CODEX ALIMENTARIUS COMMISSION

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Agenda Item 4b **CX/MAS 13/34/5**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

Thirty-fourth Session
Budapest, Hungary, 4 - 8 March 2013

PROPOSED DRAFT PRINCIPLES FOR THE USE OF SAMPLING AND TESTING IN INTERNATIONAL FOOD TRADE
Other Sections
(at step 4)

Prepared by an eWG chaired by Germany with the assistance of Japan, Netherlands, New Zealand and USA

Background

At its 33rd Session the CCMAS agreed that it would consider at this session only the principles with additional notes only if essential and that further development of the document, such as explanatory notes and examples that would be useful, should be considered at a later stage.

The Committee agreed to return the commentary to Step 2/3 and to develop examples at a later stage.

The Committee agreed to establish an electronic working group, working in English, to develop draft explanatory notes and consider what examples might be useful, for consideration at the next session.

The working group would be chaired by Germany with assistance of New Zealand (especially as regards the availability of a web-based work space), the United States, the Netherlands and Japan.

Working environment

An invitation letter to Codex members and international organizations to nominate participants and guests was circulated on 23 May 2012.

The web-based shared workspace provided by New Zealand as forum for discussion before.

New Zealand hosted, developed, managed the workspace and provided reference links.

The names, contact details and statuses of the nominated persons were uploaded in the website. A total of 22 member countries, 1 member organization and 7 international organizations nominated their participants and guests (Annex I).

Development of the Proposed Draft Explanatory Notes

The initial draft of the Proposed Draft Principles was prepared by Germany and New Zealand.

The text was taken from

The Proposed Draft Principles for the Use of Sampling and Testing in International Food Trade (CX/MAS 12/33/3)
The Proposed Draft Principles for the Use of Sampling and Testing in International Food Trade (REP12/MAS, Appendix IV)
The GUIDELINES FOR THE EXCHANGE OF INFORMATION BETWEEN COUNTRIES ON REJECTIONS OF IMPORTED FOOD (CAC/GL 25-1997);
The GENERAL GUIDELINES ON SAMPLING (CAC/GL 50-2004);
The GENERAL GUIDELINES FOR FOOD IMPORT CONTROL SYSTEMS (CAC/GL 47-2003);
The GUIDELINES ON ESTIMATION OF UNCERTAINTY OF RESULTS (CAC/GL 59-2006);
The GUIDELINES ON MEASUREMENT UNCERTAINTY (CAC/GL 54-2004);
The 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); ISO/IEC 17025:2005 (CAC/GL 27-1997) 'General requirements for the competence of calibration and testing laboratories';

These source texts were amended by comments and examples.

Germany posted the initial draft on the workspace on 18th July. The discussion was started on 30th August with deadline on 16th November. Due to several requests for allowing further contributions, the discussion was kept open until 31th December.

Comments and contributions were received from 7 countries (Canada, Cuba, Germany, Hungary, Netherlands, New Zealand and Uruguay). Uruguay provided a completely new version of the document which could not be implemented into the processed version. It was posted on the workspace on 19th November. The draft document was promptly amended as the discussion proceeded, and the current version was posted on the workspace.

A concluding version (Annex II) was posted on the workspace on 3rd January 2013.

Matters of Discussion

In general, a high level of agreement between the discussion parties was achieved. Most of the comments could be considered amending the text by consensus. Otherwise, the text contributions of Cuba and Hungary have been placed in square brackets for further consideration.

The main subjects of discussion have been the "Agreements before initiating trade" (Principle 1), "Consumers' Risk and Producers' Risk" (Principle 4), "Selecting appropriate sampling and testing procedures" (Principle 5) and "Taking account of analytical measurement uncertainty and its implications" (Principle 7).

Difficulties arising from the determination of the levels at which the probabilities of acceptance are to be controlled and the specification of the quality level at which a production lot or production consignment will be rejected with a specified low probability (the producer's risk) and the quality level at which a production lot or production consignment will be accepted with a specified low probability (the consumers' risk) have been discussed extensively. As a consequence, this was considered to be a principal point of agreements before initiating trade.

