CODEX ALIMENTARIUS COMMISSION E

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World Health Organization

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CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

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REVISION OF *THE GENERAL GUIDELINES ON SAMPLING* (CXG 50 – 2004)

(Prepared by the EWG led by New Zealand and co-chaired by Germany)

Codex members and Observers wishing to submit comments at Step 6 on this document should do so as instructed in CL 2023/15/OCS-MAS available on the Codex webpage/Circular Letters:
http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/

Introduction

1. The 39th Session of the Committee on Methods of Analysis and Sampling (CCMAS39) agreed to start new work on the revision of the *General Guidelines on Sampling* (CXG 50-2004) (the Guidelines, CXG 50). The initial Terms of Reference are set out in REP18/MAS Para 71, Appendices V (project document) and VI (prioritization areas of work). This new work was approved by CAC41 (REP18/CAC, Appendix VI).

2. CCMAS40 supported the continuation of work on the revision of CXG 50 in accordance with the prioritization of work as agreed by CCMAS39[1].

3. CCMAS40 tasked an EWG chaired by New Zealand and co-chaired by the United States of America (USA), to continue the work on revising the CXG 50, and on developing the supplementary document (e-book with sampling plan apps), taking into account written comments submitted (CX/MAS 19/40/7 Add.1) (and comments and recommendations made during the session.

4. CCMAS41 agreed to forward the revised CXG 50 to CAC 44 for adoption at Step 5, and this was adopted[2]. CCMAS41 tasked an EWG chaired by New Zealand and co-chaired by Germany to continue to revise the CXG 50 and to pay attention to the key issues identified. In addition, to continue the development of the supporting documents: e-book and the guide to the selection and design of sampling plans. It was also agreed that a webinar would be held to help inform delegates of some of the key issues under discussion in the EWG to facilitate discussion and completion of the Guideline. (REP21/MAS, paras 110)

WORK PROCESS

EWG Registration (and consultation)

5. The CCMAS Secretariat invited registration to the EWG on the revised Guidelines. Registrations included 16 countries and observer organisations[3].The list of participants is included in Appendix II.

6. The EWG undertook consultation from 28 June 2022 to 26 August 2020. The EWG was advised that the CXG 50 consisted of two parts, with part 1 being the Guide to the Design of Sampling plans and part 2 being the Reference Document. Constructive and considered comments were received and we acknowledge the EWG's time and technical effort for this process. The CCMAS41 terms of reference for the EWG also included the continued development of the e-book. This was not addressed in the EWG consultation. It will be part of the next phase of the work.

7. New Zealand and Germany worked closely to review these comments. We also met (remote platform) with some country delegations as well as an observer organization as we considered that some of the points raised

[1] Full discussion and decisions are in REP21/MAS, paras 71 - 111
[2] REP21/CAC, paras 50 – 52.
[3] Australia, Brazil, Canada, Germany, Greece, Hungary, India, Iran, Kenya, Korea, Japan, Malaysia, Mexico, New Zealand, Panama, Thailand, Association of American Feed Control Officials, Eurachem.

in writing were more effectively resolved by discussion. The CXG 50 was updated based on the review of the comments submitted and the discussions that were held.

Webinar

8. A webinar to update members and observers on the work of CCMAS was held on 25–27 May 2022. Recordings and presentations are available on the CCMAS 42 website[4]. New Zealand and Germany gave a joint presentation on the progress of the revised CXG 50, as well as an overview of the relationship between CXG 50 and CGX 54 and practical applications of these guidelines.

SUMMARY OF KEY POINTS OF DISCUSSION IN THE EWG

EWG Report for CCMAS 42

9. The EWG report for CCMAS 42 presents the Revised General Guidelines on Sampling (CXG 50-2004) including the (Guide to the Selection and Design of Sampling plans and ISO Inspection Plans as appendices to CXG50 (Appendix I).

10. The key features in the revised CXG 50 are:

- An improved format and clearer explanation to help readers understand the information provided.
- The 'Reference Guidelines' are the basis for this information. The practical 'Guide to the Selection and Design of Sampling Plans' is included as Appendix I and the ISO Inspection Plans are now included as Appendix II. These all are now part of the CXG 50.
- Inclusion of information that explains some of the comments from CCMAS 41 as well as removal of superseded text. This includes:
  - ISO Sampling Plans (Appendix II):The sampling plans included in the ISO 2859 and ISO 3951 standards differ from plans discussed elsewhere in CXG 50 in that they have been designed to explicitly control either the producer's or the consumer's risk, but not both, and use the lot size relationship to determine the required sample size.
  - Acceptance Sampling versus Conformity Assessment: Information has been included in section 2.2 to explain the differences between conformity assessment, an assessment usually based on a single measurement result to decide whether the item tested conforms to some limit, and acceptance sampling, the process of determining the number of samples and an acceptance criterion based on allowable producer's and consumer's risks, and the use of this procedure to decide whether a lot should be accepted or rejected.
  - Measurement Uncertainty: The terminology in CXG 50 has been standardised on the use of the term measurement uncertainty and more information has been added in section 5.2 to explain how different aspects of the overall sampling and testing process affect the components of measurement uncertainty and how the different components are considered in the design of acceptance sampling plans.
  - Subsampling Variation: Information has been included in section 5.2.6 to address issues in the estimation of the lot standard deviation when subsampling is performed, that might lead to over-estimation of the lot standard deviation if adjustment is not made.
  - Removal of information on retesting.
- Replacement of text for clarity.

11. The general consensus from the EWG consultation process was support for the revised CXG 50.

Conclusions and recommendations

12. The revised *General Guidelines on Sampling* (CXG 50-2004) represents the work as outlined in the initial project document and the prioritization list to describe the design and evaluation of sampling plans for the international trade of food commodities.

13. The Committee is invited to::

1. consider the revised CXG 50 (Appendix I) and agree to advance it to Step 8; and
2. re-establish the EWG to complete the development of the Information Document (e-book with sampling plan apps).

