CODEX ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS

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

CAC/GL 83-2013

Adopted in 2013. Revision: 2015.

1. INTRODUCTION

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

To ensure the sampling and testing procedures are valid, they should be based upon scientific, internationally accepted principles, and it is necessary to ensure that they can be applied fairly. With regard to sampling, the *General Guidelines on Sampling* states that "Codex Methods of Sampling are designed to ensure that fair and valid sampling procedures are used when food is being tested for compliance with a particular Codex commodity standard." With regard to testing, the methods of analysis endorsed by Codex should be considered first.

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

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

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

This document does not affect existing Codex provisions or the current way of setting those provisions. This document should be read in conjunction with the *Guidelines for Food Import Control Systems* (CAC/GL 47-2003) and the *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007).

This document provides assistance in assessing impacts of sampling and testing procedures on affected parties.[2]

2. SCOPE

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

The explanatory notes are intended:

- to explain the principles and their use in sampling and testing procedures; and
- to help governments and other interested parties to understand the principles and to establish and use sampling and testing procedures to assess whether foods in international trade comply with specifications.

3 DEFINITIONS

Testing

Process to examine the specified characteristics of a sample.

Testing procedure

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

[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).

[2] Practical examples are under development and will be available at www.codexalimentarius.org

Sampling procedure

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

Other definitions relevant to these principles include:

Consignment[a]

Lot[a]

Sample[a]

Sampling[a]

Sampling plan[a]

Result[b]

Measurement uncertainty[c]

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

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

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

4. PRINCIPLES

Principle 1: Transparency and agreements before initiating trade

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

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

Explanatory Notes

Transparent sampling, testing and assessment procedures allow all parties to operate in an open way so that each is fully aware of the actions performed by the other parties. Having full knowledge and understanding of the procedures and the inherent probabilities of wrongly accepting or wrongly rejecting a lot leads to informed decision-making by both parties which in turn can reduce the potential for disputes based on sampling and testing results. When discrepancies do occur, transparency allows for effective communications between parties to address differences.

Agreement is desirable:

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

The agreements should contain, for example:

- *The language of communication;*
- *The specification of the principles concerning acceptance or rejection of a lot or consignment* e.g. *General Guidelines on Sampling (CAC/GL 50-2004);*
- *The specification of the manner in which production lots or consignments may be linked to inspection samples;*
- *The specification of the sampling procedure;*
- *If the assessment procedure requires an estimate of lot inhomogeneity (e.g. a standard deviation), the method used to estimate the inhomogeneity should be specified. 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. applicability, limit of detection, limit of quantification, precision, recovery and trueness);*
- *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.*

In line with the principles, the agreed specifications should not restrict the flexibility of the control program in the importing country.

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

Principle 2: Components of a product assessment procedure

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

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

Principle 3: Probability of incorrect decisions

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

Explanatory Notes

Probabilities of wrongly accepting or wrongly rejecting a lot or consignment can never be entirely eliminated because of the uncertainty of measurement due to both the sampling and testing procedures. 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)[3] 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 %).

The specification of acceptable probabilities of wrongly accepting or wrongly rejecting a lot or consignment should have regard to principles of fairness towards both the consumers and the producers, as well as importing and exporting countries. This means making sure that consumers are not exposed to an unduly high probability of accepting non-compliant product and that a compliant product is not exposed to an unduly high probability of rejection.

Prior information may be useful in controlling the probabilities of wrongly accepting or wrongly rejecting a lot or consignment. For example, the importer can take into account the rate of non-compliance 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 by the exporter. Export control procedures generally include a combination of end-product testing with a range of other controls, and effective management of these is vital. These management measures should involve Hazard Analysis and Critical Control Point (HACCP), Good Agricultural Practice (GAP), Good Manufacturing/Production Practice (GMP) and traceability aspects, where appropriate. Further details can be found in the General Guidelines for Food Import Control Systems (CAC/GL 47-2003). However, non-stable or perishable foods may need special consideration.

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

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

Principle 4: Selecting appropriate sampling and testing procedures

The sampling and testing procedures selected should be:

- Scientifically based, taking into account the existing Codex standards;
- Appropriate to the commodity and lot or consignment to be sampled and tested;
- Fit for intended purposes and applied consistently.

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

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

Explanatory Notes

If sampling and testing procedures are not appropriate, there may be an unduly high probability of wrongly accepting or wrongly rejecting a lot or consignment which may lead to disputes between the interested parties[4].

The General Guidelines on Sampling (CAC/GL 50-2004) or considerable information available from elsewhere, e.g. international standards, such as ISO 2859 (Inspection by attributes), ISO 3951 (Inspection by variables) and ISO 10725 (Inspection of bulk materials), and published papers and textbooks, should be consulted when developing appropriate sampling plans. The Guidelines are applicable for control at reception, but may not be applicable for quality control of end-products by manufacturers.

The Guidelines cover the following sampling situations:

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

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

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

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

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

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

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

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

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

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

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

Principle 5: Analytical measurement uncertainty

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

Explanatory Notes

The analytical measurement uncertainty includes the contribution of all steps of the determination of the measurand in the sample delivered to the laboratory for testing compliance with the relevant specification. The steps of the determination procedure depend on the nature of the sample material and the mass of the sample. They may include sample size reduction, selection of a portion of the commodity to which the corresponding specification refers, homogenization of the sample material, extraction, removal of interfering materials, qualitative and quantitative determination, etc.

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

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

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

Principle 6: Fitness for purpose

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

Explanatory Notes

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

For example:

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

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

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

The following quality assurance 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 17025 "General requirements for the competence of testing and calibration laboratories";*
- *Participation in appropriate proficiency testing schemes for food analysis which conform to the requirements laid down in "The International Harmonized Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories", Pure & Appl. Chem. 78 (2006) 145-196;*
- *Whenever available, use methods of analysis which have been validated according to the principles laid down by the Codex Alimentarius Commission;*
- *Use of internal quality control procedures, such as those described in the Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories Pure & Appl. Chem. 67 (1995) 649-666.*

Principle 7: Review procedures

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