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CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 4 **CX/MAS 15/36/4**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

Thirty-sixth Session
Budapest, Hungary
23 - 27 February 2015

PROPOSED DRAFT PRINCIPLES FOR THE USE OF SAMPLING AND TESTING IN INTERNATIONAL FOOD TRADE: EXPLANATORY NOTES AND PRACTICAL EXAMPLES

Prepared by the Electronic Working Group led by Germany, New Zealand and The Netherlands

(At Step 3)

Governments and interested international organizations are invited to submit comments on the attached Proposed Draft Principles for the Use of Sampling and Testing in International Food Trade: Explanatory Notes and Practical Examples at Step 3 (*see* Appendix I) and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission*) **to**: The Secretariat, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy, by email codex@fao.org with a copy to the Hungarian Codex Contact Point, Hungarian Food Safety Office, h-1097 Gyáli út 2-6, Budapest, Hungary, email: HU_CodexCP@mebih.gov.hu **by 30 November 2014.**

Format for submitting comments: In order to facilitate the compilation of comments and prepare a more useful comments document, Members and Observers, which are not yet doing so, are requested to provide their comments in the format outlined in the Annex to this document.

Background

1. At its 35th Session of the Codex Committee on Methods of Analysis and Sampling, the Committee agreed to establish an electronic working group led by Germany, with assistance of New Zealand and the Netherlands, open to all members and observers and working in English only, to

(i) integrate the explanatory notes as agreed and amended;

(ii) further develop text for Principles 4 and 6, and introductory text to link the Principles to the annex on practical examples, taking into account the discussion.

2. The Committee agreed to return the explanatory notes to Step 2/3 for integration into the *Principles for the Use of Sampling and Testing in International Food Trade* and attach to it practical examples for sampling plans as an annex, for comment and consideration by the next session.

3. The member countries were invited to nominate one person as a participant in the eWG on Explanatory Notes on Principles for the Use of Sampling and Testing in International Food Trade.

4. The Committee noted that CAC/GL 83-2013 was not open for discussion nor should be revised, but that the integration of the explanatory notes may result in consequential changes in order to explain the introduction of the explanatory notes and the annex on practical examples.

5. The Committee agreed that the electronic working group would take up the development of practical examples taking into consideration the recommendations from the Discussion Paper on Sampling in Codex Standards (CX/MAS 14/35/7) and the discussion in the Committee (paragraph 83). The electronic working group would:

- Provide a brief explanation of the use of sampling and analytical measurement uncertainty in product control and testing compliance;
- Develop examples, including case-by-case advice of consideration of sampling uncertainty

(definition), that fulfil the following criteria: matrix combinations vs measurand / provision:

- Fruits/vegetables, fats/oils, fish/fishery products, milk/milk products, meat/meat products, natural mineral waters, cereals
- Sensory inspection, food additives, food hygiene, pesticide residues, contaminants, residues of veterinary drugs
- Packages/bulk material/foodstuff for consumption.
- Develop procedures for determining uncertainty of measurement results including sub-sampling, sample processing and analysis.
- Consideration of importing and exporting countries including control of production and testing compliance.

6. For the eWG, 37 persons (27 participants) were nominated from 27 member countries and observer organisations.

7. The first draft ANNEX ON PRACTICAL EXAMPLES, which had been elaborated by Germany was circulated on 2 July 2014.

8. This ANNEX ON PRACTICAL EXAMPLES should provide help in choosing appropriate sampling plans. These sampling plans are examples and should not be regarded as prescriptive. Therefore, they do not present fixed values but give reference to correspondent passages of the standards. Sampling and decision concepts include both consumers and producers risks which are interrelated and the use of sampling and analytical measurement uncertainty in product control and testing compliance. The matrix combinations are not exhaustive but some of the matrix elements are redundant.

9. The first draft INTEGRATED PRINCIPLES AND EXPLANATORY NOTES, that were elaborated by New Zealand was circulated on 22 July 2014.

10. Unfortunately, there were only a few contributions by the members of the working group. In the submitted drafts, all of the proposed amendments have been considered.

11. The leader of the working group wants to express his gratitude to all members for their interest and for active contributions.

Recommendations

12. The Committee is invited to consider the proposal of the EWG attached as Appendix I.

APPENDIX I

Principles for the Use of Sampling and Testing in International Food Trade
(integration of the explanatory notes into the Principles and an annex on practical examples)

(at Step 3)

Note: The Principles are taken unchanged from CAC/GL 83-2013. The integrated text is shaded grey and comments should be limited to these sections of the text and the annex on practical examples

SECTION 1 - INTRODUCTION

1. Sampling and testing are, among others, procedures utilized to assess whether foods in trade are compliant with particular specifications. These procedures may affect the probabilities of wrongly accepting or wrongly rejecting a lot or consignment[1]. Therefore these probabilities should be evaluated so that they can be controlled to acceptable levels for affected parties. The absence of defined, scientifically valid procedures could lead to *ad hoc* practices being used, resulting in inconsistent decisions and an increased occurrence of disputes.

2. To ensure the sampling and testing procedures are valid, they should be based upon scientific, internationally accepted principles, and it is necessary to ensure that they can be applied fairly. With regard to sampling, the *General Guidelines on Sampling* states that "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." With regard to testing, the methods of analysis endorsed by Codex should be considered first.

