the customer will set a plan unilaterally) decide on which sampling plan the customer will use[3] and how the supplier should set an appropriate sampling plan

24. Consideration of where further guidance outside of GL 50 may be useful, for example, CCMAS could prepare guidance where measurement error does, and does not need to be taken into account in the conformity assessment criterion[4]

12.5 **TECHNICAL IMPROVEMENTS MAY INCLUDE:**

25. The application of 'consumers' risk' and 'producers' risk'. Essentially random sampling or an assumption thereof, is the only simple way a sampling plan can be designed in order to control producers' and consumers' risk

26. Sampling plans in the presence of significant measurement error (GL 50 does not cover the control of homogeneous goods in cases where measurement error is not negligible compared to sampling error). Considerations of situations where there is significant measurement error

    Consideration of the use of analytical results when sampling procedures are developed |for the situation where measurement error is significant relative to sampling uncertainty. This is currently not included in GL 50

27. Sampling of materials sold in bulk, especially about the use of the terms 'consumers' risk' and 'producers' risk'. Considerations of assessments made on bulk commodities

28. Distinguishing between the various components of measurement error, and potential increases (or decreases) in 'consumers' risk' and 'producers' risk'

29. Defining, or referring to Codex definitions for commonly used terms, for example the terms; conformity assessment, sampling inspection, lot, consignment, and homogeneity[5]

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[3] Use of the same sampling plan might lead to unacceptably high risks that products of marginal quality [that having a moderate chance of being accepted] might be accepted by the producer but subsequently failed by the customer.

[4] GL 50 covers this but does not distinguish between the various components of measurement error, or consider potential increases in risk to either producers or consumers.

[5] The traditional definition of homogeneity is that the characteristic [e.g. fat content] follows the same distribution in all parts of the lot [or the quantity of product being considered]. This does not take into account that inhomogeneity is not a problem for product compliance when the characteristic is operating far from a specification limit – so closeness to specification must be taken into account. An

30. Simplifying the way in which sampling plans are presented (noting that any alternative, simpler, sampling plans should be formulated taking account of the producers' and consumers' risk, and the costs of wrong decisions)
31. Alternatives to GL 50 sampling plans for single test
32. Methods for control of the lot mean
33. Indexing of sample sizes to lot size, for lots consisting of discrete items (ISO has decided this)
34. Composite sampling approaches
35. Considerations of assessments of inhomogeneous lots or shipments comprising product manufactured in differing manufacturing lots. Clarification on what stratified sampling means, and how it can be used
36. Sampling of bulk materials, for control of the fraction non-conforming
37. Guidance on when a test for mean levels is appropriate, and when a test for 'percent defective' is appropriate
38. Determining how a science-based approach applies to 'pragmatic' or 'simplified' approaches to acceptance sampling
39. Inclusion of background information and theories, as well as more descriptions for implementation of the given tables should be included, i.e. sampling procedures for inspections of a specific commodity and groups of commodities (and existing Codex documents could be used as examples, e.g. GL 33 Pesticide)
40. Amendments to clauses carried forward, as needed

alternative … that to be considered homogeneous all parts of the lot should be running at the same level out of specification.

13 Appendix 3

Priority area	Proposed outcome	Expert advice needed or Technical input from external bodies	Other matters to consider: - Expected date for completion - Other resourcing requirements
An initial section discussing the principles of acceptance sampling and how it works, and how to determine a sampling plan for a particular application			
Sampling of materials sold in bulk, especially about the use of the terms 'consumers' risk' and 'producers' risk'. Considerations of assessments made on bulk commodities			