CODEX ALIMENTARIUS COMMISSION

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Agenda Item 9 **CX/MAS 17/38/9**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

38th Session

Budapest, Hungary, 8 - 12 May 2017

PROPOSAL TO AMEND THE *GENERAL GUIDELINES ON SAMPLING* (CAC/GL 50-2004)

(Report prepared by New Zealand)[1]

1 Proposal for new work

This document sets out the responses to an electronic working group (eWG) discussion paper to review the rationale and purpose of the General Guidelines on Sampling (CAC/GL 50-2004), as well as any improvements to the Guidelines, and consideration of how to align any changes to GL 50 with other Codex documents dealing with sampling.

Although one of the Terms of Reference for this work included preparation of a project document, we believe an interim approach is preferable given the large amount of work for the revision of GL 50, identified through the eWG. We have therefore prepared this document as a review paper. We suggest that this format would be useful for discussion at the 38th session of CCMAS. Depending of the outcome of this discussion, New Zealand will draft a project document, as set out in the Procedural Manual, to complete the requirements set out in the Terms of Reference.

1.1 RECOMMENDATION

1. We recommend that this review paper is discussed at the 38th session of CCMAS, noting the strong support from the eWG to proceed with a revision of GL 50, and in particular, the rationale and purpose (sections 5 & 6 of this document) and the list of improvements.
2. We recommend that CCMAS agree on a method to achieve this work, in particular its prioritisation, and the means of undertaking the first priority work.

2 Background

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 to understand[2]. Following these discussions CCMAS agreed to establish an electronic working group (eWG) chaired by New Zealand and working in English to develop a discussion paper for consideration by the next session of CCMAS. The specific terms of reference of the eWG as agreed at CCMAS37 are as follows:

- Identify how CAC/GL 50-2004 is meeting the stated Rationale and Purpose (Preamble and Section 1 of the current Guidelines), and if required, update the Rationale and Purpose to ensure the revised Guidelines will be fit for purpose.
- Identify any improvements needed to meet the Rationale and Purpose, including consideration of how the Guidelines should be structured to ensure coherence with other Codex documents dealing with sampling.
- Prepare a proposal for new work and an associated project document.

The Committee noted that in developing the discussion paper, the eWG would take note of the discussion at the 37th session and the work on practical examples on the selection of appropriate sampling plans as contained in the information document. It would also note feedback from Codex committees (as requested by CCMAS36) who would provide examples from within their field of competence for which they would like to receive advice from CCMAS.

[1] Based on a review of the EWG responses

[2] REP16/MAS 14: The Committee noted that when considering sampling plans in standards for fish and fishery products, CCFFP34 had found that the *General guidelines on sampling* (CAC/GL 50-2004) were difficult to understand and use and had proposed that CCMAS consider improving the user-friendliness of the guidelines.

3 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. A list of the participants is in Appendix II.

We provided a discussion paper to all those who agreed to participate. We received 8 responses from colleagues in Australia, European Commission, International Dairy Federation (IDF), Japan, Netherlands, Norway, Thailand and Uruguay. The responses were based on the questions we asked:

1. What is the current scope of GL 50:
    - What does it cover?
    - What does it not cover?
2. How has GL 50 been used, since its introduction:
    - What sampling plans have been developed using guidance from GL 50?
    - When has GL 50 been used as part of an international trade dispute?
    - Have national regulations or practice been based on GL 50?
3. Responding to Term of Reference 1:
    - • Identify how CAC/GL 50-2004 is meeting the stated Rationale and Purpose (Preamble and Section 1 of the current Guidelines), and if required, update the Rationale and Purpose to ensure the revised Guidelines will be fit for purpose
    - Is GL 50 meeting the stated Rationale and Purpose?
    - How could the current Rationale and Purpose be updated in a revised GL 50?
4. Responding to Term of Reference 2:
    - • Identify any improvements needed to meet the Rationale and Purpose, including consideration of how the Guidelines should be structured to ensure coherence with other Codex documents dealing with sampling
    - Is the proposed introduction and scope a suitable update to the current Rationale and Purpose?
    - What are the improvements needed to meet any update to the current Rationale and Purpose?
    - What other general and technical improvements are needed?
    - What about other Codex sampling guidance; is the list included in this paper a complete list?
    - How should Codex sampling guidance align across Codex, and how should GL 50 align with other Codex sampling information?
    - How should GL 50 relate to other Codex documents dealing with the use of conformity assessment?
5. How have the other sources of explanatory information helped in the understanding of GL 50:
    - Have the Principles for the Use of Sampling and Testing in International Food Trade (CAC/GL 83-2013) been useful?
    - Is the draft 'Information Document on Practical Examples on the Selection of Appropriate Sampling Plans'[3] likely to provide clarity for some or all of the sampling plans in GL 50?
6. In addition to revising GL 50 to improve the content and understanding, it is valuable to understand how Codex commodity committees see it being potentially used:
    - What are examples from Codex commodity committees that GL 50 could reasonably be used for?

[3] REP16/MAS: Noting comments are requested on the Information document on Practical examples on the selection of appropriate sampling plans by November 30 2016

7. Responding to Term of Reference 3:

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

    This phase of work will proceed once the eWG responses to questions 1 – 6 above have been collated.

New Zealand notes the effort and time that went into the comprehensive replies made by the eWG respondents. These comments provided a lot of input into the technical components of this document. We would like to sincerely thank all those who participated in the eWG.

3.1.1 EWG Response - General comments

Respondents agreed that the discussion paper covered the terms of reference well and was therefore, a good starting point, but that the volume of proposed work is considerable, and so prioritisation of the work and use of external experts was needed.

Other general comments made were:

- Noted the various factors to be considered when selecting sampling plans; notably the need to agree on the acceptable level of risk relating to each parameter. These risks are often not stated.
- Noted the similarities between GL 50 and other standards for sampling plans, and pointed out their theoretical weaknesses in view of the assumptions on which they are based as compared to the real situation of sampling and verification of food in international trade.
- Suggested that further theoretical information is not needed in GL 50, but some rearrangement of the content could be helpful, e.g. in the Preamble and Purpose, as well as consideration of other guidance on food sampling.
- Suggested that advice on how to determine acceptable risks, and how to develop or select appropriate sampling plans is needed. GL 50 could also include concrete and typical examples of sampling plans with detailed explanation of the basis for each plan.

3.1.2 EWG Response - GL 50 Scope

We asked respondents to consider what the current scope of GL 50 is, and what it covers, and does not cover.

While respondents agreed with the coverage of GL 50 as described in section 4.2 of the discussion paper, they noted in particular that GL 50 does not specifically cover bulk commodities or situations with significant measurement error, and that it does not define acceptable producer and consumer risks. It provides limited examples, and hence does not necessarily provide the reader with a practical plan to implement.

Respondents also noted that of necessity it presents complex statistical concepts, and hence it is complex to many laypeople.

3.1.3 EWG Response - Term of Reference 1

We asked respondents whether GL 50 is meeting the current Rationale and Purpose, and whether they agreed with a suggested update, or whether they could provide an alternative to this.

Respondents had mixed views on whether GL 50 is meeting the stated Rationale and Purpose:

- some considered it is, and that it is clear and comprehensive, others considered it is not, or not in all aspects.
- one respondent noted feedback from commodity committees suggests they expect GL 50 would do more than just 'contain the elementary principles of statistical control at reception'.

Respondents also had mixed views on the proposals to update the rationale and purpose:

- some agreed with the proposals, and there was a suggestion for additional areas that should be included to cover situations that are common in trade.
- some did not agree with the proposed update, and that the current Rationale and Purpose should be retained. One respondent commented that the expectation of commodity committees is that GL 50 will provide a detailed and succinct sampling plan, but to achieve this, it will require detailed knowledge of the commodity characteristics, including characteristic distribution within the commodity, and how the commodity is traded internationally is required.