In order to facilitate the application of the GENERAL GUIDELINES ON SAMPLING (CAC/GL 50-2004) with respect to product variation, helpful comments and examples have been elaborated for selecting appropriate sampling and testing procedures.

The introduction of definitions "inspection lot/consignment" proved not beneficial and finally the terms "lot/consignment", "production lot/production consignment", "lot as defined by the inspector" and "inspection samples" remained by consensus.

After discussion, the participants agreed, that in order to control producers' and consumers' risks it is necessary to specify a quantity that the standard deviation of measurement error is not expected to exceed, such as a 95% confidence limit. This takes into consideration the fact that even the statistical significance of 95% does not prove compliance or non compliance beyond any reasonable doubt.

Attachments:

Annex I: List of participants

Annex II: Proposed Draft Explanatory Notes on Principles for the Application of Sampling and Testing Activities in International Food Trade

Annex I

ELECTRONIC WORKING GROUP ON EXPLANATORY NOTES ON PRINCIPLES FOR THE USE OF SAMPLING AND TESTING IN INTERNATIONAL FOOD TRADE

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Annex II

PRINCIPLES FOR THE USE OF SAMPLING AND TESTING IN INTERNATIONAL FOOD TRADE

EXPLANATORY NOTES

CONTRIBUTED BY GE, NZ, CU, CA, NL AND HU

Introduction

This document provides practical notes which refer to the *Proposed Draft Principles for the Use of Sampling and Testing in International Food Trade (REP12/MAS, Appendix IV)* for assessing impacts of sampling and testing procedures on affected parties in terms of producers' and consumers' risks but does not give guidance on choosing an appropriate level of risk for affected parties.

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 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.

Explanatory Notes to Principles

Principle 1: Agreements before initiating trade

Before starting trading activities, the parties concerned should reach agreement related to the sampling and testing procedures that will be applied to determine whether the food in trade meets the specifications of the importing country and also on the sampling and testing procedures to be followed in the case of a dispute.

Agreement is desirable:

- *to allow the producers' and consumers' risks associated with the procedures to be assessed and maintained 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:

- *Language of communication*
- *Specification of the quantities that will be used to quantify the quality level of a lot (for example the mean analyte level or the percentage of product above a certain level)*

  [Hungary: The accept reject limit (A/RL) should be specified based on prior experience and taking into account the know uncertainties of sampling and analysis.

  The A/RL should be lower than the maximum or higher than the minimum permitted concentration. The A/RL shall be applied for the analyte content or the tested parameter of the duplicate samples taken by the producer/exporter. The first sample shall be analysed before the shipping of the product, the second sample shall be retained for analysis in case of dispute. Utmost precaution shall be taken to ensure that the content of the two samples is as similar as possible and the second sample is stored under conditions which assure the integrity of the sample material.

  The A/RL may be linked to AQL and LQ discussed in principle 5]

- *Specification of maximum acceptable producers' and consumers´ risks, and the quality levels (see above) at which they are to apply*

  [Hungary: In case of inhomogeneous lots such as raw agricultural commodities the extent of heterogeneity may vary from lot to lot. Consequently an appropriate sampling strategy assuring specified consumer/producer risk cannot be defined without extensive (expensive and time consuming) case-by case testing. One possible solution is the agreement on an A/RL which is decided

based on all available prior experience and scientific results. The A/RL should be re-evaluated time to time.]