3. Sampling and testing procedures are often used in international food trade for the purpose of risk management related to safety. For this purpose, sampling and testing procedures should be established as an integral part of a national food control system to the extent possible.

4. Risk management decisions should be commensurate to the assessed risk, and should take into account risk assessment and other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in the food trade and, if needed, selecting appropriate prevention and control options.

5. It should be recognised that end-product sampling and testing is only one of the methods by which an exporter can validly claim that a product meets specifications. Other means of establishing whether foods in trade meet specifications exist in Codex.

6. This document does not affect existing Codex provisions or the current way of setting those provisions. These responsibilities are set out in committees' terms of reference. This document should be read in conjunction with 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).

7. This document also provides explanatory notes for the principles, and practical examples in an Annex, to assist in assessing impacts of sampling and testing procedures on affected.

SECTION 2 - SCOPE

8. These principles are intended to assist governments in the establishment and use of sampling and testing procedures for determining, on a scientific basis, whether foods in international trade are in compliance with particular specifications. Compliance with these principles will also assist in avoiding potential disputes.

9. The explanatory notes are intended:

- to explain the principles and provide practical examples of their use in sampling and testing procedures, thus demonstrating the role of sampling and testing in international food trade;
- to help governments and other interested parties to understand the principles and to establish and use sampling and testing procedures to assess whether foods in international trade comply with specifications.

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[1] 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 (see for example CAC/GL 50-2004). A consignment is a quantity of some commodity delivered at one time. It may consist of either a portion of a lot, or a set of several lots. However, the consignment shall be considered as a new lot for the interpretation of the results, if the consignment is a portion of a lot.
If a consignment is to be accepted or rejected in its entirety, the sampling should be carried out over the entire consignment.

The practical examples are presented for reference purposes, and sampling and testing taken by governments are not limited to these examples.

SECTION 3 - DEFINITIONS

Testing

Process to examine the specified characteristics of a sample.

Testing procedure

Operational requirements and/or instructions relating to the testing; i.e. preparation of sample and method of analysis to yield knowledge of the characteristic(s) of the sample.[1]

Sampling procedure

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).

Other definitions relevant to these principles include:

Consignment[1]

Lot[1]

Sample[1]

Sampling[1]

Sampling plan[1]

Result[2]

Measurement uncertainty[3]

[1] *General Guidelines on Sampling* (CAC/GL 50-2004)

[2] *Guidelines on Analytical Terminology* (CAC/GL 72-2009)

[3] *Guidelines on Measurement Uncertainty* (CAC/GL 54-2004)

SECTION 4 – PRINCIPLES

Principle 1: Transparency and agreements before initiating trade

Before starting trading activities, or when introducing or modifying an import testing program, the parties concerned should reach agreement related to the sampling and testing procedures that will be applied to assess whether the food in trade meets the specifications of Codex or the importing country. This agreement should also specify the sampling and testing procedures to be followed in the case of a dispute.

When a lot or consignment is to be assessed, the sampling and testing procedures to be used and the criteria for acceptance of a product should be documented and communicated by all parties. In the event of a rejection of a lot or consignment, all relevant information should be shared between governments using mutually agreed upon format and language(s).

Explanatory Notes

Transparent sampling, testing and assessment procedures allow all parties to operate in an open way so that each is fully aware of the actions performed by the other parties. 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 by both parties which in turn can reduce the potential for disputes based on sampling and testing results. When discrepancies do occur, transparency allows for effective communications between parties to address differences.

Agreement is desirable:

- *to maintain the probability of wrongly accepting or wrongly rejecting a lot at reasonable levels fair to both parties*
- *to avoid future disputes concerning the appropriateness of the methods of sampling and analysis or the criteria used to judge the results.*

The agreements should contain, for example:

- *The language of communication*
- *The specification of the principles concerning acceptance or rejection of a lot or consignment (e.g. General Guidelines on Sampling (CAC/GL 50-2004))*
- *The specification of the manner in which production lots or consignments may be linked to inspection samples*
- *The specification of the sampling procedure*
- *If the assessment procedure requires an estimate of lot inhomogeneity (e.g. a standard deviation), the method that should be used to estimate it. If the standard deviation is treated as "known", the assumed value should be scientifically based and accepted by both parties*
- *The specification of analytical methods including criteria of appropriateness in order to ensure equivalent measurements*
- *Whether recovery correction is applied to analytical results or not*
- *The specification of criteria for compliance assessment*
- *The process for resolving disputes over analytical (test) results (for example CAC/GL 70-2009)*
- *The procedures in case of any variations of the above-mentioned terms.*

The agreed specifications should not restrict the flexibility of the control program in the importing country and should preferably be done in general terms.

In the case of a rejection the exchange of information should be done according to the Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food (CAC/GL 25-1997).

Principle 2: Components of a product assessment procedure

Sampling and testing of food in trade to assess whether the food meets specifications involves three components, and all three of these should be considered when an assessment procedure is selected:

- Selection of samples from a lot or consignment as per the sampling plan;
- Examination or analysis of these samples to produce test results (sample preparation and test method(s));

and

- Criteria upon which to base a decision using the results.

Principle 3: Probability of incorrect decisions

Whenever food is sampled and tested, the probabilities of wrongly accepting or wrongly rejecting a lot or consignment affect both exporters and importers and can never be entirely eliminated. These probabilities should be evaluated and controlled, preferably using methodology described in internationally recognized standards.