3.1.4 EWG Response - Term of Reference 2

We asked respondents whether any improvements are needed to meet the Rationale and Purpose.

We received many useful comments on this.

Most respondents considered the proposed scope for updating the Guidelines was suitable, but that the work was significant and that there needed to be an agreed process to achieve it. Included in this would be clarity on the relationship of the information document on practical examples with the updating of the Guidelines.

This work should align, and not overlap, with other Codex guidance on sampling. One respondent suggested that ideally all Codex guidance on sampling should appear in a single document.

There were no suggestions for improvement of the list of other Codex guidance for sampling procedures.

3.1.5 EWG Response - Other sources of information to support GL 50

We asked respondents how other sources of explanatory information has helped in their understanding of GL 50, and in particular, whether the Principles for the Use of Sampling and Testing in International Food Trade (CAC/GL 83-2013) had been useful. We also asked whether the 'Information Document on Practical Examples on the Selection of Appropriate Sampling Plans' was likely to provide sufficient clarity for some or all of the sampling plans in GL 50.

Respondents agreed that GL 83 was useful but that these guidelines were intended as broad principles rather than detailed sampling guidance and more introductory material to explain the principles of sampling and how to determine a sampling plan for a particular application was needed.

Respondents agreed that the Practical Examples seemed likely to be helpful, however they might be seen as 'how to do it' rather than examples. It was also noted that background information and theories should be included, 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).

3.1.6 EWG Response - Use of GL 50 by Codex commodity committees

We asked respondents to provide some examples from Codex commodity committees that GL 50 could be used for, to help guide improvement of the content and understanding.

Respondents did not provide examples of where GL 50 could be used.

One respondent suggested that the guidelines could potentially be used for any non-microbiological parameter covered by a Codex standard.

One respondent proposed that CCMAS should develop, rather than endorse, sampling plans based on information provided by commodity committees, given the difficulty of commodity committees to elaborate sampling plans.

Proposal for discussion - new work to revise the *General Guidelines on Sampling* (CAC/GL 50-2004)

4 A general summary of GL 50

4.1 GL 50 - BACKGROUND

4.1.1 Development and Establishment of GL 50

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.

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[4], 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.

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[5].

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’[6], 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.

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[4] Dr. Edward G. Schilling, Ph.D., P.E., Director and Professor, Center for Quality and Applied Statistics, Rochester Institute of Technology, New York, NY; Dr. Ray Coker, Ph.D., Principal Natural Products Scientist, Natural Resources Institute, Chatham, UK; and an unnamed Codex consultant.

[5] In the field of acceptance sampling, the probability of wrongly accepting a lot and the probability of wrongly rejecting a lot are referred to as “Consumers’ Risk” and “Producers’ Risk”, respectively.

[6] Operational requirements and/or instructions relating to the use of a particular sampling plan; i.e. the planned method of selection, withdrawal and transport to the laboratory of sample(s) from a lot or consignment to yield knowledge of its characteristic(s)