- *Specification of the manner in which production lots or consignments may be linked to inspection samples. It is more straightforward where the consignment and lot are the same. If a consignment contains multiple lots, acceptance may be for individual lots within the consignment or for the entire consignment. This situation must be clarified in the agreements as outlined in CAC/GL 47-2003 Guidelines for Import Control Systems paragraph 28. It should be noted that if acceptance is for a consignment as a whole, then that entire consignment should be treated as a single lot for the purposes of sampling.*
- *Sampling procedure (that is, methods used to select and physically take the samples, and the specific portions of material to be analysed)*
- *Analytical methods (that is, methods used to estimate the relevant characteristics of the samples)*
- *Specification of the acceptance criteria following sampling and analysis, including specification of any allowances to be made for sampling and analytical measurement uncertainty*
- *Agreement on a process for resolving disputes over analytical (test) results (for example CAC/GL 70-2009)*
- *Specifications regarding the retention of reserve samples by the importing country for the purposes of resolving disputes*

  [Hungary: reserve sample(s) should be taken before the shipment and stored by the exporter(supplier). Alternately an A/RL could also be specified and applied at the importer side. Good example for this is the EC regulation specifying 50% uncertainty on the results of pesticide residue analysis (lots are rejected if the residue measured in the sample is larger than times the MRL. Ideally, if the A/RL is properly selected at the producer/exporter side no sample taken from a compliant lot should contain residue above the importers A/RL.]

- *Communication procedures in case of any variations of the above-mentioned terms*

Principle 2: Transparency

The selection of sampling and testing procedures and the process for comparing test results to specifications should be documented, communicated and agreed upon by all parties. All relevant information should be shared between governments using mutual agreed upon format and language(s).

[CUBA: In order to minimize the inconveniences that can be caused by the application of different ways to identify production lots or consignments in the original country (exporter) with respect to inspected lots or consignments in the destination country (importer), which becomes frequently, a serious problem, the exporter and the importer should apply the same sampling procedures, to the same portions of the commodity (lot, consignment, container, hold of ship, production date, etc.) and identical or equivalent testing methods must be used. These situations should be very well stated and clarified in the previous agreements before initiating trade to make possible the quality results' comparison of commodities produced in origin and inspected in destination.]

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). The information should document the link between the particular 'production lot' or 'production consignment' of the exporter and inspection samples of the importer. The information should contain:

- *The details of the applied sampling procedure*
- *A description of the inspection samples (e.g. size, location in the consignment)*
- *The analytical method used to measure the inspection samples, and the laboratory performing the measurements, including fit for purpose evaluation according to Principle 9*
- *The measured result for each inspection sample, together with any information (e.g. container identification, manufacturer's codes) which may identify to the exporter the part of the production consignment from which it was drawn*

- *Values for any components of measurement and sampling uncertainty used in the assessment, and their source*
- *A description of the raw data, the calculations performed and the results obtained, sufficient for the exporting country to comprehend these results*
- *A description of the criteria applied in deciding to reject the production lot or consignment*
- *Justification for these criteria, (e.g. in terms of prior agreement, use of published sampling plans, mathematical argument and so on).*

[Hungary: it would be more appropriate to exchange all necessary information listed above and agree on the procedures which would be applied and specify them in the trade agreement before the shipments of goods. In case of rejection, only potential deviations should be listed and justified. Otherwise we open the door for a lengthy dispute situation.]

Principle 3: Components of a product assessment procedure

Sampling and testing of food in trade to determine 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 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.

For a given lot, this decision may not be predictable because of variation between samples and variation due to measurement error: of two identical lots, one may be accepted and the other rejected, because of this variation. On the other hand, the probability of such a discrepancy can be controlled, if the sampling and measurement uncertainties are considered correctly. This is a fact that must be well understood and considered by both the producer and consumer when making and acting on decisions.

[H: If the concept of A/RL is accepted, then the above problem is eliminated]

Principle 4: Consumers' Risk and Producers' Risk

Whenever food is sampled and tested, the probability of wrongly accepting or wrongly rejecting a lot or consignment affects both exporters and importers and can never be entirely eliminated. The Consumers' Risk and Producers' Risk should be evaluated and controlled, preferably using methodology described in internationally recognized standards.

The WORKING PRINCIPLES FOR RISK ANALYSIS FOR FOOD SAFETY FOR APPLICATION BY GOVERNMENTS (CAC/GL 62-2007) provide guidance to national governments for risk analysis (risk assessment, risk management and risk communication) with regard to food related risks to human health).