[4] CCMAS 42 Webinar May 2022

Appendix I

Revised *General Guidelines on Sampling* (CXG 50-2004) including Appendix I (Guide to the Selection and Design of Sampling plans) and Appendix II (ISO Inspection Plans)

(For comment at Step 6 through CL 2023/15/OCS-MAS)

1 Reference Guidelines

1.1 Introduction

The Guidelines are primarily intended for use by Codex commodity committees responsible for developing acceptance sampling plans for provisions in Codex standards, and by governments responsible for import or export inspection of foods to describe the design and evaluation of sampling plans for the international trade of food commodities.

Foods are frequently sampled, throughout the food supply chain from producers to consumers, for the purpose of checking their quality. Clear definition of sampling plans is an integral part of specifications for the sampling and testing of foods. Sampling plans are included in Codex standards and may be used by governments in standards for foods.

Codex sampling plans, in conjunction with methods of analysis, are intended as a means of verifying that foods comply with provisions relating to composition, chemical or microbiological contaminants or pesticide residues contained in Codex standards.

Sampling therefore plays an important role in achieving the Codex objectives of protecting consumers' health and ensuring fair practices in the food trade. Codex sampling plans also have an important role in avoiding or removing difficulties which may be created by diverging legal, administrative, and technical approaches to sampling and by diverging interpretation of results of analysis in relation to lots or consignments of foods, in the light of the relevant provision(s) of the applicable Codex standard.

It is important that sampling is undertaken in a way that contributes to these objectives.

Specification of these quality objectives, the quality level acceptable to the customer and the rate of acceptance of compliant products, enable the development of sampling plans.

A Codex standard may set out a specific sampling plan for a particular context, or it may specify the outcome to be achieved by a sampling plan.

Although these Guidelines provide a generic approach to the design of sampling plans, Codex sampling plans are intended primarily for inspection of foods upon receipt, for example by importing country regulatory agencies, and might not be suitable for use by producers. However, a clear definition of quality objectives in Codex standards will allow producers to devise appropriate control and inspection procedures to achieve them.

1.2 Scope

In these Guidelines, the focus is on acceptance sampling plans for the inspection of isolated homogeneous lots, in which the risks to consumers and producers are controlled.

The term 'isolated' means that the inspection of each lot is done in isolation, without considering the outcome of the inspection of adjacent lots or, for example, other lots from the same producer. This does not mean that information from previous inspections cannot be used; in particular, there are cases where the lot standard deviation may be known from the inspection of previous lots.

The following situations are covered:

- acceptance sampling plans for the control of the percentage nonconforming for homogeneous lots by attributes or by variables, for goods in bulk or individual items
- inspection by variables sampling plans for normally distributed characteristics
- adjustment for measurement uncertainty in cases where it is non-negligible as compared to the lot standard deviation with a focus on cases where the measurement uncertainty is normally distributed.
- sampling plans for the control of the average content
- in addition, some guidance is provided on issues involved with the design of plans for bulk materials.

In section 2, general concepts which are relevant for the sampling of foods are defined, sections 3, 4 and 5 cover acceptance sampling plans for different situations of statistical food control. Section 6 covers other matters such as physical sampling, reinspection, and inhomogeneous lots.

Appendix I contains a step-by-step guide for the selection of sampling plans. Appendix II contains tables of ISO[5] attributes and variables plans indexed by producer's risk.

These Guidelines are not intended to be comprehensive; these Guidelines do not provide information on all types of sampling plan options that may be available. Sampling plans from other sources are still acceptable subject to their endorsement by the Codex Committee of Methods of Analysis and Sampling (CCMAS).

Note: In CXG 50, acceptance sampling plans may be referred to as 'sampling plans' or 'plans', and acceptance sampling inspection may be referred to as 'sampling inspection' or 'inspection'.

1.3 Definitions

For the terms commonly used in these Guidelines the following definitions are provided, in addition to those in the Guidelines on Analytical Terminology (CXG 72-2009).

Note: In some of the definitions, reference is made to the process standard deviation or the process quality level. In CXG 50, the focus lies on lots rather than processes. For this reason, the relevant quantities in CXG 50 are the lot standard deviation and the lot quality level.

Acceptance criterion

Acceptance criterion is used to cover terms such as acceptance and rejection numbers for attributes plans and acceptability constants for variables plans.

[*SOURCE: ISO 3534:2]*

Note: In CXG 50 the term 'acceptance criterion' is used to describe the rule which is applied to the test results obtained during the lot inspection in the decision whether to accept the lot.

Acceptance sampling

Sampling after which decisions are made to accept a lot, or other grouping of products, materials, or services, based on sample results

[SOURCE: ISO 3534:2]

Acceptance sampling plan

Plan which states the sample size(s) to be used and the associated criteria for lot acceptance.

[SOURCE: ISO 3534:2]

Acceptance sampling by attributes

Acceptance sampling inspection whereby the presence or absence of one or more specified characteristics of each item in a sample is observed to establish statistically the acceptability of a lot or process.

[SOURCE: ISO 3534:2]

Acceptance sampling by variables

Acceptance sampling inspection in which the acceptability of a process is determined statistically from measurements on specified quality characteristics of each item in a sample from a lot.

[SOURCE: ISO 3534:2]

Consumer and producer

The terms 'consumer' and 'producer' are conventional and may apply to a range of different operators in the food supply chain, such as a grower, manufacturer, the manufacturer's own quality control system, supplier, exporting country, processor, on-seller, or importing country. In general, 'producer' refers to a supplier or seller of foodstuffs and 'consumer' to an importing country regulator, a purchaser, or an actual consumer of those foods.

[5] The International Organization for Standardization

Consumer's risk (CR)

Probability of acceptance when the quality level of the process has a value stated by the acceptance sampling plan as unsatisfactory.