4.2 GL 50 - WHAT IT COVERS, WHAT IT DOES NOT COVER

1. GL 50 provides guidance on sampling and sets out sampling plans intended for use by Codex commodity committees or, if applicable, by governments in case of international trade disputes.
2. GL 50 is designed to be used when food is being controlled at reception[7] by statistical inspections for compliance with a particular Codex commodity standard. The sampling plans in GL 50 are designed to provide reasonable assurance that the producers' and consumers' risk as specified by the Codex commodity committees are achievable.
3. GL 50 covers:
    a. the control of homogeneous goods (with exceptions set out in point 4)
    b. the control of percentage of defective items using inspection by attributes or inspection by variables, for goods in bulk or in individual items
    c. the control of a mean content
    d. where measurement uncertainty is negligible relative to sampling uncertainty, the sampling plans are applicable for conformity assessment lot by lot, and no allowance for measurement uncertainty needs to be made.
4. GL 50 does not cover:
    a. the provision of sampling plans for non-homogeneous goods
    b. the control of homogeneous goods in cases where measurement error is not negligible compared to sampling error
    c. double, multiple and sequential sampling plans (too complex) and
    d. bulk commodities, or situations with significant measurement error.
5. GL 50 does give information on:
    a. how to proceed for sampling of heterogeneous[8] food
    b. recommendation not to prepare composite samples[9]
    c. the criteria for choosing an appropriate sampling plan[10] and
    d. a definition of acceptable producer and consumer risks and a practical plan to implement these.
6. GL 50 methods are only applicable in the absence of significant measurement error.
7. GL 50 does not provide for non-random sampling. 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. GL 50 covers cases where some items in a lot are compliant and some are not[11], without qualification, by means of simple attribute sampling plans.
8. GL 50 can be used, if applicable, by governments in case of international trade dispute.

[7] "reception" seems to mean the point of import (port of entry).
[8] If the lot is heterogeneous, a random sample may not be representative of the lot. In such cases, stratified sampling may be a solution. Stratified sampling consists of dividing the lot into different strata or zones, each stratum being more homogenous than the original lot. Then a random sample is drawn from each of these strata, following specified instructions which may be drafted by the Codex product committees. Each stratum can then be inspected by random sampling which usually includes from 2 to 20 items or increments per sample (see the sampling plans of ISO 2859-1 of letter-codes A to F at the inspection level II). But before sampling, it is necessary, where appropriate, to refer to the specific instructions of the Codex product committees.
[9] Composite samples are not to be recommended given the loss of information on sample-to-sample variation due to the combination of primary samples.
[10] According to considerations such as the type of characteristic; whether the lot is considered in isolation or is part of a continuous series; whether the measurement is qualitative or quantitative; and whether determining percentage non-conforming or average content
[11] Goods that are not homogeneous in that, say, one part of the lot has a large percentage of non-compliant items and another a small percentage can still be validly sampled using these plans provided that the sampling is random. It is only when sampling is non-random that an insistence on homogeneity is necessary

9. GL 50 sampling plans presuppose a random sampling of the entire lot; in acceptance sampling a ‘lot’ is the product to be accepted or rejected (in its entirety).

4.3 SAMPLING PLANS ADOPTED BY CODEX SINCE GL 50 WAS ESTABLISHED

Refer Appendix 1: Sampling Plans

5 Proposed update to the rationale and purpose

The rationale and purpose could be updated to include an introduction and scope. A draft scope may be:

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 that risk.
- **Knowledge of the commodity characteristics including how the commodity is traded internationally** so that GL50 will provide 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.

6 Improvements to meet the proposed update to the rationale and purpose

The proposed ‘scope’ will need a 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.

Improvements to GL 50 need to present the information so it is technically complete and understandable. Also there are other important and relevant factors that an updated GL 50 needs to cover, including how a science based approach applies to alternate options such as for ‘pragmatic’ sampling plans, as well as the relationship between GL 50 and other international sources of sampling guidance. Additionally, the relationship between GL 50 and the information document on practical examples needs to be considered.

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

General improvements may include:

- GL 50 should align, 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. 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
- Limiting this guidance to only the scope of CCMAS, and 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.

- 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
- Review and update section 1.5 of GL 50, and include guidance on re-inspection, and on selection of appropriate AQL and LQ, along with specific examples. Additionally, how this aligns with the GL 47 (Guidelines for Food Import Control Systems)
- An initial section discussing the principles of acceptance sampling and how it works, and how to determine a sampling plan for a particular application
- 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
- Updating GL 50 to reference GL 83, and incorporate the key principles and explanatory notes
- 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
- 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
- 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
- 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
- Consideration of other Codex documents dealing with sampling, and in particular, 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
- Review the work on practical examples on the selection of appropriate sampling plans as contained in the information document (CCMAS37)
- 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
- Review the sampling information in the Codex Procedural Manual, to ensure alignment
- Review of the criteria for judging when measurement uncertainty is negligible
- 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.