[Canada: Canada suggests that this reference might be deleted. It is our recollection that the discussion of Risk within the scope of this Working Group is to address the risks of wrongly accepting or rejecting food in trade and that references to human health risks are not within the scope of this work.]

[Hungary: the CAC/GL 62-2007 is very general and does not provide any useful information for deciding on the acceptable consumer risk in connection with a particular commodity analyte combination. It might be useful to include a section to link this GL to relevant general Codex Principles.]

The GENERAL GUIDELINES ON SAMPLING (CAC/GL 50-2004), sections 3, 4 and 5, provide guidance on sampling plans for various situations. Principle 1 recommends consultation between exporting and importing countries in selecting a plan. Whether agreement is reached or not, the choice of plan to be used is ultimately the responsibility of the importing country. Particularly where consultation has not taken place or agreement has not been reached, the responsible authority should have regard to principles of fairness towards the producer. This means making sure that compliant product is not exposed to an unduly high probability of rejection. In other words, the producers' risk should not be too high. What is "too high" may depend on the product and analyte concerned, and also the AQL (Acceptable Quality Level) considered appropriate. The "usual" value for the producer's risk (as stated in the GL 50, section 2.2.14, second paragraph) is 5%, the sampling plan being chosen to apply this producers' risk at a lot quality (the AQL) appropriate to the hazard presented by non-compliant material. As stated in the GL 50, section 2.2.14, the

characteristics which may be linked to critical defects (for example to sanitary risks) shall be associated with a low AQL (i.e. 0,1 % to 0,65 %) whereas the compositional characteristics such as the fat or water content, etc. may be associated with a higher AQL (e.g., 2,5 % or 6,5 % are values often used for milk products).

According to ISO 2859-2, it is recommended that the particular consumers' risk LQ (Limiting Quality), which is normally 10%, should be set at least three times the desired AQL, in order to ensure that lots of acceptable quality have a reasonable probability of acceptance. Accordingly, the LQ is generally very low when the plans aim at the control of food safety criteria. It is often higher when the plans aim at the control of quality criteria.

Therefore, determination of the AQL, LQ and their associated risks may involve risk analysis. An importing country that bases its risk management strategy on sampling and testing at the border may find it is difficult or impossible to obtain satisfactory consumers' risk at moderate cost (that is, using small numbers of samples), while at the same time ensuring that producers' risk is adequately controlled.

Prior information may be useful in managing these risks efficiently. For example, the importing country can take into account the rate of non-compliances of certain exporter/importer combinations in controlling risk, using procedures with relatively low sampling rates (and therefore in principle relatively high consumers' risks) in cases where past records show that there is in any case a low risk of non-compliance, and higher sampling rates for other situations.

It may also be possible 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 and traceability aspects, where appropriate.

Auditing of the exporting country's control system can lead to choosing a less strict sampling plan compared to the situation without prior knowledge, in accordance with the GUIDELINES FOR THE DEVELOPMENT OF EQUIVALENCE AGREEMENTS REGARDING FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS (CAC/GL 34-1999).

An importing country's overall risk management strategy, of which sampling and testing at the border is one of a number of measures used to manage risk, should take account of the exporting country's risk management strategy

Principle 5: Selecting appropriate sampling and testing procedures

The sampling and testing procedures selected should be scientifically based and appropriate to the commodity and lot or consignment to be sampled and tested, fit for intended purposes and applied consistently.

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.*
- *Definition of a quantity defining the "quality level" of a lot as defined by the inspector (e.g. the mean analyte level of the lot or a percentage of the lot with analyte concentrations outside a certain range) which the sampling and testing procedure is to control, and in terms of which the AQL and LQ are to be stated.*
- *Determination of the levels at which the probabilities of acceptance are to be controlled and the specification of the AQL, which is a quality level at which a lot or consignment will be rejected with a specified low probability (the producer's risk) and of the LQ which is a quality level at which a lot or consignment will be accepted with a specified low probability (the consumers' risk).*
- *Specification of the two specified probabilities of acceptance above, the producer's and consumer's risks.*

Whether the measurement methods available to assess the quality of inspection samples are qualitative or quantitative.