Explanatory Notes

Probabilities of wrongly accepting or wrongly rejecting a lot or consignment can never be entirely eliminated because both the samples taken and the measurement errors associated with the analysis are subject to random variation. This leads to random variation in the calculated quantity that is to be compared to a limit for compliance assessment. This means that if the same lot were assessed twice using the same procedure, there is a possibility that it may pass one assessment and fail the other.

The General Guidelines on Sampling (CAC/GL 50-2004), sections 3, 4 and 5, provide guidance on sampling plans for various situations.

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 choice of Acceptable Quality Level (AQL)[2] and Limiting Quality (LQ) for characteristics in foods to be tested.

Characteristics which may be linked to critical defects, for example relating to the sanitary condition of food, should be associated with a low AQL (i.e. 0.1 % to 0.65 %), whereas compositional characteristics, such as the fat or water content, may be associated with a higher AQL (e.g., 2.5 % or 6.5 %).

[2] In ISO 3534, *Statistics – Vocabulary and Symbols*, the term used is "acceptance quality level".

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. 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.

Prior information may be useful in controlling the probabilities of wrongly accepting or wrongly rejecting a lot or consignment. For example, the importer can take into account the rate of non-compliances of certain exporter/importer combinations, using procedures with relatively lower sampling rates in cases where past records show that there is a low probability of non-compliance, and higher sampling rates for other situations.

It may also be useful to take into account testing that has already been carried out in the exporter. Export control procedures generally include a combination of end-product testing with a range of other controls, and effective management of these is vital. These management measures should involve Hazard Analysis and Critical Control Point (HACCP), Good Agricultural Practice (GAP), Good Manufacturing/Production Practice (GMP) and traceability aspects, where appropriate. Further details can be found in the General Guidelines for Food Import Control Systems (CAC/GL 47-2003). However, non-stable or perishable foods may need special consideration.

Auditing of the exporter's control system can lead to choosing a less strict sampling plan compared to the situation without prior knowledge. If the historical data suggest that the manufacturing process is in statistical control, a good estimate of the process standard deviation may be available, permitting reduced testing whilst maintaining the original stringency.

Principle 4: Selecting appropriate sampling and testing procedures

The sampling and testing 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 tested;
- Fit for intended purposes and applied consistently.

The selection of sampling and testing procedures should take into account:

- practical matters such as cost and timeliness of the assessment and access to lots or consignments, provided that the probability of accepting a non-compliant lot or consignment is not too high.
- variation within a lot or consignment.

Explanatory Notes

If sampling and testing procedures are not appropriate, there may be an unduly high probability of wrongly accepting or wrongly rejecting a lot or consignment which may lead to disputes between the interested parties[3].

The General Guidelines on Sampling (CAC/GL 50-2004) or 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. The Guidelines are applicable for control at reception, but may not be applicable for quality control of end-products by manufacturers.

The Guidelines cover the following sampling situations:

- *control of percentage of defective items, by attributes or by variables, for a continuous series of lots or in individual items*
- *control of mean content.*

Information that is needed in order to define an appropriate sampling plan and method of analysis includes:

- *Whether the procedure is to apply to single lots considered in isolation, or to lots forming part of a continuing series*
- *Whether the methods available to assess the characteristics of samples are qualitative or quantitative*
- *whether sampling plans will be on inspection by attributes basis or inspection by variables basis*
- *parameters such as the AQL or LQ.*

[3] Note that it might not be appropriate for producers to apply the same sampling plans as those used by receivers of commodities.

Each lot or consignment that is to be examined must be clearly defined. In order to avoid any dispute over the representativeness of the sample, a random sampling procedure (CAC/GL 50-2004, 2.3.3) should be chosen whenever possible, alone, or in combination with other sampling techniques.

If it is required to control the percentage of non-conforming items in a lot, then—

- *For inspected characteristics that are qualitative (including quantitative data classified as attributes, for example "conforming" or "not conforming" with respect to a limit) or distributed in an unknown manner, attributes plans should be used for sampling*
- *In case of measurable characteristics with normally distributed variability, variables plans should be chosen.*

If it is required to control the average of a characteristic in a lot, then

- *Single Sampling Plans for Average Control (CAC/GL 50-2004, 4.4) are recommended as tests which aim at ensuring that, on average, the content of the controlled characteristic does not fall outside a specified range.*

Note that CAC/GL 50-2004 does not cover the control of non-homogeneous lots. In case of non-homogeneous lots or consignments (e.g. chemical or microbiological contaminants in food), an appropriate sampling procedure should be selected.

In addition, the physical obtaining of samples for the purpose of laboratory analysis should be performed in accordance with appropriate standards related to the commodity of concern (for example ISO 707|IDF 50 Milk and milk products – Guidance on sampling or CAC/GL 33-1999 – Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLs for pesticide residues).

Principle 5: Analytical measurement uncertainty

The selection of the product assessment procedure should take into account analytical measurement uncertainty and its implications.

Explanatory Notes

The exporting country and the importing country should make available clear statements on how the analytical measurement uncertainty is taken into account when assessing the conformity of a measurement against a legal limit. This agreement should cover all situations where a limit or specification level is to be met, including limits for potential health hazards if such characteristics are to be assessed under the agreement.

Section 8.1 of the Explanatory Notes of Guidelines on Measurement Uncertainty (CAC/GL 54-2004) shows an example of several situations when decisions are made based on a single test sample where an analytical result with analytical measurement uncertainty is compared against a specification level (e.g., a maximum level).

