CODEX ALIMENTARIUS COMMISSION E

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**Agenda Item 4** **CX/MAS 14/35/4**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING**

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

*(Prepared by the eWG chaired by Germany with the assistance of New Zealand, according to comments of Australia [AU], Canada [CA], Cuba [CU], Germany [DE], Japan, Mauritius, Netherlands, New Zealand [NZ], Switzerland, Thailand, United Kingdom, Uruguay, FIL/IDF, ICUMSA, ICMSF, OIML and the Chair of the Committee)*

Governments and interested international organizations are invited to submit comments at Step 3 in writing preferably by email to the Secretariat, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy, e-mail codex@fao.org with copy to Hungarian Codex Contact Point, Hungarian Food Safety Office, H-1097 Gyáli út 2-6. Budapest Hungary, e-mail: HU_CodexCP@mebih.gov.hu by **15 February 2014**.

## Introduction

This document provides practical notes which refer to the *Principles for the Use of Sampling and Testing in International Food Trade* (CAC/GL 83-2013) for assessing impacts of sampling and testing procedures on affected parties in terms of probabilities of wrongly accepting or wrongly rejecting a lot or consignment[1].

This document does not affect existing Codex limits or the current way of setting those limits. These responsibilities are set out in committees' terms of reference.

## Scope

[These explanatory notes are intended to assist governments in understanding the principles, and 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.]

**[AU: These explanatory notes are intended to expand on the principles in CAC/GL 83-2013 and provide practical examples of their use in sampling and testing procedures. Thus demonstrating the role of sampling and testing in standards, guidelines and agreements developed by the relevant international organisations including the WTO Agreement on the application of Phytosanitary Measures (SPS Agreements) and the Agreement on the Technical Barriers of Trade (TBT Agreement).]**

**[NZ: These explanatory notes are intended to:**

- **Interpret the main document**
- **Help governments establish and use sampling and testing procedures to assess whether foods in international trade comply with specifications**
- **Help governments understand the principles involved.]**

[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.

**[Chair: These explanatory notes are intended to:**

- **Interpret the main document**
- **Help trading partners (producers, exporters, importers, buyers and governments, etc.) understand the principles involved.**
- **Help trading partners establish and use sampling and testing procedures to assess whether foods in international trade comply with specifications.]**

**Explanatory Notes to 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.

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, communicated and agreed upon 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).

*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 (e.g. limit of detection, sensitivity and precision)*
- *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, all three of which should be considered when an assessment procedure is chosen:

- 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 inspection (test) 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 affects 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.

***Why can probabilities of wrongly accepting or wrongly rejecting a lot or consignment never be entirely eliminated?***

[*In terms of sampling, dispersion of the analytical results from samples (random error and bias from sample mean) is observed even if the samples are obtained following identical sampling procedures.*

*In conformity assessment, analytical results encompassing an agreed level of variability, which follows a probability distribution, are assessed against a uniquely defined specification level. Therefore, probabilities of wrongly accepting or wrongly rejecting a lot or consignment can never be entirely eliminated.*]

**[NZ: *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. One of these two outcomes is presumably a "wrong decision".*]**

*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) 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 %).*

*As mentioned in Principle 1, the specification of acceptable probabilities of wrongly accepting or wrongly rejecting a lot or consignment should have regard to principles of fairness towards the consumer and towards the producer respectively. This means making sure that a compliant product is not exposed to an unduly high probability of rejection. Typically, sampling plans are set to wrongly reject with probability 5% and wrongly accept with probability 10%.*

*Prior information may be useful in controlling the probabilities of wrongly accepting or wrongly rejecting a lot or consignment. For example, the importing country 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 exporting country. 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 HACCP, good agricultural practice (GAP), good manufacturing/production practice (GMP) and traceability aspects,*

*where appropriate. For further details, the GENERAL GUIDELINES FOR FOOD IMPORT CONTROL SYSTEMS (CAC/GL 47-2003) should be consulted. However, non-stable or perishable foods may need special consideration.*

*In accordance with the GUIDELINES FOR THE DEVELOPMENT OF EQUIVALENCE AGREEMENTS REGARDING FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS (CAC/GL 34-1999), auditing of the exporting country'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.*

*In order to build and maintain the necessary confidence in the inspection and certification systems of the exporting and importing countries, the GUIDELINES FOR THE DESIGN, OPERATION, ASSESSMENT AND ACCREDITATION OF FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS (CAC/GL 26-1997) should be consulted.*