[SOURCE: ISO 3534:2]

Consumer's risk quality (CRQ)

Quality level of a lot or process which, in the acceptance sampling plan, corresponds to a specified consumer's risk.

[SOURCE: ISO 3534:2]

Note: The CRQ corresponds to the LQL in the ISO 2859 and ISO 3951 standards.

Lot

Definite part of a population (constituted under essentially the same conditions as the population with respect to the sampling purpose).

[SOURCE: ISO 3534:2]

Operating characteristic curve

Curve showing the relationship between probability of acceptance of product and the incoming quality level for given acceptance sampling plan.

[SOURCE: ISO 3534:2]

Producer's risk (PR)

Probability of non-acceptance when the quality level of the process has a value stated by the plan as acceptable.

[SOURCE: ISO 3534:2]

Producer's risk quality (PRQ)

Quality level of a lot or process which, in the acceptance sampling plan, corresponds to a specified producer's risk

[SOURCE: ISO 3534:2]

Note: The PRQ corresponds to the AQL in the ISO 2859 and ISO 3951 standards.

Quality level

Quality expressed as a rate of nonconforming units or rate of number of nonconformities.

[SOURCE: ISO 3534:2]

Note: In CXG 50, the quality level of a given lot is often expressed in terms of the percentage of nonconforming items.

Sample

One or more items taken from a population and intended to provide information on the population and possibly serve as a basis for a decision on the population or on the process which had produced it.

[SOURCE: ISO 3534]

2 Acceptance Sampling – General Principles

2.1 Reasons for Sampling

While various measures such as Hazard Analysis and Critical Control Point systems (HACCP), Good Manufacturing Practice (GMP), process control and sampling are available to producers to provide assurance about the quality of products they supply, consumers usually rely on acceptance sampling if they wish to verify the quality of incoming products.

Acceptance sampling procedures are used when goods are transferred between two parties. The purpose of these procedures is to provide unambiguous rules for releasing a product after inspection of only a limited sample. Both parties should be fully aware of the limitations and risks associated with using such procedures and therefore most acceptance sampling procedures should include provisions

for dealing with disputes and non-conforming items found in lots that have been accepted by the sampling plan.

An acceptance sampling plan specifies the number of samples to be taken and how they are to be taken, the procedure used to test or examine those samples, and the acceptance criterion, based on the results from the testing of those samples, used to decide whether a lot should be accepted.

In general acceptance sampling is used to:

- reduce costs
- allow product assessment when tests are destructive
- enable faster decision making.

2.2 Approaches to Acceptance Sampling

There are three possible approaches to acceptance sampling:

(a) 100 % inspection, involving inspection of the entire (i.e.,100 %) lot

(b) Sampling based on statistical principles

(c) *Ad hoc* inspection, i.e., sampling plans without a statistical basis.

The risks and costs associated with each of these three options will be briefly discussed.

Approach (a) is usually not feasible due to the prohibitive cost of testing and in addition, there might not be any product left to sell if the inspection method necessitates destructive testing.

Approach (b) has the disadvantage of higher risks as compared to approach (a), since a part of the lot is not inspected. However, by applying an approach based on statistical principles, the risks can be calculated, and a sampling plan can be chosen that ensures these risks are controlled to desired levels. It also has the advantage of practicability and lower costs.

In lot inspection, there are two types of risks:

- acceptance of a lot of unsatisfactory quality (consumer's risk)
- rejection of a lot of acceptable quality (producer's risk).

Sampling plans should be designed to control these risks to suitable levels, whereby suitable risk levels are determined based on fitness for purpose considerations.

Approach (c) is not recommended. It may be used for practical reasons, such as limited resources, or for simplicity. However, such plans might not provide the expected level of assurance of food quality and may inadvertently impose high costs, for instance through unwarranted acceptance of food that could lead to illness or unjustified rejection that, in turn, could lead to the imposition of fines, penalties or trade sanctions. The risks associated with such plans should be evaluated where possible. Decisions on acceptance or rejection should not be made solely based on these plans except by mutual agreement of the consumer and producer with an understanding of the risks involved.

In summary, approach (b) allows for practicability while ensuring that risks are controlled to levels considered appropriate based on fitness for purpose considerations.

Acceptance sampling versus conformity assessment

Acceptance sampling and conformity assessment do not have the same purpose. Conformity assessment is the use of a single measurement result to decide whether a single item conforms to a limit. Acceptance sampling is the process in which a sample[6] is taken from a lot and involves the determination of acceptance criteria and sample size to decide whether a lot is accepted or rejected.

The broadest definition of conformity assessment may be considered to include acceptance sampling. However, in a narrower sense, conformity assessment can be understood to refer specifically to the situation where a one single measurement result is used to decide if one single item of interest conforms to a specified requirement. If conformity assessment is understood in this narrower sense, then it is important to distinguish conformity assessment and acceptance sampling. In this section, conformity assessment will be understood in the narrower sense.

[6] Refer to the definition in section 1.3.

Although acceptance sampling and conformity assessment involve similar procedures, and although consumer and producer risks are defined for both, they are performed in different contexts and follow different objectives.

Conformity assessment

In conformity assessment, conformity is assessed via the application of a decision rule which accounts for measurement uncertainty. Depending on the measurand, the measurement uncertainty may or may not include uncertainty from sampling. Depending on the decision rule, there may be cases where the assessment is inconclusive.

Acceptance sampling

In acceptance sampling, at least one measurement result (typically more than one) is used to decide whether to accept or reject a lot under inspection. The acceptance sampling plan consists in both requirements regarding the sampling procedure (e.g. the number of items to be taken from the lot) and an acceptance criterion. The acceptance sampling plan is determined in such a way as to ensure that producer and/or consumer risks are sufficiently low at a given quality level. The variation of the property of interest in the lot is always taken into consideration in acceptance sampling; however, analytical uncertainty is only taken into consideration if non-negligible. The context for lot inspection is typically a commercial agreement between two trading partners. In acceptance sampling, a lot is always either accepted or rejected; there are no cases of inconclusive lot inspections.