Technical improvements may include:

- 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 this desired level of risk
- 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
- 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

- Sampling plans in the presence of significant measurement uncertainty (GL 50 does not cover the control of homogeneous goods in cases where measurement error is not negligible compared to sampling error)
- Sampling of materials sold in bulk, especially about the use of the terms ‘consumers’ risk’ and ‘producers’ risk’
- Distinguishing between the various components of measurement error, and potential increases in ‘consumers’ risk’ and ‘producers’ risk’
- 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[12] and how the supplier should set an appropriate sampling plan
- Defining, or referring to Codex definitions for commonly used terms, for example the terms; conformity assessment, sampling inspection, lot, consignment, and homogeneity[13]
- 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)
- Alternatives to GL 50 sampling plans for single sample
- Methods for control of the lot mean
- Indexing of sample sizes to lot size, for lots consisting of discrete items
- Composite sampling approaches
- 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[14]
- Clarification on what stratified sampling means, and how it can be used
- Sampling of bulk materials, for control of the fraction non-conforming
  - Amendment to the following clauses
  - Guidance on when a test for mean levels is appropriate, and when a test for ‘percent defective’ is appropriate.
  - Determining how a science-based approach applies to ‘pragmatic’ or ‘simplified’ approaches to acceptance sampling
  - Reviewing the role of sampling uncertainty when assessing conformance
- Considerations of situations where there is significant measurement error, assessments made on bulk commodities, and assessments of inhomogeneous lots or shipments comprising product manufactured in differing manufacturing lots
- 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).
- Review of GL 50 to correct any errors, and correction of these. Suggested amendments to date are:

* Page 15, 2nd last line, (‘that is ~~1069~~ non-conforming’, should be ‘that is 1096 non-conforming…’
* Page 16, 2nd line, ‘(3136-~~1069~~), should be ‘(3136-1096)…’

[12] 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.
[13] 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 alternative … that to be considered homogeneous all parts of the lot should be running at the same level out of specification.
[14] 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.

- Page 34, EXAMPLES: (i) 5th line, 'Case 4 in Table ~~10'~~, should be 'Case 4 in Table 8'.
- Page 47, Table 14: Values do not appear to correspond to those in ISO 3951-1 Annex B, but it is noted that these values are those presented in NMKL Procedure# 12(2014) Table #6, page 35-37.
- Page 48, Table 15: all the P_{95}, P_{50} and P_{10} values do not match the tabulated data below those values. Also the LQ below Figure 9 does not correspond to P10 graphed in Figure 9.
- Page 54, Table 17: Is missing a number of values.

6.1 OTHER CODEX GUIDANCE FOR SAMPLING PROCEDURES

Principles for the Use of Sampling and Testing in International Food Trade (CAC/GL 83-2013)

This is intended to provide assistance in assessing impacts of sampling and testing procedures on affected parties in international food trade. It should be read in conjunction with GL 50 as well as the *Guidelines for Food Import Control Systems* (CAC/GL 47-2003) and the *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007).

Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLs (CAC/GL 33-1999)

This covers pesticide residues and describes sampling procedures to enable a representative sample to be obtained from a lot, for analysis to determine compliance with Codex MRLs for pesticides.

GL 33 recommends the number of primary samples to be taken from a lot, and the size and nature of the samples, and sets out criteria for determining compliance.

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)

This provides guidance on the design and implementation of food safety assurance programmes for residues of veterinary drugs. This recommends verification using a combined system of inspection/audits and sampling/laboratory analysis. The frequency, point and type of activity should be based on assessment of the food safety risk. The verification programme may be chosen as appropriate from system verification, risk-targeted verification or surveys. In designing a sampling protocol it is essential to define both the purpose of the programme and the population of interest. It is also important to define the criteria to be applied when analysing the results with respect to the need/desirability for any further action, and especially how such criteria and actions directly relate to the protection of human health.