**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.
- characteristic of samples and the objective of control

***Why is selection of appropriate sampling and testing procedures needed?***

[*Without selecting an appropriate sampling and testing procedure, it is difficult to reach an agreement between the exporting and importing country.*]

**[NZ: *If the sampling and testing procedures are not appropriate, one or both parties may be exposed to undue levels of risk.*]**

*Sampling procedures 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 RECOMMENDED METHODS OF SAMPLING FOR THE DETERMINATION OF PESTICIDE RESIDUES FOR COMPLIANCE WITH MRLS (CAC/GL 33-1999) for pesticide residues).*

*Otherwise, the GENERAL GUIDELINES ON SAMPLING (CAC/GL 50-2004) or considerable information available from elsewhere, e.g. international standards as far as possible, 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*

- *The choice between sampling plans by attributes and sampling plans by variables, followed by the choice of the parameters of the sampling plan process.*

*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—*

- *If the inspected parameter is 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 parameters 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 goods. In case of non-homogeneous lots or consignments (e.g. chemical or microbiological contaminants in food), an appropriate sampling procedure should be selected, by agreement between the parties.*

***The Annex provides practical examples of sampling plans.***

[*Unless other conventions or regulations (e.g. for testing compliance with MRLs of pesticide residues and several other chemical contaminants) exclude sampling uncertainty from the assessment, it is desirable that the sampling uncertainty (expressed by the sampling standard deviation) associated with any sampling plan, as well as the measurement uncertainty associated with the analysis, should be quantified and combined, as stated in the GENERAL GUIDELINES ON SAMPLING (CAC/GL 50-2004), Section 2.4, and in the GUIDELINES ON ESTIMATION OF UNCERTAINTY OF RESULTS (CAC/GL 59-2006), Section 2, when setting up a sampling plan.*

*The sampling uncertainty to be used when setting up a sampling plan can be based on an estimate of standard deviation obtained from experimental data during an extended period of production, made available by the professionals ($\sigma$-method), or can be estimated by testing a number of primary samples (s-method) if there is insufficient product experience.*]

**[DE:** ***Setting up a sampling plan, in principle, it is desirable that the sampling uncertainty (expressed by the sampling standard deviation as a measure of the dispersion of sample characteristics in the lot), as well as the measurement uncertainty (expressed by the analytical standard deviation as a measure of the dispersion of single analytical results ) should be quantified and combined according to GENERAL GUIDELINES ON SAMPLING, CAC/GL 50-2004, Section 2.4, although the Guidelines cover only the most frequent case where the analytical error is negligible compared to the sampling error.***

***The sampling uncertainty can be based on an estimate of the standard deviation obtained from experimental data on an extended period of production, made available by the professionals ($\sigma$-method) or can be estimated by testing a number of primary samples (s-method) in case of nonsufficient product experience.***

***This sampling uncertainty must not be confused with the uncertainty which is associated with the sampling as part of the testing procedure (e.g. the dispersion of sample characteristics in the test samples caused by selection of sampling position, time of sampling, decomposition of analyte or contamination of the sample) as quoted in the GUIDELINES ON ESTIMATION OF UNCERTAINTY OF RESULTS (CAC/GL 59-2006). It is the latter of which concerns testing for compliance.*****]**

**Principle 5: Analytical measurement uncertainty**

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

***Why should analytical measurement uncertainty be taken into account for product assessment?***

*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). The exporting country and the importing country should reach agreement to take into account analytical measurement uncertainty in criteria of the conformity assessment according to CAC/GL 54-2004. This agreement should cover all situations where a limit or specification is to be met, including limits for potential health hazards if such characteristics are to be assessed under the agreement.*

*Different 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 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. The procedures for estimating measurement uncertainty and interpreting results should be agreed by the parties. In all cases the key thing to consider during uncertainty estimation is the evaluation of all significant sources of error to obtain a representative measure of the overall error of the result.*

**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.

*To ensure that their own sampling and testing procedures are fit for purpose and of acceptable quality, the testing laboratories employed 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. rev.1997).*

*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 FOOD CONTROL LABORATORY MANAGEMENT: RECOMMENDATIONS (CAC/GL 28-1995, Rev.1-199)*
- *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 ESTABLISMENT 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.