In the case that the quality level is expressed in terms of the percentage of nonconforming items, the distinction between acceptance sampling and conformity assessment is quite clear; the measurand is defined for the individual items, and thus the question of conformity to a specified requirement can only be framed in relation to the individual items. However, lot acceptance or rejection is not decided on the basis of the compliance or non-compliance of an individual item; instead, the acceptance criterion is expressed in terms of the percentage of nonconforming items, i.e., in terms of the distribution of the property of interest among the items in the lot. The differences between acceptance sampling and conformity assessment are summarized in the following table.

	Conformity assessment	Acceptance sampling
Number of measurement results	Typically: one	Typically: several (For instance: if the lot consists of discrete items, several items are taken, and there is one measurement result per item)
Is analytical measurement uncertainty taken into account in the decision rule/acceptance criterion?	Always (if possible)	Only if the analytical measurement uncertainty is non-negligible (compared to the lot standard deviation)
Is sampling component of measurement uncertainty considered?	Depending on the measurand, it may or may not be necessary to include sampling uncertainty	Sampling uncertainty is always considered
Context/background	In many cases: conformity assessment is carried out against a legal limit	The context is often an agreement between trading partners
Inconclusive assessment	Depending on the decision rule, the assessment may be inconclusive	There are no inconclusive inspections: lots are either accepted or rejected.

Further clarifications regarding the term measurand and the distinction between sampling and analytical uncertainty are provided in section 5.2.1.

Note 1: Figure 1 in CXG 54 illustrates a procedure which can be applied in conformity assessment (this procedure may yield inconclusive results). This procedure should not be applied in acceptance sampling.

Note 2: If the sample taken in lot inspection consists of one single item, then producer/consumer risks may be poorly controlled. Nonetheless, there are special sampling plans for lot inspection based on a single item. These must not be confused with the procedure for conformity assessment illustrated in Figure 1 of CXG 54.

2.3 Acceptance Sampling Plan Performance

Variation is present everywhere; raw materials vary in their composition, manufacturing processes vary and, consequently, the products manufactured by those processes will also vary. Therefore, when we take several samples from a lot, we do not expect those samples to be of the same composition. Furthermore, the presence of measurement uncertainty means that when those samples are tested, we will not get the same result, even if the same sample is retested. Similarly, we would not expect results from different sets of samples taken from the same lot or those taken from different lots (from the same process) to be the same; there will always be some variation.

Due to this variation, the incorrect acceptance or rejection of lots cannot be avoided. However, using a statistical description of the variation within a lot and of the uncertainty of the measurement process allow us to calculate the probability of correctly or incorrectly accepting a lot at any given quality level and for any given sampling plan.

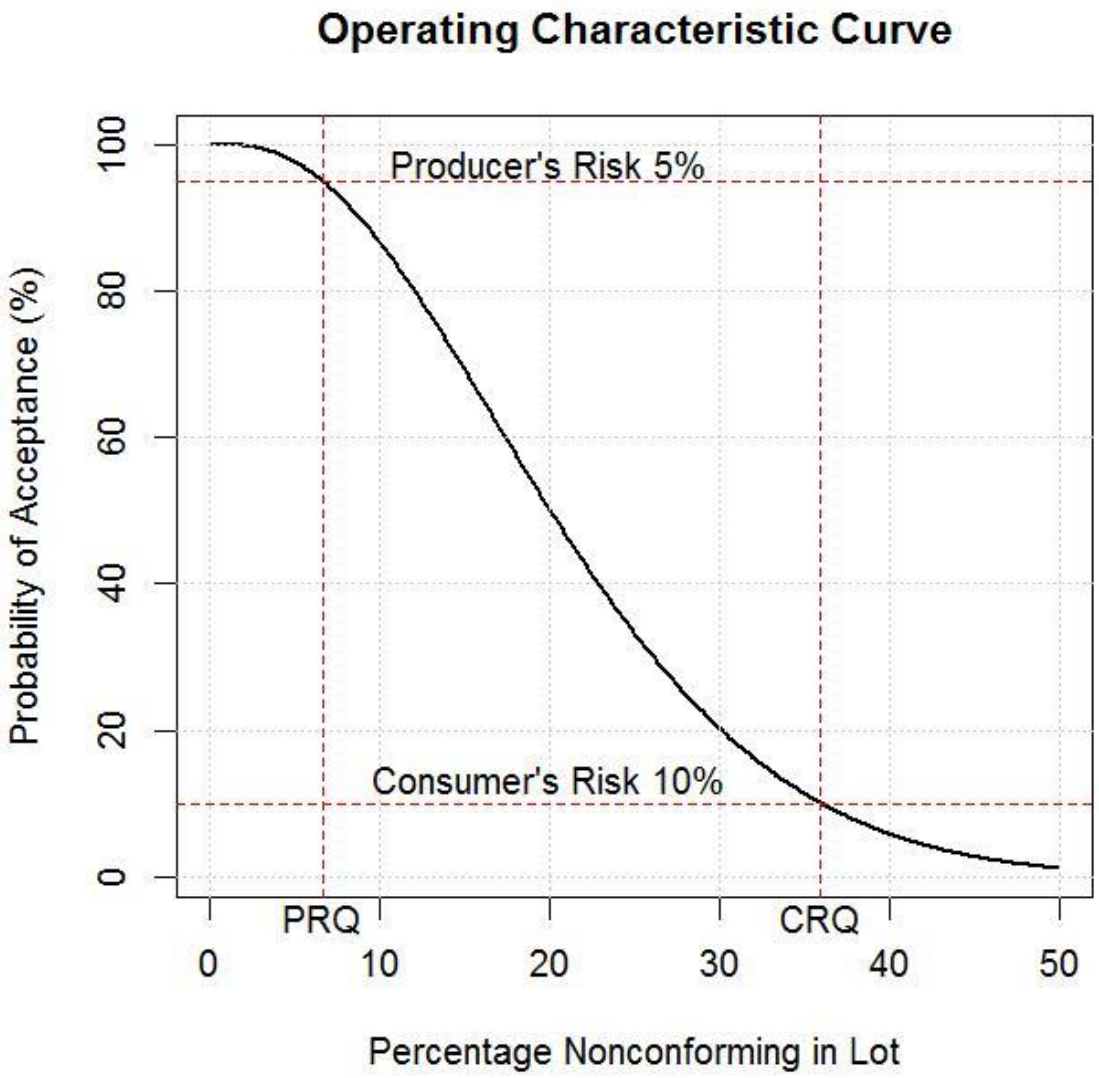
In acceptance sampling, the probability of acceptance depends on:

- the quality level (percent nonconforming) of the lot under inspection
- the acceptance criterion (i.e. for the particular sampling plan)
- the variation of the characteristic within the lot
- the bias and variation inherent in the measurement process (in the case of non-negligible analytical uncertainty).

In practice, the quality level (percent nonconforming) of a lot is not known beforehand; however, for a particular acceptance sampling plan, it is possible to calculate the probability of acceptance at any quality level. The relationship between the probability of acceptance and the quality level for a particular sampling plan is described by the operating characteristic curve.

2.3.1 Operating characteristic curve

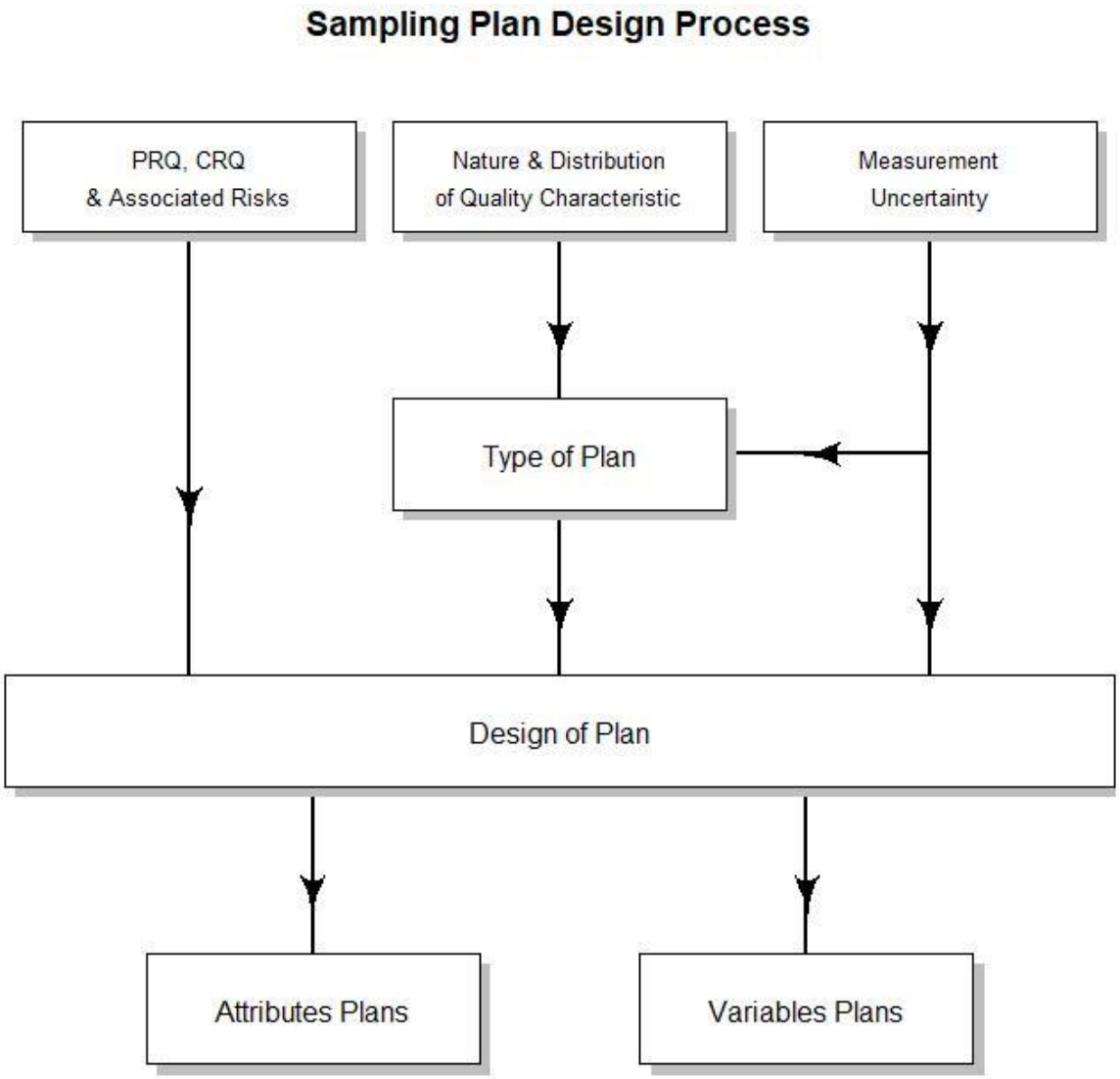
The following diagram is an example of an operating characteristic curve (OC curve) that shows the probability of accepting (or rejecting) a lot in terms of its quality level in the lot (expressed as percent nonconforming). This highlights that specification of the quality levels is fundamental to design of a sampling plan.



Note: The OC curve does not say anything about the quality of a given lot; it serves only to show the probability of accepting a lot with a particular quality level.