The guidelines recommend port of entry testing programmes only as a secondary system verification tool. The guidelines recommend the type of programme that is appropriate for this purpose, and actions following the detection of non-compliant results.

General Standard for Contaminants and Toxins in Food and Feed (GSCTF, CODEX STAN 193-1995)

This lists the maximum levels and associated sampling plans of contaminants and natural toxicants in food and feed. Among the criteria to be considered when developing MLs are validated qualitative and quantitative data on representative samples and appropriate sampling procedures.

The GSCTF includes sampling plans for aflatoxins in peanuts and tree nuts.

Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods (CAC/GL 21 - 1997)

This include a section on sampling plans, methods and handling for microbiological sampling. The section describes the information that should be included in the sampling plan, and notes the issues to be taken into account in designing the plan. The issues include the risks to public health associated with the hazard, the heterogeneity of distribution of microorganisms where variables sampling plans are employed, the Acceptance Quality Level (AQL) the desired statistical probability of accepting a non-conforming lot, and the administrative and economic feasibility.

Guidelines for Food Import Control Systems (CAC/GL 47-2003)

This discusses risk-based sampling of imported food using Codex or other scientifically-based sampling plans, and also verification sampling (to verify information supplied by the exporting country), audit sampling (sampling at low frequency to confirm conformance), and audit of exporting countries' sampling programmes.

6.2 IDENTIFY HOW GL 50 SHOULD ALIGN WITH OTHER CODEX SAMPLING GUIDANCE

GL 50 needs to align primarily with GL 83, by incorporating the key principles and explanatory notes.

GL 50 alignment with other Codex sampling guidance needs to be clarified, not only for common areas, but also for alternate approaches. Notably, GL 47, Guidelines for Food Import Control Systems, provides for scientifically-based sampling on the basis of risk to human health. GL 47 also covers verification sampling (to verify information supplied by the exporting country), audit sampling (sampling at low frequency to confirm conformance), and audit of exporting countries' sampling programmes. Perhaps GL 50, as a 'general guideline' needs to say something about these latter types of sampling, particularly if they're more efficient than routine statistical sampling.

There also needs to be clarity in the relationship of GL 50 to other Codex documents dealing with the use of analytical results, including the relationship between the analytical result, the measurement uncertainty, recovery factors and the specification in Codex standards.

Any update to GL 50 would also need an amendment to the Codex Procedural Manual.

7 Appendix 1: Sampling Plans

7.1 SAMPLING PLANS ADOPTED BY CODEX SINCE GL 50 WAS ESTABLISHED

Year	Standard	Sampling plan proposed	Sampling plan endorsed	Sampling plan adopted	Comments
2005	Maximum Levels for cadmium in various foods (and other contaminants in later years)	None			
2005	Revision of the Standard for Salted Fish and Dried Salted Fish of the *Gadidae* Family	Examination of the product: FAO/WHO Codex Alimentarius Sampling Plans for Prepackaged Foods (AQL - 6.5) (CAC/RM 42-1969). Net weight: FAO/WHO Sampling Plans for the Determination of Net Weight (under elaboration).	Endorsed	Adopted	
2005 and later years	MRLs for pesticides				*(See GL33, Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLs)*
2005 and later years	MRLs for veterinary drugs				*(See GL71, Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals)*
2005	Fruit Juices and Nectars	None			
2005	Instant Noodles	GL 50	No need to endorse as not	Adopted	CCMAS recommended that Commodity Committees should not include statements referring to the General Guidelines in commodity standards but should select specific sampling plans