*According to the "General requirements for the competence of calibration and testing laboratories" (ISO/IEC 17025:2005), analytical laboratories should maintain a quality management system which implements a fixed time period of scientific literature research and a prompt revision service based on the current technical documentation in force.*

**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)*

*FOOD CONTROL LABORATORY MANAGEMENT: RECOMMENDATIONS (CAC/GL 28-1995. rev.1997)*

*RECOMMENDED METHODS OF SAMPLING FOR THE DETERMINATION OF PESTICIDE RESIDUES FOR COMPLIANCE WITH MRLS (CAC/GL 33-1999)*

*GUIDELINES FOR THE DEVELOPMENT OF EQUIVALENCE AGREEMENTS REGARDING FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS (CAC/GL 34-1999)*

*GENERAL GUIDELINES FOR FOOD IMPORT CONTROL SYSTEMS (CAC/GL 47-2003)*

*GENERAL GUIDELINES ON SAMPLING (CAC/GL 50-2004)*

*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)*

*PRINCIPLES FOR THE USE OF SAMPLING AND TESTING IN INTERNATIONAL FOOD TRADE (CAC/83-2013)*

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

## ANNEX : Practical Examples of Sampling Plans

This Annex intends to illustrate the applicability of the principles of CAC/GL 50-2004 with some examples, without attempting to cover all situations. It is emphasized that CAC/GL 50 is based on several presumptions (e.g. that the qualitative or quantitative characteristic is distributed homogeneously, that the measurement error is negligible and for some procedures that the characteristic is normally distributed within the lot[2]). The Codex Sampling GL cannot be applied automatically: special characteristics of products require special sampling solutions, with agreements accordingly. (Examples for the latter case are for instance: pesticide residues, veterinary drugs, mycotoxins and other chemical contaminants in raw agricultural commodities). In any case, sampling solutions should be developed using competent advice.

In general, the agreement between importing and exporting countries should consider CAC/GL 50 or considerable information available from elsewhere, e.g. international standards, published papers and textbooks.

The following Table provides a summary of examples included in this Annex:

| Item in text | Lot type | Sampling plan | | Parameter | Standard to apply |
|---|---|---|---|---|---|
| A | Isolated | Single | Attributes | Visible defects on fruits | CAC/GL 50, 3.1; ISO 2859-2:1985, table A |
| B1 | Continuous | Single | Attributes | Visible defects on fruits (from a single source) | CAC/GL 50, 4.2, table 10; ISO 2859-1:1999 |
| B2 | Continuous | Single | Variables | Sodium in dietary cheese | CAC/GL 50, 4.3, table 14; ISO 3951-4:2011 |
| B3 | Continuous | Single | Average Control | Net weight of sugar packages | CAC/GL 50, 4.41 |
| B4 | Continuous | Single | Variables | Cadmium content of wheat bulk material | CAC/GL 50, 5; ISO 10725 |
| C | Not specified | OIML | Average Control/Attributes | Net weight of sugar packages | OIML R 87 (Edition 2004) |
| D | Not specified | ICMSF | Three-class attributes | *Staphylococcus aureus* in fresh or frozen poultry meat | CAC/GL 50, 3.2 |
| E | Not specified | Single | Average Control/Attributes | Aflatoxins in nuts (intended for processing) | CODEX STAN 193-1995 |

When the controlled characteristic is quantitative and known to be normally distributed, and where measurement error may be treated as negligible, it is possible to use either an attributes or a variables sampling plan. Since the efficacy of an attributes sampling plan is lower, it is preferable in this case to choose a variables sampling plan. Agreements should specify whether sampling should be done by attributes or by variables, and specify the parameters to be used in selecting the plan.

According to CAC/GL 50, 2.4, when the analytical error is negligible (i.e. the analytical measurement error is less than or equal to one third of the sampling error based on lot characteristics), analytical measurement error contributes less than 5% to the total standard deviation.

A higher measurement uncertainty will both increase the probability of wrongly rejecting a lot or consignment (higher probability of rejection of compliant products) and the probability of wrongly accepting a lot or consignment (higher probability of acceptance of non-compliant products) and therefore the size of the measurement uncertainty should be an issue of agreement.

**Example A for isolated lot inspection: Visible defects on fruits (single sampling plans by (qualitative[*)]) attributes (CAC/GL 50, 3.1; ISO 2859-2:1985) for isolated lot inspection):**

[*)]Qualitative data includes quantitative data classified as attributes, for example with respect to a limit.