3 Design of Sampling Plans

3.1 Sampling Plan Design Process



3.2 Inputs to Sampling Plans

3.2.1 Stringency

As explained, the application of acceptance sampling plans does not eliminate the risk that a lot of poor quality will be incorrectly accepted nor that a lot of good quality will be incorrectly rejected.

However, designing such plans using statistical principles allows these risks to be controlled. This is achieved by specifying a particular producer's risk quality level, the PRQ, and a particular consumer's risk quality level, the CRQ, along with a corresponding producer's risk (PR) and a consumer's risk (CR) respectively. Once these four parameters, the PRQ, CRQ, PR and CR, are specified the probability of acceptance and therefore the producer's and consumer's risks at any quality level are uniquely determined.

The term stringency is used in these Guidelines to refer to the ability of a sampling plan to control consumer's and producer's risks, of incorrectly accepting or incorrectly rejecting a lot, at any specified quality level.

Often, the producer's risk is specified as 5%, meaning that the probability of rejecting a lot with PRQ is at most 5%. Similarly, the consumer's risk is typically chosen as 10%, meaning that the probability of accepting a lot with CRQ is at most 10%. If any one of the four parameters is altered, the control of the producer's and consumer's risks will change.

In certain situations, such as characteristics relating to food safety where control of the consumer's risk is paramount, it might not be appropriate to take account of the producer's risk in the design of sampling plans. This leads to two different options for the specification of risks.

Option 1: Plans that explicitly control both the consumer's risk and the producer's risk:

- both the PRQ and CRQ, along with the respective allowable probabilities of incorrect rejection (PR) and incorrect acceptance (CR) are specified.

Option 2: Plans that explicitly control only the consumer's risk:

- plans for assessments of lots consisting of discrete items.

3.2.2 Fitness for purpose

Codex methods of sampling should be *'designed to ensure that fair and valid sampling procedures are used when food is being tested for compliance with a particular Codex commodity standard'*[7]. When commodity committees have included sampling plans in a Codex commodity standard, these should be referred to CCMAS for endorsement along with relevant information relating to the sampling plan.

Sampling plans from other sources are still acceptable subject to their endorsement by CCMAS.

The Principles for the Use of Sampling and Testing in International Food Trade (CXG 83-2013) states:

'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'.

Fairness

Fairness must involve consideration of both the consumer's risk and the producer's risk, to avoid situations such as the following:

- sampling plans having inappropriate stringency, e.g. plans for the assessment of composition that are more stringent than for food safety
- high producer or consumer risks that may arise due to the use of sampling plans not based on appropriate specifications of allowable risks
- sampling plans not based on statistically valid principles, e.g. *ad hoc* plans or plans that do not (properly) allow for measurement uncertainty.

In addition, in the interests of fairness, designers of plans should also take account of the measures that the producer may have to take to ensure compliance, given that it is usually not suitable for the producer to use the same sampling plan as that used by the consumer.

In selecting a sampling plan, it should be ensured that producers are not exposed to unreasonable costs in terms of sampling and testing, loss of yields, or excessive rejection of their products to achieve compliance.

Practicality

it is important to ensure that any sampling plan chosen will be practical to apply in terms of cost of sampling and testing and ease of use.

Other strategies could be used to develop sampling plans that are more economical in terms of sampling and testing, such as:

- managing average non-compliance rates over the medium to long term, rather than possibly paying a high premium in terms of testing costs for high levels of assurance on a lot-by-lot basis

[7] –Section II: Elaboration of Codex Texts: Principles for the Establishment or Selection of Codex Sampling Procedures: Purpose of Codex Methods of Sampling (Codex Procedural Manual, latest edition)

- the use of 'indifference' plans that are designed around the 'Indifference Quality Level' (IQL), the level of defects at which there is 50% acceptance, rather than based on PRQ, CRQ. This leads to plans having more manageable sample sizes
- offsets, sometimes called guardbands or buffers, between the limits used in the acceptance criteria and the actual specification limits for a provision can be used to reduce consumer's risk and to mitigate possibly unreasonably high sample numbers. However, offsets should be used with caution in the interest of fairness to producers.

Acceptance sampling often necessitates levels of protection for both the consumer and the producer that require large sample sizes relative to the lot size. A given sample size can, however, apply to several lots jointly if the lots can be shown to be homogeneous. This reduces the economic impact of a necessarily large sample size. If the lots are not homogeneous, then this is unable to occur.

3.2.3 Specification limits

For a given characteristic, a specification limit may be expressed as a minimum or a maximum limit (or both) applied either to each individual item in a lot, or to the average level.

Specification limits should apply to the 'true' values of the characteristics rather than to the measurements themselves. It follows that the assessments of lot compliance should also be in terms of the 'true' values of the characteristic within the lot (refer section 5.2.1).

Offsets

It is important to consider whether a given specification limit has an in-built offset (guard band), and whether the offset reflects the measurement uncertainty associated with a particular testing procedure.

Many provisions for chemical and microbiological contaminants have in-built offsets between the specification limits and the levels of contamination at which foods might become unsafe to consume. In such cases one may not need to design plans to provide high levels of protection against exceeding the limits as the consumer's risk is already well controlled by these offsets.

The use of offsets enables a reduction in sample size; for example, while large sample sizes are needed to show that a lot contains no more than say 1% nonconforming product, much smaller sample sizes are required to show that no more than 10% of the product in a lot exceeds a tightened limit.

3.2.4 Lot homogeneity

Acceptance sampling plans are usually based on the assumption that lots are homogeneous; indeed, the international definition of a lot is 'a quantity of product produced under conditions presumed uniform'.

If these plans are applied to inhomogeneous lots, the producer's and consumer's risks may exceed allowed levels.

Sampling procedure

in considering homogeneity, one needs to draw a distinction between:

- the type (shape) of the distribution, as determined based on previous knowledge (e.g., *normal* distribution)
- the *spatial distribution* of the characteristic within the lot.