- *The measurement errors associated with these measurement methods: e.g. the probabilities of false positives and false negatives, the probability distribution of measurement errors.*

- *In the case of quantitative measurements, whether the values obtained after randomly sampling can be treated as normally distributed (possibly after a suitable transformation).*
- *In the case of quantitative measurements, whether there is information on the likely variability within the lot, for example based on historical information or manufacturer's information.*
- *In cases where an assessment procedure is based on an estimate of the mean analyte(s) content in a lot and a predetermined estimate of within lot variation, the extent to which individual lots may be expected to vary about this latter estimate should be considered, along with variation in producers' and consumers' risks that may result.*

Sampling procedures should be performed in accordance with appropriate Standards related to the commodity of concern (for example ISO 707 for sampling of milk and milk products or RECOMMENDED METHODS OF SAMPLING FOR THE DETERMINATION OF PESTICIDE RESIDUES FOR COMPLIANCE WITH MRLS (CAC/GL 33-1999)).

The GENERAL GUIDELINES ON SAMPLING (CAC/GL 50-2004) should be consulted when developing appropriate sampling plans. The Guidelines cover the following sampling situations for the control exclusively of homogeneous goods:

- *control of percentage of defective items by attributes or by variables, for goods in bulk or in individual items,*
- *control of a mean content.*

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 as described in GL 50, section 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 (provided measurement uncertainty is negligible, in relation to sampling uncertainty)

- *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 (consult ISO 5479:1997, "Statistical interpretation of data - Tests for departure from the normal distribution"), Attributes Plans (CAC/GL 50-2004, 4.2) should be performed for sampling.*
- *In case of measurable parameters with normally distributed variability, Variables Plans (CAC/GL 50-2004, 4.3) should be chosen.*

If it is required to control the average of a characteristic in a lot, then (again providing measurement uncertainty is not an issue)

- *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 is at least/at most equal to either the quantity given on the label of the product, or the quantity fixed by the regulation or a code of practice (e.g. net weight, net volume etc.).*

The Guidelines are applicable for control at reception, but may not be applicable for quality control of end-products by manufacturers.

The selection of a sampling plan will often depend on the variability of the product being assessed. The exporting country is likely to have greater knowledge of a food's variability. In many cases producers, who have access to the food before it is packed and put in containers, may well carry out more extensive product testing before export than it is feasible for the importing country to apply. It may also be easier for the producer to conduct valid sampling procedures, for example random sampling. Information from such testing, if made available to the importing country, may be useful in estimating the variability of product, and may reduce the testing burden of the importing country. For instance if the producer's data showed that production was in control, it would allow the sigma method to be used instead of the s method.

Principle 6: Practical considerations

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 Consumers' Risk is not compromised.

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.

In some cases, reliance on sampling and testing by importing countries may not be a feasible means of providing assurance that the product meets specifications (e.g. costs may make trade uneconomic, or turnaround times may be too slow for perishable product, or it might not be possible to determine a sampling plan that will control the risks satisfactorily).

In such cases, alternative or supplementary means of assessing the product should be considered, such as reliance on the manufacturer's or exporting country's assessment. For further details, the GENERAL GUIDELINES FOR FOOD IMPORT CONTROL SYSTEMS (CAC/GL 47-2003) should be consulted. However, the case of non-stable or perishable foods may need special consideration. For example a perishable food may change its state during transport or a lot or consignment may become heterogeneous. In such cases, sampling and testing by importing countries may provide assurance that the product still meets specifications.

Deviations from accepted analytical methods and sampling plans may change producers' and consumers' risks; the new risks should be considered and accepted by both parties.