[2] In case of doubt consult ISO 5479:1997, "Statistical interpretation of data - Tests for departure from the normal distribution".

Agreement before trading activities:

Sampling and decision according to CAC/GL 50.

Choosing to set LQ=12.5%, i.e. a lot with 12.5% non-compliant items will be accepted with a probability of 10% (consumers' risk).

Sampling and decision (ISO 2859-2:1985, Table A):

For a lot size between 151 and 280 the importer should take 20 samples from the lot and allow no non-compliant item. For a lot size between 3201 and 10,000 the importer should take 80 samples from the lot and allow 5 non-compliant items.

**Examples B1 to B4 for Continuous Series of Lots**

**Example B1: Visible defects on fruits (single sampling plans by (qualitative[*)]) attributes (CAC/GL 50, 4.2, Table 10; ISO 2859-1:1999) for a continuous series of lots coming from a single source:**

[*)]Qualitative data includes quantitative data classified as attributes, for example with respect to a limit.

Agreement before trading activities:

Sampling and decision according to CAC/GL 50.

1. Choosing to set AQL=6.5%, i.e. a lot with 6.5% non-compliant items will be rejected with a probability of 5% (producers' risk).

2. Whether the inspection level is set to "normal" or to "reduced" in case of other confidence-building measures.

Sampling and decision:

In the case of Inspection Level II, for a lot size between 151 and 280 the importer should take 32 samples from the lot and allow 5 non-compliant items (ISO 2859-1:1999, Table 1 and 2a). For a lot size between 3201 and 10,000 the importer should take 200 samples from the lot and allow 21 non-compliant items. With these criteria, in the case of 32 samples, a lot with 27.1% non-compliant fruits will be accepted with a probability of 10% (consumers' risk) (ISO 2859-1:1999, Table 6A). In the case of 200 samples, a lot with 13.8% non-compliant fruits will be accepted with the same probability.

**Example B2: Dietary cheese low in sodium (single sampling plans for inspection by (quantitative) variables for percent nonconforming (CAC/GL 50, 4.3; ISO 3951-4:2011):**

A lot is compliant if the percentage of items with sodium content exceeding an upper limit L does not exceed 2.5% (AQL = 2.5 %).

Agreement before trading activities:

Sampling and decision according to CAC/GL 50.

1. Whether the dispersion of the sodium content in the lot is already known, as standard deviation □ (□-method) (e.g. according to experimental data on an extended period of production, made available to the inspectors by the professionals), or is to be estimated as a standard deviation *s* (*s*-method) by the importer.

**[The chair recommends to delete the text "or is to be estimated as a standard deviation *s* (*s*-method) by the importer"; NZ recommends to retain it.]**

2. Whether the inspection level is set to "normal" or to "reduced" in case of other confidence-building measures.

3. Choosing a producers' risk of 5%, i.e. a lot meeting the specification will be rejected with a probability of at most 5%.