If random sampling is used (as recommended for all plans in these Guidelines) then the spatial distribution does not matter. Consider the following example: a given lot consists of discrete items in a container. Across all items, the characteristic follows a normal distribution. However, the lower half of the container contains items with lower values, and the upper half contains items with higher values. In other words, the spatial distribution is *not* random. As long as random sampling[8] is performed, the sample will be representative of the lot. However, if only items from the top layer are taken, this will not be the case.

For this reason, if no prior information regarding the spatial distribution is available, then random sampling should be performed. Another way of saying this is if random sampling is performed, the spatial distribution has no impact on homogeneity.

[8] In connection with lot inspection, random sampling means that all items or parts of the lot have the same probability of being taken in the sample.

On the other hand, if prior knowledge indicates that the spatial distribution of the characteristic within the lot is random, then random sampling is not required to obtain a representative sample.

If random sampling cannot be performed, then the sample will only be representative to the extent that the spatial distribution is random. In this sense, if random sampling cannot be performed, the homogeneity of the lot depends on the spatial distribution.

Sections 4.4 and 6.3 provide further guidance regarding the inspection of inhomogeneous lots consisting of bulk materials or discrete items, respectively.

3.2.5 Distribution of the characteristic

The options for sampling plans depend on whether the test results are measurements (variables data) or have nominal outcomes (attributes data). In some cases, variables data can be classified as binary outcomes, but this should only be done after careful consideration of the sampling options available as the sample size for attributes inspection can be much larger than for variables data.

In the case of variables data, the assumed statistical distribution of the measurements in the lot must also be specified, i.e. whether the characteristic is normally distributed, a compositional proportion, or follows some other distribution. If is not possible to make an assumption regarding the distribution of the data, results can be classified as attributes (as long as measurement uncertainty is negligible (refer section 3.2.8), or plans based on the Fractional Nonconformance (FNC) method can be used (as long as measurement uncertainty is non-negligible (refer section 5.2.6).

However, the characteristic does not have to follow the assumed distribution exactly (and, in any case, it is difficult to verify conformance to a distribution based on a small sample size). In practice, it is sufficient that the assumed distribution provides a satisfactory model for the behaviour of the characteristic in the lot. However, if the actual distribution in the lot differs markedly from the assumed distribution, then the producer's and consumer's risks may exceed the allowed levels specified in the design of the plan.

A typical ('default') assumption in variables plans is that the characteristic follows a normal assumption.

It is important to note that in the case of attributes plans, the binomial distribution is always available as 'default' assumption, and that departures from this assumption regarding the type (shape) of the distribution will have very little impact on the producer's and consumer's risks.

Sections 4.4 and 6.3 provide further guidance regarding the inspection of inhomogeneous lots consisting of bulk materials or discrete items, respectively.

Prior knowledge the distribution of a characteristic

In acceptance sampling, acceptance/rejection of a lot is decided on the basis of a sample (the set of individual samples taken from the lot). The relationship between the probability of acceptance (upon application of a given sampling plan) and the quality level of the lot is determined on the basis of prior knowledge regarding the distribution of the characteristic within the lot.

This means that prior knowledge is required *even in connection with the inspection of isolated lots.* In other words, the inspection of isolated lots does not mean that no prior information is available. On the contrary, prior information is always required. Sometimes the prior information takes the form of (tacit) assumptions based on experience and expert judgment. For example, a typical ('default') assumption in variables plans is that a characteristic follows a normal assumption.

If the actual distribution in the lot differs markedly from the assumed distribution, then the producer's and consumer's risks may exceed the allowed levels specified in the design of the plan. There are two ways in which the actual distribution can differ from the distribution which was assumed on the basis of prior knowledge:

- the type (shape) of the distribution. For example, the assumption is that the distribution is normal whereas, in fact, the distribution is lognormal
- the parameters of the distribution. For example, it is assumed that the lot standard deviation is the same as the (underlying) process standard deviation, whereas in fact it is twice as large.

It is important to note that in the case of attributes plans, the binomial distribution is always available as 'default' assumption, and that departures from this assumption regarding the type (shape) of the distribution will have very little impact on the producer's and consumer's risks.

3.2.6 Lot standard deviation

In the context of these Guidelines, the population under consideration is the lot itself rather than the underlying process. For this reason, the role which the *process* standard deviation σ plays in the ISO 3951 standards is now played by the lot standard deviation. The lot standard deviation can be represented by either its true value σ (sigma) or by an estimate (often denoted s) of σ.

The lot standard deviation is relevant only for variables plans, particularly for characteristics that are normally distributed or follow distributions, such as the lognormal distribution[9], that are related to the normal distribution.

For a given characteristic, the lot standard deviation is a measure of the random variation of the characteristic within the lot under inspection.

It is expected that for isolated lots the lot standard deviation will usually be calculated from the test results obtained during the inspection. Notwithstanding, there are cases where the lot standard deviation may be known, especially when the lot has been produced by a process with a known process standard deviation. This can be adopted as lot standard deviation. In such cases, the sample size of the sampling plan can be considerably reduced.

If the process standard deviation is known, it is important to consider whether it was obtained on the basis of a sufficiently large number of data to ensure it provides a reliable characterization of the variation within the process.

Note: In acceptance sampling, the lot standard deviation is always based on a simple random sample. However, in principle, other sampling procedures may be applicable, such as those described in Annex C.2 of EURACHEM[10] / CITAC guide Measurement uncertainty arising from sampling. This guide describes several procedures for the calculation of sampling uncertainty. It does not describe procedures for acceptance sampling.

3.2.7 Measurement uncertainty

In connection with lot inspection, it is important to determine whether the analytical components of measurement uncertainty – including the uncertainty which arises from subsampling from the laboratory sample (refer section 5.2.6) – can be considered negligible. This is typically done by considering the ratio of the analytical uncertainty and the lot standard deviation. If the analytical component of measurement uncertainty cannot be considered negligible, it should be taken into consideration in the acceptance criterion.

