CRD3/A

AS POSTED IN THE EWG: Uruguayan draft document

The Uruguayan CCMAS analyzed the drafts of the document "Principles for the use of sampling and analysis in the international food trade-Explanatory notes". After discussion, a final version of the document was proposed considering during the followings issues:

• The document should be as general as possible and include clear and well defined concepts, avoiding confusing terms and excessive explanation. It was considered that the specific procedures will be better further explained in the examples, which will be included in a separate upcoming document.

• The principles should be linked with the Codex documents which are applicable to each case to facilitate access to relevant documentation.

• Concepts and criteria should be grouped and harmonized among the different principles, to gain better understanding thereof.

• The word "lot" should be included as a general concept (not specifying production, inspection or consignment) in order to avoid confusions and inconvenient between parties. There is a strong need for harmonizing terminology with other related Codex documentation.

The uruguayan working group wants to highlight the gratitude to participate in this discussion and expected that the draft document proposed will be useful to this forum.

Principles for the Use of Sampling and Testing in International Food Trade

Explanatory Notes

*Notes on sources of this text (not intended to be included)*

*The text of these Explanatory Notes is taken from:*

1. *The Proposed Draft Principles for the Use of Sampling and Testing in International Food Trade (CX/MAS 12/33/3)*
2. *The Proposed Draft Principles for the Use of Sampling and Testing in International Food Trade (REP12/MAS, Appendix IV)*
3. *The Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food (CAC/GL 25-1997);*
4. *The General Guidelines on Sampling (CAC/GL 50-2004);*
5. *The General Guidelines for Food Import Control Systems (CAC/GL 47-2003);*
6. *The GUIDELINES ON ESTIMATION OF UNCERTAINTY OF RESULTS (CAC/GL 59-2006);*
7. *The GUIDELINES ON MEASUREMENT UNCERTAINTY (CAC/GL 54-2004);*
8. *The Guidelines for the Assessment of the Competence of Testing Laboratories involved in the Import and Export Control of Food (CAC/GL 27-1997);*
9. *Food Control Laboratory Management: Recommendations (CAC/GL 28-1995. rev.1997);*
10. *ISO/IEC 17025:2005 (CAC/GL 27-1997) ’General requirements for the competence of calibration and testing laboratories’;*

# 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)*
* *Specification of maximum acceptable producers' and consumers´ risks, and the quality levels (see above) at which they are to apply uy:consideramos incluido en la anterior frase)*
* *Specification of the manner in which production lots or consignments may be linked to inspection lots and inspection samples*
* *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)*
* *Consideration on how to handle sampling and analytical measurement uncertainty*
* *Specification of the acceptance criteria following sampling and analysis*
* *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*
* *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).

*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 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 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.

**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.*

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

*The 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 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.

*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 FOR THE ASSESSMENT OF THE COMPETENCE OF TESTING LABORATORIES INVOLVED IN THE IMPORT AND EXPORT CONTROL OF FOOD (CAC/GL 27-1997) should be consulted when evaluated competence of laboratories.*

*A list of recommended methods of analysis and sampling is established in RECOMMENDED METHODS OF ANALYSIS AND SAMPLING (CODEX STAN 234-1999).*

**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 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 conformity of 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.*

*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 illustrates 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.*

*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 associated with any sampling plan, as well as the measurement uncertainty associated with the analysis should be quantified and combined.*

*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.*

*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 or -consignment variation that are universally applicable, even for a well-defined single food type. In these cases there may be a need for lot- or consignment-specific estimation of within-lot or -consignment variation, normally requiring a multi sample assessment.*

*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 production lots or consignments should be subdivided into sub-inspection lots or -consignments to be sampled separately. 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.*

**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.

*An analytical method 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 analytical method 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 quality criteria to be adopted by laboratories involved in the import and export control of foods should be the described on the standard ISO/IEC 17025:2005 “General requirements for the competence of calibration and testing laboratories” and on the Guidelines for the Assessment of the Competence of Testing Laboratories involved in the Import and Export Control of Food (CAC/GL 27-1997)*

*Fitness for purpose of an alternative analytical method 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) ,The* *Guidelines for the Assessment of the Competence of Testing Laboratories involved in the Import and Export Control of Food (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 legal position.*