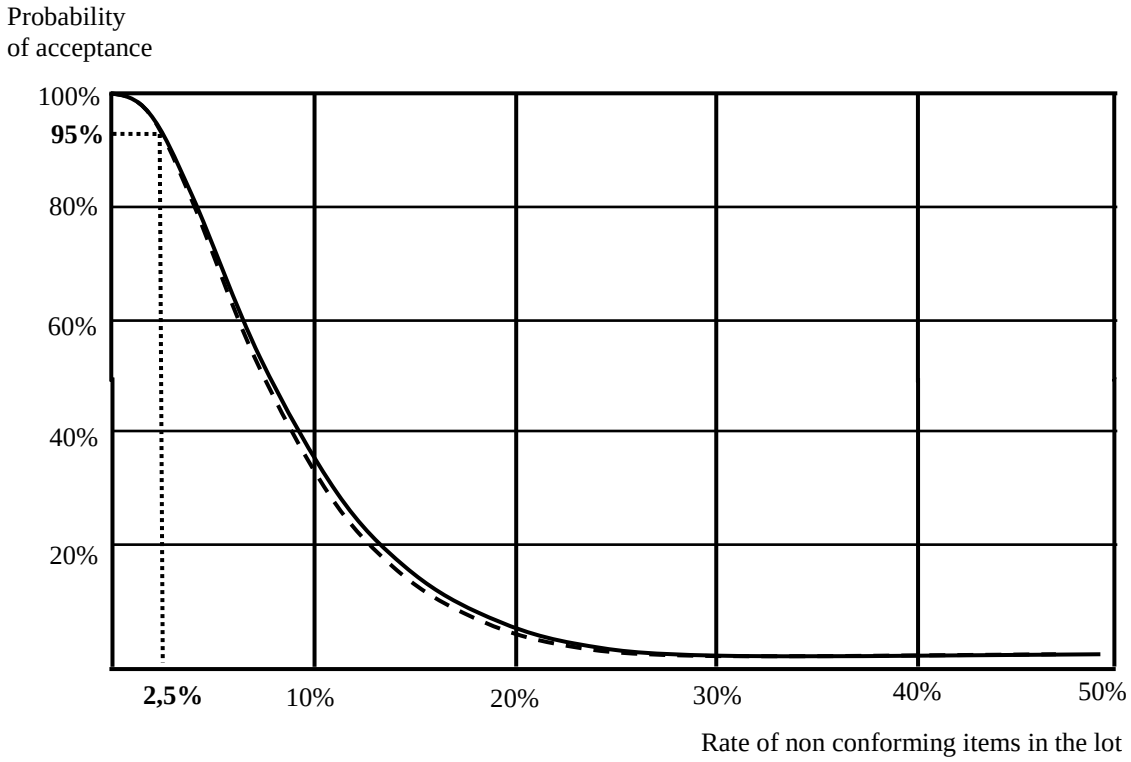


Figure B2: OC curves, variables sampling plan, AQL = 2.5 %, for s-method (CAC/GL 50, Table 16/Figure 11), n = 15, k = 1.47 (solid line) and $\sigma$-method (CAC/GL 50, Table 19/Figure 15), n = 7, k = 1.45 (dashed line).

Sampling and decision:

For a lot size between 151 and 280 the importer should take 15 (7)[*)] samples (CAC/GL 50, 4.3 Table 14 and Table 17 respectively) randomly from the lot. The corresponding OC curves are shown in Figure B2. The sodium content of each of the samples should be measured. From the results the mean should be estimated. When the *s*-method is applied, the standard deviation *s* should also be calculated.

The corresponding acceptability constant is k = 1.47 (1.45).

The lot is accepted if the mean value is less than or equal to the limit *L* minus the 1.47-fold of *s* (1.45-fold of $\sigma$).

Comment:

From Figure B2 it is obvious that the σ-method is more efficient than the s-method, since for a given lot size and AQL, fewer samples have to be taken from the lot.

[*)] The values in brackets refer to the $\sigma$-method

**Example B3: Net weight of sugar prepackages (single sampling plan for average control (CAC/GL 50, 4.4)):**

Such a control is performed by using a test which aims at ensuring that, on average, the content of the controlled characteristic is at least equal to either the quantity given on the label of the product, or the quantity fixed by a regulation or a code of practice (e.g. net weight or net volume).

The recommended procedure is similar to example B2.1 where the normally distributed dispersion of the analyte is unknown and must be estimated.

The standard deviation *s* as a measure of dispersion is estimated ad hoc by measuring a number *n* of randomly taken samples *i* (*i=1....n*).

$$s = \sqrt{\sum_{i=1}^{n} \frac{(x_i - X)^2}{n-1}}$$

where *X* is the mean value of the *n* single values of the variable $x_i$.

This estimator is a simple approach based on the prerequisite that the analytical measurement uncertainty should be less than or equal to one-third of the sampling uncertainty and therefore contributes less than 5% to the combined uncertainty.

For the control of a specified minimum value $X_{min}$, the lot is accepted if:

$$X \geq X_{min} - \frac{t_{\alpha} \cdot s}{\sqrt{n}}$$

where $t_{\alpha}$ is the value of the Student's t-distribution, on *n-1* degrees of freedom, corresponding to the significance level $\alpha$.

From this formula it is clear that the significance level $\alpha$ (one- or two-sided) and the number of samples are decisive parameters and must be defined beforehand.

For the net weight of sugar prepackages, a lot is compliant if the mean net weight does not significantly fall below the declared value.

Agreement before trading activities:

Sampling and decision according to CAC/GL 50.

Number of samples $n = 20$.