Various guidelines (e.g. Guidelines on Estimation of Uncertainty of Results (CAC/GL 59-2006) and Guidelines on Measurement Uncertainty (CAC/GL 54-2004)) describe procedures for estimating analytical measurement uncertainty based on different combinations of in-house validation data, in-house precision data and inter-laboratory data, and illustrate how analytical measurement uncertainty might be taken into account in the most simple case, i.e. when decisions are made based on a single test sample. In all cases the key consideration during uncertainty estimation is the evaluation of all significant sources of uncertainty.

Principle 6: Fitness for purpose

Sampling and testing procedures are fit for purpose in a given product assessment, if, when used in conjunction with appropriate decision criteria, they have acceptable probabilities of wrongly accepting or wrongly rejecting a lot or consignment.

Explanatory Notes

*In terms of developing a sampling plan, the number of samples and decision criterion are determined by the risks. In this context**, fitness for purpose** means that the sampling plan is commensurate with the risks posed to consumers from inappropriate acceptance of poor quality product and the risks posed to producers from inappropriate rejection of good quality product.*

For example:

a. Use of an AQL of 0.1% may be inappropriate for a compositional character such as fat in whole milk powder because this is costly and difficult to achieve for the producer, and

b. Use of an AQL of 6.5% may be inappropriate for a hazardous character intended for a consumer because this does not adequately protect the consumer´s health

In terms of using a testing procedure, testing laboratories should adhere to the Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Food (CAC/GL 27-1997) and to Food Control Laboratory Management: Recommendations (CAC/GL 28-1995).

The following quality criteria should be adopted by laboratories involved in the import and export control of foods:

- *Compliance with the general criteria for testing laboratories laid down in ISO/IEC Guide 17025:2005 (CAC/GL 27-1997) "General requirements for the competence of calibration and testing laboratories"*
- *Participation in appropriate proficiency testing schemes for food analysis which conform to the requirements laid down in "The International Harmonized Protocol for the Proficiency Testing of(Chemical) Analytical Laboratories", Pure & Appl. Chem. 78 (2006) 145-196(CAC/GL 27-1997)*
- *Use of internal quality control procedures, such as those described in the Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories (CAC/GL 65-1997)*
- *Consideration of the Principles for the Establishment of Codex Methods of Analysis as described in Section II of the Codex Procedural Manual.*

Principle 7: Review procedures

Sampling and testing procedures should be reviewed periodically to ensure they take into account new science and information.

Bibliography:

Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food (CAC/GL 25-1997)

Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997)

Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Food (CAC/GL 27-1997)

The International Harmonized Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories", Pure & Appl. Chem. 78 (2006) 145-196 (CAC/GL 27-1997)

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

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

General Guidelines on Sampling (CAC/GL 50-2003)

Guidelines on Measurement Uncertainty (CAC/GL 54-2004)

Guidelines on Estimation of Uncertainty of Results (CAC/GL 59-2006)

Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories (CAC/GL 65-1997)

Publications and resources of the ISO Committee on Conformity Assessment (ISO CASCO) at http://www.iso.org/iso/resources/conformity_assessment.htm. (2013)

ANNEX ON PRACTICAL EXAMPLES

Introduction:

This ANNEX provides help in choosing appropriate sampling plans. These sampling plans are examples and should not be regarded as prescriptive. Therefore, they do not present fixed values but give reference to correspondent passages of the standards. Sampling and decision concepts include both consumers and producers risks which are interrelated. Some of the matrix elements in Table 1 are redundant.

Table 1: Code of Examples

	Fruits/ vegetables	fats/oil	fish/fishery products	milk/milk products	meat/meat products	natural mineral waters	cereals
Qualitative/quantitative characteristics/sensory inspection	FV-Q	FO-Q	F-Q	MI-Q			
food hygiene			F-FH		M-FH	MW-FH	
pesticide residues	FV-P				M-P		
contaminants	FV-C1/2					MW-C	C-C
residues of veterinary drugs			F-R	MI-R			

Table 2: Example sampling plans

Example	Criteria	Type of Sampling Plan	Sampling and Decision Reference	
			Isolated Lots	**Continuous series of lots**
FV-Q	Visible defects in fruits	Attribute Plan, sampling uncertainty not applicable	**Consumer:** ISO 2859-2:1985: Sampling: Procedure A: A plan is identified by the lot size, limiting quality (LO) and the inspection level (unless otherwise specified, level II shall be used). The sampling size (n) is given in table A. Procedure B: A plan is identified by the lot size, limiting quality (LO) and the inspection level (unless otherwise specified, level II shall be used). The sampling size (n) is given in table B1 to	**Consumer:** ISO 2859-1:1999: Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection Sampling: Normal inspection: use of a sampling plan with an acceptance criterion that has been devised to secure the producer a high probability of acceptance when the process average of the lot is better than the acceptance quality limit. Normal inspection is used when there is no reason to suspect that the process