Year	Standard	Sampling plan proposed	Sampling plan endorsed	Sampling plan adopted	Comments
			a specific sampling plan		for the commodities covered by the standards, taking into account the guidance provided in the Guidelines.
2005	Rambutan (and other fresh fruits and vegetables in later years)	None			*(Codex has adopted no sampling plans for fresh fruits and vegetables. Some sampling plans for fruits and vegetables are developed by OECD, http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=C(99)10/FINAL&docLanguage=En, but these are not referenced in the Codex standards.)*
2005	Named Vegetable Oil (Sesame Seed Oil, fatty acid profile)	None			
2006	Processed Cereal-Based Foods for Infants and Young Children (composition)	Refers to Infant Formula			
2008	Raw and Live Bivalve Molluscs (*E coli*, quality factors, count or net weight, biotoxins)	Each sample shall contain a sufficient number of bivalve molluscs to ensure that the sample is representative. *E coli*: Specific sampling plan Quality factors and count: not exceeding acceptance number (c) of the appropriate sampling plan in GL 50 Net weight: an appropriate sampling plan meeting the criteria established by the CAC Biotoxins:	Not considered by CCMAS	Adopted	
2008	Foods for Special Dietary Use for	None			

Year	Standard	Sampling plan proposed	Sampling plan endorsed	Sampling plan adopted	Comments
	Persons Intolerant to Gluten (gluten content)				
2008	Aflatoxin Sampling Plans for Aflatoxin Contamination in Ready-to-eat Treenuts and Treenuts Destined for Further Processing: Almonds, Hazelnuts and Pistachios	Specific sampling plan	Not considered by CCMAS (?)	Adopted	
2008	Natural Mineral Waters (health-related limits for certain substances)	None			
2009	Gochujang (quality factors, min. weight)	The number of “defectives” does not exceed the acceptance number (c) of the appropriate sampling plan.	Not considered by CCMAS	Adopted	
2009	Ginseng Products (quality factors, defects)	The number of “defectives” does not exceed the acceptance number (c) of the appropriate sampling plan.	Not considered by CCMAS	Adopted	
2009	Named Vegetable Oil (Rice Bran Oil, composition and quality factors, identity characteristics)	None			
2009	Fermented Soybean Paste	The number of “defectives” does not exceed the acceptance number (c) of the appropriate sampling plan.	Not considered by CCMAS	Adopted	

Year	Standard	Sampling plan proposed	Sampling plan endorsed	Sampling plan adopted	Comments
2009	Microbiological Criteria for *Listeria monocytogenes* in Ready-to-Eat Foods	Specific sampling plan		Adopted	
2009	Microbiological Criteria for Powdered Follow-up Formulae and Formulae for Special Medical Purposes for Young Children	Specific sampling plan		Adopted	
2010	Sturgeon Caviar (defects, net weight)	Defects: GL 50 Net weight: appropriate sampling plan meeting the criteria established by CAC Pathogenic microorganisms and parasites: GL 21			
2010	Milk products	ISO 707 | IDF 50:2008	Endorsed	Adopted	General Instructions for obtaining a sample from a bulk
2010	Milk products	ISO 5538 | IDF 113 :2004	Endorsed	Adopted	Inspection by attributes
2011	Sampling plans for aflatoxin contamination in shelled Brazil nuts	Specific sampling plan	Endorsed	Adopted	
2011	Certain canned vegetables, jams and jellies (quality criteria, minimum fill)	Lot acceptance: AQL 6.5, Inspection levels I and II.	Endorsed	Adopted	
2011	Chili sauce (foreign matter, minimum fill)	Lot acceptance: AQL 6.5, Inspection levels I and II. The number of “defectives” does not exceed the acceptance number (c) of the	Endorsed	Adopted	