Definition of the one-sided significance level $\alpha = 5\%$.

Sampling and decision:

The specification for the sample items in the lot is 1 kg. According to the agreement, 20 sugar packages are taken from the lot and are weighted separately. From the results the mean $X$ and the standard deviation $s$ are estimated as 0.97 kg and 0.02 kg respectively. The value $t_{\alpha}$ of the Student's t-distribution for n=20 and one-sided $\alpha = 5\%$ is 1.73.

The significance level was defined as 5%. The lot is to be accepted if:

$$X \geq 1.00 - \frac{1.73 \cdot 0.02}{\sqrt{20}} = 0.99$$

The mean net weight is less than the limit of tolerance and the lot is rejected.

Comments:

Obviously, the standard deviation $s$ has a significant impact on the limit of tolerance. A lot with a higher dispersion would be rejected only on a lower mean content. In the above-mentioned example, a standard deviation of 0.05 kg would result in the acceptance of the lot. Therefore, the specification of the standard deviation (as *known standard deviation* $\sigma$, CAC/GL 50, 4.41) might be an issue of agreement before trading activities.

**Example B4: Cadmium content of wheat (inspection by variables of bulk materials, known standard deviation (CAC/GL 50, 5; ISO 10725:2000)):**

Agreement before trading activities:

Sampling and decision according to ISO 10725:2000.

Probability $\alpha$ of wrongly rejecting a conforming lot and probability $\beta$ of wrongly accepting a nonconforming lot.

Cost level.

A prerequisite is long term monitoring of the cadmium content in order to evaluate the standard deviation of that characteristic 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 (ISO 10725:2000, 6.2.1).

Sampling and decision:

The concept of the procedure is as follows:

The following four quantities are chosen: the acceptance quality limit for the lot mean $m_A$ (corresponding to AQL, producers' risk), the probability $\alpha$ 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 $\beta$ of wrongly accepting a nonconforming lot. From these are deduced the precision with which the lot mean must be estimated. The various numbers of increments, test portions and replicate measurements are then chosen to achieve this precision (presumably at least cost).

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 $\bar{x}_U$ where

$$\bar{x}_U = m_A + \gamma D$$

with the discrimination interval

$$D = m_R - m_A$$

which is the interval between the acceptance quality limit and the non-acceptance quality limit.

It is recommended that the value of D be specified, taking account of the values of standard deviation of sampling increments $\sigma_I$, the standard deviation of test samples $\sigma_T$ and the measurement standard deviation $\sigma_M$. The combination of these standard deviations gives the estimation standard deviation $\sigma_E$ (ISO 10725:2000, 6.2).

For a given probability $\alpha$= 5% of wrongly rejecting a conforming lot and for a given probability $\beta$ = 10% of wrongly accepting a nonconforming lot, $m_R$ and D can be calculated from $m_A$ (e.g. the legal maximum level of cadmium in wheat) according to figure B4.1:

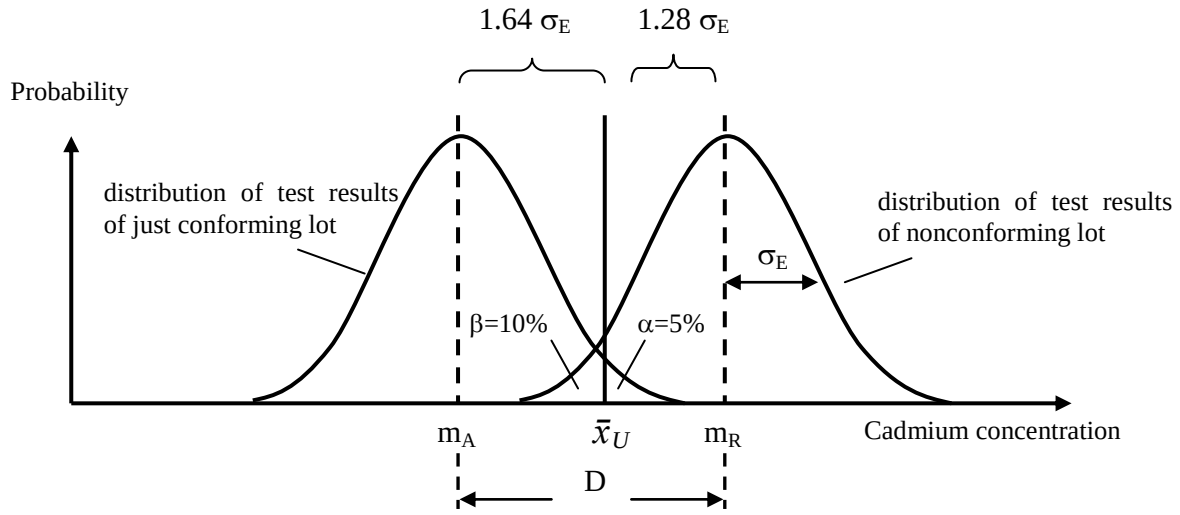


Figure B4.1: Relationship between $m_A$, $m_R$, D and $\bar{x}_U$ for given $\sigma_E$, $\alpha$ = 5% and $\beta$ = 10%

$K_{\alpha=5\%} = 1.64$
$K_{\beta=10\%} = 1.28$

$$D = m_R - m_A = 2.92\ \sigma_E$$

and finally

$$\gamma = K_{\alpha=5\%} / (K_{\alpha=5\%} + K_{\beta=10\%}) = 0.65$$

For $\sigma_E$ = 0.04 mg/kg and $m_A$ = 0.2 mg/kg as an example, this gives

$$\bar{x}_U = 0.20 + 0.65 \cdot 2.92 \cdot 0.04 = 0.28 \text{ mg/kg}$$

The number of samples (figure B4.2) and the number of measurements are estimated according to the standard (ISO 10725:2000, 6.3) as follows:

The sample size can be estimated using table 3 of the standard (for $\alpha$=5%, $\beta$=10% and the low cost level 1) from the relative standard deviations $d_I = \sigma_I/D$ and $d_T = \sigma_T/D$. Assuming $d_I$ = 0.6 and $d_T$ = 0.4, this gives $n_I$ = 2 and $n_T$ = 5. The number $2n_I$ = 4 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 $2n_T$ = 10 test samples should be prepared (e.g. homogenized).

For the example of cadmium in bulk wheat grains the ratio $\sigma_M/\sigma_T$ might be assumed to be 0.3. For imprecise standard deviations, one measurement per test sample should be performed (ISO 10725:2000, 6.3.2.2).

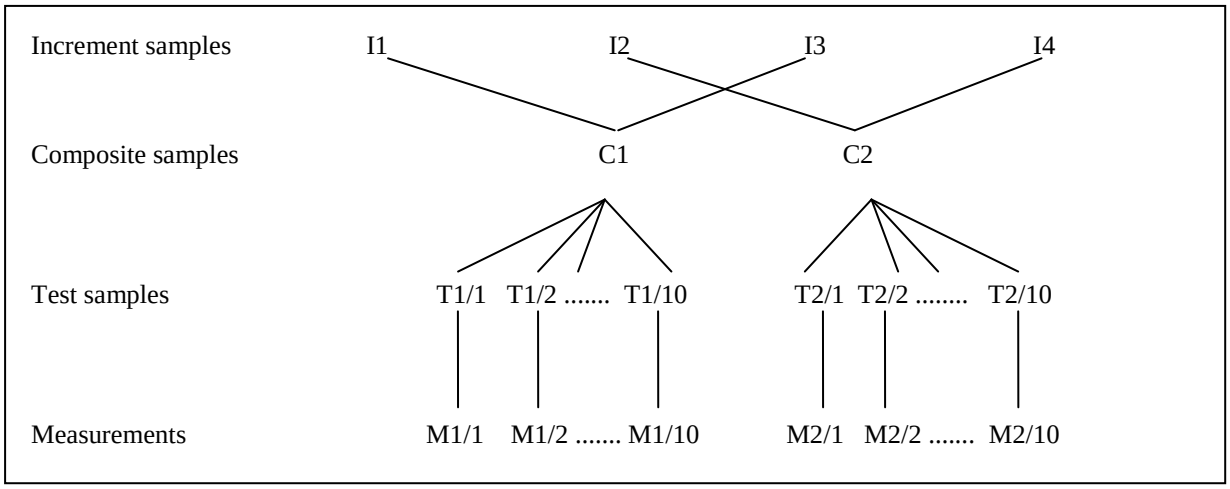


Figure B4.2: Sample size for the example of cadmium in bulk wheat grains

Comment:

The final method suggests that measurement uncertainty is the dominant source of imprecision, i.e. twenty measurements are being made on two composite samples each of two increments. This allocation is based on the low cost level 1 of sampling and analysis.