			B10. Decision: For given limiting quality (LQ) (typically 10%, less than 13%) and number of samples *n*, a lot is compliant if the number of items with visible defects does not exceed the Rejection number Re (Tables A, D4). **Producer:** ISO 2859-2:1985: Sampling: see “Consumer” Decision: For given LQ (typically 10%, less than 13%, corresponding to AQL of consumer sampling plan from ISO 2859-1 if applicable, Table D5) and number of samples *n*, a lot is compliant if the number of items with visible defects does not exceed the Acceptance number Ac (Table A).	average differs from an acceptable level. The sample size is taken from Table 1 and Table 2-A. Tightened inspection: use of a sampling plan with an acceptance criterion that is tighter than that for the corresponding plan for normal inspection. Tightened inspection is invoked when the inspection results of a predetermined number of consecutive lots indicate that the process average might be poorer than the AQL. The sample size is taken from Table 1 and Table 2-B. Reduced inspection: use of a sampling plan with a sample size that is smaller than that for the corresponding plan for normal inspection and with an acceptance criterion that is comparable to that for the corresponding plan for normal inspection. The discriminatory ability under reduced inspection is less than under normal inspection. Reduced inspection may be invoked when the inspection results of a predetermined number of consecutive lots indicate that the process average is better than the AQL. The sample size is taken from Table 1 and Table 2-C. Switching rules: when normal inspection is being carried out, tightened inspection shall be implemented as soon as two out of five (or fewer than five) consecutive lots have been non-acceptable on original inspection (that is, ignoring resubmitted lots or batches for this procedure). When tightened inspection is being carried out, normal inspection shall be re-instated when five consecutive lots have been considered acceptable on original inspection. The outline of the switching rules is shown in Figure 1. Decision: for given inspection level, Acceptable Quality Level (AQL) and number of samples *n*, a lot is compliant if the number of items with visible defects does not exceed the Rejection number Re (Tables 1 and 2 e.g. for single sampling).

				Producer: ISO 2859-1:1999: Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection Sampling: see “Consumer” Decision: for given inspection level, Acceptable Quality Level (AQL) and number of samples *n*, a lot is compliant if the number of items with visible defects does not exceed the Acceptance number Ac (e.g. Tables 1 and 2 for single sampling).
MI-Q	Fat content in Milk products	Variables Plan Prerequisites: 1. The lots have not been screened previously for nonconforming items. 2. Continuing series of lots of discrete products all supplied by one producer using one production process 3. quality characteristic must be measurable on a continuous scale 4. the measurement error is negligible, i.e. with a standard deviation no more		**Consumer and Producer:** ISO 3951-1:2008: Sampling procedures for inspection by variables – Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL Sampling: for the “s” method acceptance sampling plan the sample standard deviation is used, for the “σ” method acceptance sampling plan the presumed value of the process standard deviation is used. If there is sufficient evidence from the control charts (e.g. ´autocontrol´) that the variability is in statistical control, consideration should be given to switching to the “σ” method. If this appears advantageous, the consistent value of s (the sample standard deviation) shall be taken as σ. Normal inspection is used at the start of inspection (unless otherwise designated) and shall continue to be used during the course of inspection until tightened inspection becomes necessary or reduced inspection is allowed. Tightened inspection shall be instituted when two lots on original normal inspection are not accepted within any five or fewer successive lots. Reduced inspection may be instituted after ten successive lots have been accepted under normal

		than 10 % of the sample standard deviation s or process standard deviation □ 5. production is stable (under statistical control) and the quality characteristic x is distributed according to a normal distribution or a close approximation to the normal distribution		inspection, provided that these lots would have been acceptable if the AQL had been one step tighter, production is in statistical control. In case that switching rules are not applicable, a particular consumer's risk quality (CRQ) associated with a consumer's risk should be fixed (e.g. Table K1 or K2). In case of very short series of lots, ISO 2859-2:1985 might be applied, where the fat content of the sample items with respect to the limit (taking into account the measurement uncertainty) might be classified as attribute (see example FV-Q). Summary table 1 directs users to the paragraphs and tables concerning any situation with which they may be confronted. Sample sizes are given in table A2 for the sample size letters given in Clause 23, Chart A (for agreed and fixed AQL at 95 % probability of acceptance and LQ at 10 % probability of acceptance). This should be verified by inspecting the OC curve from among Clause 24, Charts B to R relating to this code letter and AQL. For the "s" method (Clause 15), the procedure for obtaining and implementing a plan is as follows. a) With the inspection level given (normally this will be II) and with the lot size, obtain the sample-size code letter using Table A.1. b) For a single specification limit, enter Table B.1, B.2 or B.3 as appropriate with this code letter and the AQL, and obtain the sample size n and the acceptability constant k. For combined control of double specification limits when the sample size is 5 or more, find the appropriate acceptance curve from among Charts s-D to s-R. c) Take a random sample of size n, measure the characteristic x in each item and then calculate x, the sample mean and s, the sample standard deviation (see Annex J). Where a contract or standard defines an upper specification

				limit U, a lower specification limit L, or both, the lot can be judged unacceptable without even calculating s if x is outside the specification limit(s). For the "σ" method (Clause 16), from Table A.1 the sample-size code letter is obtained. Then, depending on the severity of inspection, enter Table C.1, C.2 or C.3 with the sample-size code letter and the specified AQL to obtain the sample size n and acceptability constant k. Take a random sample of this size, measure the characteristic under inspection for all items of the sample and calculate the mean value. The sample standard deviation s should also be calculated, but only for the purpose of checking the continued stability of the process standard deviation (see Clause 19). Decision: a lot is compliant if the average fat content of sample items does not fall below the minimum value fixed by AQL and LQ taking into account the corresponding standard deviation (s or σ) and acceptability constant K. The acceptability constant is given in tables B1 to B3 (s-method) and C1 to C3 (σ-method). s: sample standard deviation of the measured values of the quality characteristic (also an estimate of the standard deviation of the production process): σ: standard deviation of a production process that is under statistical control
FO-Q	water content in butter	Variables Plan Prerequisites: see example MI-Q		**Consumer and Producer:** Sampling: see example MI-Q Decision: A lot is compliant if the average water content of sample items does not exceed the maximum value fixed by AQL taking into account the corresponding standard deviation (s or σ) and acceptability constant K. See also example MI-Q