Year	Standard	Sampling plan proposed	Sampling plan endorsed	Sampling plan adopted	Comments
		appropriate sampling plan			
2011	Desiccated Coconut (chemical and physical characteristics)	The number of “defectives” does not exceed the acceptance number (c) of the appropriate sampling plan	Endorsed	Adopted	CCMAS noted that the sampling plan was based on the guidance in the *General Guidelines on Sampling* and that this approach should be generally followed by commodity committees.
2011	Canned Bamboo Shoots (defects, net weight)	The number of “defectives” does not exceed the acceptance number (c) of the appropriate sampling plan with an AQL of 6.5	Not considered by CCMAS	Adopted	
2012	Harissa		Not endorsed		In individual standards, reference should not be made to the *General Guidelines on Sampling* as they do not provide sampling plans but instructions to select sampling plans, and encouraged individual committees to select appropriate sampling plans.
2012	Halwa Tehenia		Not endorsed		
2012	Fish Sauce		Not endorsed		
2012	Food Grade Salt (NaCl content)	Specific sampling plan	Not considered by CCMAS	Adopted	
2012	Sampling plan for aflatoxin contamination in dried figs	Specific sampling plan	Endorsed with amendments	Adopted	
2013	Table olives (quality, minimum fill, drained weight	Specific sampling plan	Endorsed	Adopted	
2013	Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish; Live Abalone and for Raw Fresh Chilled or Frozen Abalone for Direct Consumption or for Further Processing	Sampling plan: GL 50 Lot acceptance	Not endorsed Not considered by CCMAS	Adopted without sampling plans	In individual standards, reference should not be made to the *General Guidelines on Sampling* as they do not provide sampling plans but instructions to select sampling plans, and encouraged individual committees to select appropriate sampling plans.
2013	Tempe	None		Adopted	

Year	Standard	Sampling plan proposed	Sampling plan endorsed	Sampling plan adopted	Comments
2013	Date Paste	None		Adopted	
2014	Maximum Level for Deoxynivalenol (DON) in Cereals and Cereal-Based Products	Specific sampling plan	Not endorsed		Request CCCF (1) to provide the rationale why the aggregate sample weight was 1-5 kg; (2) to consider whether 3 increment samples is sufficient for samples not more than 50 kg; and (3) to consider whether particle size should be specified for the test portion.
2014	Live Abalone and For Raw, Fresh Chilled or Frozen Abalone for Direct Consumption or for Further Processing; Smoked Fish, Smoke-Flavoured Fish and Smoked-Dried Fish; and Draft Standard for Fresh and Quick Frozen Raw Scallop Products	Sampling plans selected from GL50 for consideration by CCFFP			The sampling plan for determination of the presence of viscera should depend on whether it is a source of biotoxins and could be considered as a health issue or a quality defect and that whether or not viscera would be found depends on the technology used for processing. A sampling plan in any standard should not be a simple reference to the *General Guidelines on Sampling* (CAC/GL 50-2004), but could be a reference to a specific table in the Guidelines accompanied by an AQL.
2015	Certain Canned Fruits	The number of “defectives” does not exceed the acceptance number (c) of the appropriate sampling plan with an AQL of 6.5	Endorsed	Adopted	The sampling plans apply to defects only.
2015	Ginseng and Ginseng Products	Specific sampling plans for AQL of 6.5, Inspection levels I and II.	Not endorsed		The values in the table did not correspond to those recommended in GL 50. It was unclear whether the attributes sampling plan actually applied to attributes and not to characteristics that might be described as variable and requested CCPFV to reconsider the values in line with GL 50.
2016	Fumonisins (B1+B2) in maize grain and maize flour and maize meal	Specific sampling plan	Endorsed		When considered in 2015 there were several inconsistencies between the tables and text in the sampling plans. The Committee agreed to request CCCF to consider removing the inconsistencies as presented in CRD 25. An amended version was considered in 2016.

Year	Standard	Sampling plan proposed	Sampling plan endorsed	Sampling plan adopted	Comments
2015	Fish oils	ISO 5555: Animal and vegetable fats and oils – Sampling	Endorsed		
2015	Quick Frozen Vegetables	Specific sampling plans for AQL of 6.5, Inspection levels I and II.	Not considered by CCMAS	Adopted	
2015	Non-fermented Soybean Products	Specific sampling plans for AQL of 6.5, Inspection levels I and II.	Not considered by CCMAS	Adopted	
2016	Deoxynivalenol (DON) in Cereals	Specific sampling plan	Endorsed		
2016	Milk products	ISO 3951-1	Endorsed		Inspection by variables

Appendix II

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