**Example C (Ref. OIML R 87 (Edition 2004) ), Net weight of sugar prepackages:**

A lot is compliant if the average actual quantity of product in a prepackage is at least equal to the nominal quantity and if not more prepackages that a given percentage exceed the defined tolerable deficiencies and if no prepackage contains an actual quantity less than the nominal quantity minus twice a given tolerable deficiency.

Agreement before trading activities:

Sampling and decision according to OIML R 87.

According to Type I Risk of the reference document, the probability of rejecting an inspection lot containing 2.5 % of inadequate prepackages (i.e. prepackages found to contain an actual

quantity less than the nominal quantity minus the tolerable deficiency) shall not exceed 5 % (corresponding to AQL=2.5%).

Sampling and decision:

The specified net weight for the sample items in the lot is 1 kg. The lot contains more than 3200 prepackages. According to the OIML Recommendation, 125 sugar packages are taken from the inspection lot and the contents are weighted separately (see table 1 of the reference document).

The lot is accepted if all of the following criteria are met:

1. The average actual quantity of product in a prepackage 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 prepackage is given by the sum of the differences between the individual product weights and the nominal weight of 1 kg. The average error is given by that total error divided by the sample size of 125.

   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 0.234 (see table 1 of the reference document for the sample size >3200) is higher than the absolute value of the average error.

2. The number of prepackages containing an actual quantity less than the nominal quantity minus 15 g is 7.

3. No prepackage contains an actual quantity less than the nominal quantity minus 30 g.

**Example D, *Staphylococcus aureus* [a)] in fresh or frozen poultry meat (CAC/GL 50, 3.2, three-class attributes sampling plan, ICMSF[b)], Table 22) :**

[a)]If either packaged or repackaged after processing; not for products processed in packages that are kept closed until time of final preparation.

[b)] Microorganisms in Foods 8. Sampling for microbiological analysis: Principles and specific applications (2011) 8th Ed. International Commission on Microbiological Specifications for Foods.

Agreement before trading activities:

Application of an appropriate ICMSF plan (Sampling for microbiological analysis, Table 22).

Sampling and decision

n = 5 (number of items in the inspection sample per lot)

c = 1 (maximum number of items of the sample where the concentration x of *Staphylococcus aureus* is higher than m)

m = $10^3$ CFU/g (limit between good and marginal).

The lot is accepted if not more than 1 item in the sample shows the presence of *Staphylococcus aureus* with a maximal content of $10^3$ CFU/g. The lot is rejected in the opposite case.

Comment:

The ICMSF publication does not distinguish between isolated lot inspection and inspection of continuous lots. It is based on the definition of a lot as a quantity of food supposedly produced under identical conditions, all packages of which would normally bear a lot number that identifies the production during a particular time interval, and usually from a particular 'line', retort, or other critical processing unit. Statistically, a lot is considered as a collection of units of a product from which a sample is to be drawn to determine acceptability of the lot.

Where there is risk of severe direct health hazard (such as *Salmonella*), a two-class attributes sampling plan with absence in 25 grams in up to 60 items is recommended.

**Example E, Aflatoxins in nuts intended for processing** (Similar principles are applied, for instance, in the case of dioxins, heavy metals, PCBs, pesticide residues, and veterinary drugs (perhaps together with the relevant standards))**:** A lot is compliant if its mean aflatoxin content does not exceed the required limit of 15 µg/kg (CODEX STAN 193-1995).

Agreement before trading activities:

Sampling and decision according to CODEX STAN 193-1995.

Sampling and decision:

Recommended specifications of the manner in which production lots or consignments may be linked to inspection samples are provided in CAC/RCP 22-1979 under Processing, Packaging, Lot identification, and Processing and production records.

For a lot size of 4 tonnes, the importer should take at least 25 increment samples of 800 g randomly from the lot after subdivision into sub-lots (CODEX STAN 193-1995, Annex 2, Table 1). On the homogenized aggregate (laboratory) sample of 20 kg, the content of total aflatoxins should be measured. The lot is rejected if the aflatoxin test result significantly exceeds 15 µg/kg total aflatoxins, taking into account the variance associated with the test procedure (CODEX STAN 193-1995, Annex I, Table 1).