M-FH	*Staphylococcus aureus* in fresh or frozen poultry meat	Three-class attributes Plan	**Consumer and Producer:** ICMSF (1986)[a)]: Chapter 13 SAMPLING PLANS FOR POULTRY AND POULTRY PRODUCTS Sampling: see Table 22: Sampling plans and recommended microbiological limits for poultry and poultry products Decision: the lot is accepted if not more than 1 item of 5 samples shows the presence of *Staphylococcus aureus* with a maximal content of 1000 CFU/g. The lot is rejected in the opposite case.	
F-FH	*Salmonella* in fresh, frozen and cold-smoked fish	Two-class attributes Plan	**Consumer and Producer:** ICMSF (1986)[a)]: Chapter 17 SAMPLING PLANS FOR FISH AND SHELLFISH Sampling: see Table 27: Sampling plans and recommended microbiological limits for seafoods Decision: the lot is accepted if no item out of 5 samples show the presence of *Salmonella* in 1g. The lot is rejected in the opposite case.	
F-Q	Net weight in prepackaged fish	Special Plan	**Consumer and Producer:** OIML R 87 (Edition 2004)[b)]: Quantity of product in prepackages Sampling: see Table 1: Sampling plans for prepackages Decision: for fixed Risk Type (according to fixed AQL) the lot is accepted if all of the following criteria are met: 1. The average actual quantity of product in a package is at least equal to the nominal quantity, which is evaluated in the following way: The total error of the quantity of product in a package is given by the sum of the differences between the individual product weights and the nominal weight. The average error is given by that total error divided by the sample size. The lot is accepted if the average error is a positive number. In case of a negative number, the lot is accepted if the standard deviation of the individual product weights times the sample correction factor of Table 1 is higher than the absolute value of the average error. 2. The number of packages containing an actual quantity less than the nominal quantity minus the tolerable deficiency (Table 2) is less or equal the Number of packages in a sample allowed to exceed the	

			tolerable deficiencies (Table 1). 3. No package contains an actual quantity less than the nominal quantity minus twice the tolerable deficiency.
C-C	Cadmium content in wheat	Variables Plan on Bulk Material Sampling uncertainty implemented	**Consumer and Producer:** ISO 10725:2000: Acceptance sampling plans and procedures for the inspection of bulk materials / ISO 11648-1:2003: Statistical aspects of sampling from bulk materials — Part 1: General principles Sampling: sampling from a commodity is classified into two different procedural types: - sampling of bulk materials for the accurate estimation of an average value of the quality characteristic assessed in the lot by suppliers - inspection procedure for bulk materials for making a decision concerning lot acceptance by consumers. ISO 11648 is an International Standard for the first type of procedure, ISO 10725 for the second type, which is based on the assumption that the value of the individual standard deviation of the specified quality characteristic is known and stable. The sample size can be estimated using Tables 3 - 22 of the standard ISO 10725:2000 with fixed producer's risk □ and consumer's risk □ and fixed cost ratio level from the relative standard deviations $d_I = \sigma_I/D$ and $d_T = \sigma_T/D$ (ISO 10725:2000, 6.3.4) with the sampling increment standard deviation σ_I and test sample standard deviation σ_I. The number $2n_I$ increment samples should be taken from the lot and each two of them should be pooled to two composite samples. From each of the two composite samples $2n_T$ test samples should be prepared (e.g. homogenized). For imprecise standard deviations, one measurement per test sample should be performed (ISO 10725:2000, 6.3.2.2). Decision: as emphasized above, prerequisite is the determination of the estimation standard deviation □$_E$ (ISO 10725:2000, 6.2.7 / ISO 11648-1:2003) by monitoring of the cadmium content and to assess that it is stable. It is permitted to use the values of standard deviations specified by an agreement between the supplier and the purchaser (e.g. ´autocontrol´) (ISO 10725:2000, 6.2.1). Taking into account the discrimination interval $D = (K_\alpha + K_\beta)\,\sigma_E$ (formula C6 in C.4.2), the following four quantities might be fixed by agreement: the acceptance quality limit for the lot mean m_A (corresponding to AQL, producers' risk), the probability α of wrongly rejecting a conforming lot, the non-acceptance quality limit for the lot mean m_R (corresponding to LQ, consumers' risk), and the probability β of wrongly accepting a nonconforming lot. For a given acceptance quality limit m_A, the lot is accepted if the sample grand average of these results $\bar{x}$ is lower than an upper acceptance value $\bar{x}_U = m_A + \gamma D$ with the constant for obtaining the acceptance