Principle 7: Taking account of analytical measurement uncertainty and its implications

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

The GUIDELINES ON ESTIMATION OF UNCERTAINTY OF RESULTS (CAC/GL 59-2006) and the GUIDELINES ON MEASUREMENT UNCERTAINTY (CAC/GL 54-2004) describe acceptable procedures for estimating the measurement uncertainty based on different combinations of in-house validation data, in-house precision data and inter-laboratory data and illustrate how the concept of analytical measurement uncertainty might be taken into account, in the most simple case when decisions are made based on a single test sample. Note that such decisions, if based only on an estimate of the measurement uncertainty, do not satisfactorily control the producers' and consumers' risks. In order to control these risks it is necessary to specify a quantity that the standard deviation of measurement error is not expected to exceed, such as the proposed 95% confidence limit. The analytical measurement uncertainty is composed of contributions by sample preparation, sample processing, extraction, clean up, evaporation, derivatisation and instrumental determination.

In many situations the impact of measurement uncertainty on the test statistic may be negligible compared to its sampling uncertainty. In that case it will therefore have a negligible impact on the operating characteristics of the sampling plan and need not be taken into account in the assessment.

Other things being equal, a high measurement uncertainty will increase either the producers risk (high rate of rejection of compliant products in quality control may make trade uneconomic) or the consumers risk (high probability of acceptance of non compliant products may affect consumer protection) and possibly both.

Principle 8: Product variation

The selection of sampling and testing procedures should take into account the potential variations within a lot or consignment.

Variation of foods may exist per se *and may be caused or influenced by differences due to storage and transport conditions. However it may be difficult or impossible to determine estimates of within lot variation that are universally applicable, even for a well-defined single food type. In these cases there may be a need for lot-specific estimation of within lot variation, normally requiring a multi inspection sample assessments.*

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, 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.

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

It must be considered that the GUIDELINES ON SAMPLING (CAC/GL 50-2004) do not cover the control of non-homogeneous goods. In case of non-homogeneous lots or consignments, an appropriate sampling procedure should be selected. The sampling procedure should consider the risk and the intended use of the product. Large lots or consignments should be subdivided into parts to be sampled separately and accepted and rejected independently. As far as possible primary samples (CAC/GL 50-2004, p. 17, 2.3.5.1) should be taken at various places distributed throughout the lots or consignments, preferably using random sampling.

The influence of the intended use on the selection of sampling and testing procedures is illustrated by the following examples for products with health-related properties:

For products subjected to further sorting or mixing treatment, the analytical result of the composite sample of the mixed primary samples or the average of the analytical results of the primary samples might be used for assessment. Acceptance might be achieved if the result of the composite sample (CAC/GL 50-2004, p. 17, 2.3.5.2) or the average of the results of the primary samples do not exceed the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty. For products intended for direct human consumption acceptance might be achieved if in addition none of the analytical results of the primary samples exceeds a higher limit at which health or safety is significantly compromised. This latter test would preclude compositing of the samples.

Principle 9: Fitness for purpose

A testing procedure is fit for purpose in a given product assessment procedure, if , when used in conjunction with the sampling plan and the decision criteria, it has accepted probabilities of wrongly accepting or wrongly rejecting a lot or consignment.

A method of analysis and a sampling plan for a parameter in a specification could be interpreted as an implied statement of fitness for purpose for the product. This in turn would imply that the consumers' and producers' risks resulting from use of both the method of analysis and sampling plan are acceptable (to both parties). To ensure that their own test results are fit for purpose and of the highest 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 the standard ISO/IEC 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).*
- *Whenever available, use of methods of analysis which have been validated according to the principles laid down by the Codex Alimentarius Commission (CAC/GL 27-1997)*

  [CUBA: when they are not available, then, a sampling plan and a method of analysis for a parameter in a specification could be interpreted as an implied statement of fitness for purpose for the product, provided that they could be: registered procedures and used historically, internationally recognized or based in international methods and appropriate to the commodity and lot or consignment to be sampled and tested; always previous agreement among exporter and importer.]
- *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).*

Fitness for purpose of an alternative method of analysis can be assessed in terms of its effect on consumers' and producers' risks arising from the use of that method, in

conjunction with a sampling plan, compared to the specified method and sampling plan.

Principle 10: 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) ,(CAC/GL 27-1997) the analytical laboratories should maintain a quality management system, which implements a fixed time period of scientific literature research and a revision service promptly based on the current technical documentation in force.