			value $\gamma = K_\alpha / (K_\alpha + K_\beta)$.
FV-P	Pesticides Residues in Apples for Compliance with MRL	Variables Plan sampling uncertainty not applicable	**Consumer and Producer:** CAC/GL33-1999: RECOMMENDED METHODS OF SAMPLING FOR THE DETERMINATION OF PESTICIDE RESIDUES FOR COMPLIANCE WITH MRLS Sampling: the minimum number of primary samples to be taken from a lot is determined from Table 1b or Table 4, 1.2. The primary samples must contribute sufficient material to enable all laboratory samples to be withdrawn from the bulk sample. The position from which a primary sample is taken in the lot should preferably be chosen randomly but, where this is physically impractical, it should be from a random position in the accessible parts of the lot. The primary samples should be combined and mixed well, if practicable, to form the bulk sample. The Minimum size of each laboratory sample is given by Table 4, 1.2. Decision: analytical results must be derived from one or more laboratory samples. The lot complies with a MRL (Pesticide Residues in Food and Feed, Codex Pesticides Residues in Food Online Database, FAO and WHO 2013) where the MRL is not exceeded by the analytical result(s) taking into account the expanded measurement uncertainty. Where results for the bulk sample exceed the MRL, a decision that the lot is non-compliant must take into account: (i) the results obtained from one or more laboratory samples, as applicable; and (ii) the accuracy and precision of analysis, as indicated by the supporting quality control data.
M-P	Fat soluble Pesticides Residues in cattle carcass for Compliance with MRL	Variables Plan sampling uncertainty not applicable	**Consumer and Producer:** CAC/GL33-1999: RECOMMENDED METHODS OF SAMPLING FOR THE DETERMINATION OF PESTICIDE RESIDUES FOR COMPLIANCE WITH MRLS Sampling: the minimum number of primary samples to be taken from a lot is determined from Table 1a, or Table 2 (in the case of a suspect lot). The position from which a primary sample is taken in the lot should preferably be chosen randomly but, where this is physically impractical, it should be from a random position in the accessible parts of the lot. Each primary sample is considered to be a separate bulk sample. The Minimum size of each laboratory sample is given in Table 3, 2.1. Decision: analytical results must be derived from one or more laboratory samples. The lot complies with a MRL (Pesticide Residues in Food and Feed, Codex Pesticides Residues in Food Online Database, FAO and WHO 2013) where the MRL is not exceeded by the analytical result(s) taking into account the expanded measurement uncertainty. Where results for the bulk sample exceed the MRL, a decision that the lot is non-compliant must take into account: (i) the results obtained from one or more laboratory samples, as

			applicable; and (ii) the accuracy and precision of analysis, as indicated by the supporting quality control data.
F-R	Residues of Veterinary Drugs in Packaged Fish	Variables Plan sampling uncertainty not applicable	**Consumer and Producer:** CAC/GL71-2009: GUIDELINES FOR THE DESIGN AND IMPLEMENTATION OF NATIONAL REGULATORY FOOD SAFETY ASSURANCE PROGRAMME ASSOCIATED WITH THE USE OF VETERINARY DRUGS IN FOOD PRODUCING ANIMALS Sampling: for non-suspect lots a statistically-based, non-biased sampling program is recommended. In stratified random sampling the consignment is divided into non-overlapping groups or strata e.g. geographical origin, time. A sample is taken from each stratum. In systematic sampling units are selected from the population at a regular interval (e.g., once an hour, every other lot, etc.). Where non-compliant results are detected it is possible to derive a crude estimate of the likely prevalence in the general product population (e.g. ´autocontrol´). The number of primary samples required to give a required statistical assurance can be read from Appendix A, Table 4. For exact or alternative probabilities to detect a non-compliant residue, or for a different incidence of non-compliance, the number of samples n to be taken may be calculated from: n = ln(1-p) / ln(1-i) where p is the probability to detect a non-compliant residue (e.g. 0.95), i is the supposed incidence of non-compliant residues (e.g. 0.10) in the lot. In biased or estimated worst case sampling, investigators use their judgment and experience regarding the population, lot, or sampling frame to decide which primary samples to select. Such directed or targeted sampling protocols on a sub-population (biased sampling) are designed to place a greater intensity of inspection/audit on suppliers or product considered to possibly have a greater potential than the general population of being non-compliant. If compliant results from biased sampling confirm non-biased program results, they provide increased assurance that the system is working effectively. The canned or packaged product should not be opened for sampling unless the unit size is at least twice the amount required for the final laboratory sample. The final laboratory sample should contain a representative portion of juices surrounding the product. The minimum quantity required for laboratory samples is 500 g of edible tissue (Table C VII Class B – Type 08, A). Decision: for purposes of control, the maximum residue limit for veterinary drugs (MRLVD) is applied to the residue concentration found in each laboratory sample taken from a lot. Lot compliance with a MRLVD is achieved when the mean result for analysis of the laboratory test portions does not indicate the presence of a residue which exceeds the MRLVD taking into account the expanded measurement uncertainty.

Mi-R	Residues of Veterinary Drugs in Raw Milk	Variables Plan on Bulk Material Sampling uncertainty not applicable	**Consumer and Producer:** CAC/GL71-2009: GUIDELINES FOR THE DESIGN AND IMPLEMENTATION OF NATIONAL REGULATORY FOOD SAFETY ASSURANCE PROGRAMME ASSOCIATED WITH THE USE OF VETERINARY DRUGS IN FOOD PRODUCING ANIMALS Sampling: see example F-R, The minimum quantity required for laboratory samples is 500 mL (Table B I Group 033). Decision: see example F-R
FV-C1	Aflatoxin in ready-to-eat Treenuts	Variables Plan on Bulk Material Sampling, sample preparation, and analytical variances used to compute operating characteristic curves	**Consumer and Producer:** CODEX STAN 193-1995: GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED Sampling: see ANNEX 2. Each lot, which is to be examined for aflatoxin, must be sampled separately. Lots larger than 25 tonnes should be subdivided into sublots to be sampled separately. If a lot is greater than 25 tonnes, the number of sublots is equal to the lot weight in tonnes divided by 25 tonnes. It is recommended that a lot or a sublot should not exceed 25 tonnes. The minimum lot weight should be 500 kg. Representative sampling should be carried out from the same lot. In the case of *static lots* of treenuts contained either in a large single container or in many small containers, it is not ensured that the contaminated treenut kernels are uniformly dispersed throughout the lot. Therefore, it is essential that the aggregate sample be the accumulation of many small incremental samples of product selected from different locations throughout the lot. The minimum number of incremental samples, the minimum incremental sample size and the minimum aggregate sample size depend on the lot weight and are given by Table 1. In the case of *dynamic lots*, the samples are taken from a moving stream of treenuts. The size of the aggregate sample depends on the lot size, the flow rate of the moving stream and the parameters of the sampling device. Two laboratory samples each of 10kg are taken from the aggregate sample. The laboratory samples should be finely ground and mixed thoroughly. The test portions taken from the comminuted laboratory samples by a random process should be approximately 50 grams. Decision: if the aflatoxin test result is less than or equal to 10 µg/kg total aflatoxin in the test samples from both laboratory samples, the lot is accepted.
FV-C2	Total Aflatoxins in Peanuts intended for		**Consumer and Producer:** CODEX STAN 193-1995: GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED

	further Processing		Sampling: see AFLATOXINS TOTAL, ANNEX 1: Each lot which is to be examined must be sampled separately. Large lots should be subdivided into sublots to be sampled separately. The weight or number of sublots depend on the lot size and is laid down in Table 1. The number of incremental samples to be taken depends also on the weight of the lot, with a minimum of 10 and a maximum of 100 (Table 2). For the sampling procedure see example FV-C1. The weight of the incremental samples should be approximately 200 grams or greater, depending on the total number of increments, to obtain an aggregate sample of 20 kg. The laboratory sample may be a portion of or the entire aggregate sample. If the aggregate sample is larger than 20 kg, a 20 kg laboratory sample should be removed in a random manner from the aggregate sample. A minimum test portion size of 100 g should be taken from the finely ground and mixed laboratory sample. Decision: if the aflatoxin test result is less than or equal to 15 µg/kg total aflatoxin in the test sample, the lot is accepted.
MW-FH	Microorganisms in Natural Mineral Water	Two-class attributes Plan	**Consumer and Producer:** CAC/RCP 33-1985: CODE OF HYGIENIC PRACTICE FOR COLLECTING, PROCESSING AND MARKETING OF NATURAL MINERAL WATERS (see also ICMSF (1986)[a)]: Chapter 25: Sampling plans for natural mineral waters, other bottled waters, process waters, and ice.) Sampling and Decision: Annex I: Microbiological Criteria, Table: Microbiological Criteria, Point of application: at source, during production and end product. Assuming a log normal distribution and an analytical standard deviation of 0.25 log cfu/ml, the sampling plans would provide 95% confidence that a lot of water containing a defined not acceptable geometric mean concentration of specific microorganisms would be detected and rejected based on any of five samples testing positive.
MW-C	Arsenic in Natural Mineral Water	Variables Plan on Bulk Material Sampling uncertainty implemented	**Consumer and Producer:** ISO 10725:2000: Acceptance sampling plans and procedures for the inspection of bulk materials / ISO 11648-1:2003: Statistical aspects of sampling from bulk materials — Part 1: General principles for liquid samples Sampling: see example C-C Decision: for the given maximum limit ML=0.01 mg/kg (CODEX STAN 193-1995: GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED), the lot is accepted if the sample grand average of these results $\bar{x}$ is lower than an upper acceptance value $\bar{x}_U = m_L + \gamma$ D with the constant for obtaining

			the acceptance value $\gamma = K_\alpha / (K_\alpha + K_\beta)$.

[a)] Microorganisms in Foods 2. Sampling for microbiological analysis: Principles and specific applications. 1986. 2nd Ed. International Commission on Microbiological Specifications for Foods.

[b)] International Organization of Legal Metrology (OIML), Bureau International de Métrologie Légale 11, rue Turgot - 75009 Paris - France, Publication OIML R 87 Edition 2004 (E)

APPENDIX II

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Annex

GENERAL GUIDANCE FOR THE PROVISION OF COMMENTS

In order to facilitate the compilation and prepare a more useful comments' document, Members and Observers, which are not yet doing so, are requested to provide their comments under the following headings:

(i) General Comments

(ii) Specific Comments

Specific comments should include a reference to the relevant section and/or paragraph of the document that the comments refer to.

When changes are proposed to specific paragraphs, Members and Observers are requested to provide their proposal for amendments accompanied by the related rationale. New texts should be presented in **underlined/bold font** and deletion in ~~strikethrough font~~.

In order to facilitate the work of the Secretariats to compile comments, Members and Observers are requested to refrain from using colour font/shading as documents are printed in black and white and from using track change mode, which might be lost when comments are copied / pasted into a consolidated document.

In order to reduce the translation work and save paper, Members and Observers are requested not to reproduce the complete document but only those parts of the texts for which any change and/or amendments is proposed.