Adjustment for the analytical component of measurement uncertainty in acceptance sampling is discussed in more detail in section 5.

The lot standard deviation already represents the heterogeneity within the lot and any further uncertainty arising from the sampling procedure. For this reason, in determining whether an adjustment is necessary, only the analytical component of measurement uncertainty needs to be considered.

The term *measurement error* should not be used, as the term has been superseded by the focus on uncertainty across JCGM[11], ISO and EURACHEM standards and guides, as reflected in the Guidelines on Measurement Uncertainty (CXG 54-2004) and as adopted in the present guideline.

3.2.8 Lot size

Lot size is not normally an input required for the design of sampling plans intended to control both the consumer's and producer's risks in acceptance sampling. However, specification of the lot size is required for attributes plans applied to small lots and it is an input in the sampling plans described in the ISO 2859 and ISO 3951 standards (refer sections 4.2.3, 4.3.4 and Appendix II).

[9] For lognormally distributed characteristics, the logarithms of the 'measurements' are normally distributed
[10] A network of organisations in Europe having the objective of establishing a system for the international traceability of chemical measurements and the promotion of good quality practices
[11] The Joint Committee for Guides in Metrology (JCGM)

4 Sampling Plans

4.1 Selection of Sampling Plans

The following table provides direction to the relevant sections within these Guidelines:

Table 2: Direction to the relevant part for the selection of sampling plans

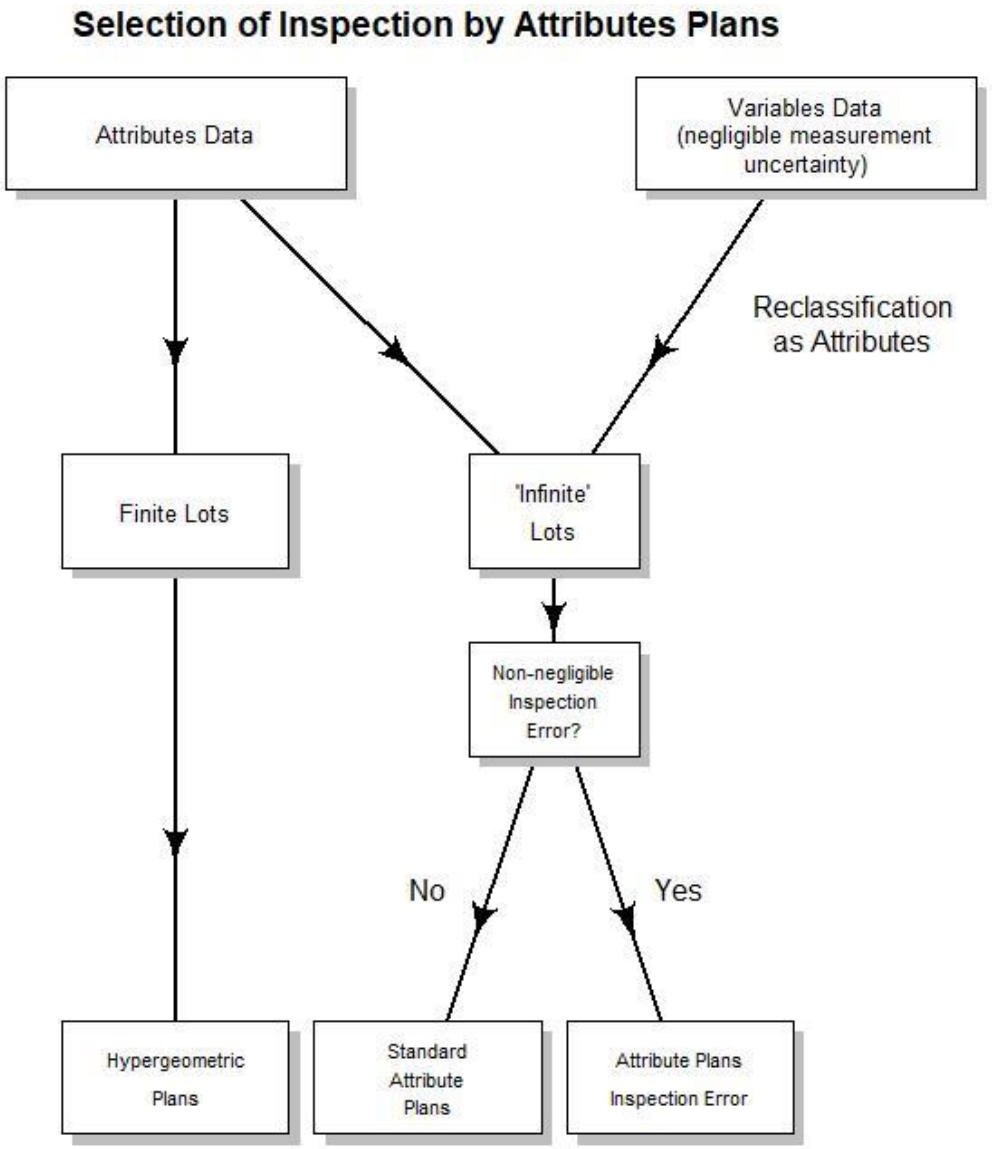
Homogeneous lots				
Data Type	**Nature of Provision**	**Distribution**	**Negligible** measurement uncertainty	**Non-negligible** measurement uncertainty
Attributes	Minimum or maximum	Not applicable	Inspection by Attributes Plans (section 4.2) Appendix II Table 8.4.1	Known inspection errors (section 5.1.1)
Variables	Minimum or maximum	Normal	Inspection by Variables Plans (section 4.3) Appendix II Table 8.4.2	Repeatability error (no laboratory bias) (section 5.2.6)
				General measurement uncertainty (sections 5.2.5, 5.2.7, 5.2.8)
				Fractional nonconformance Plans (section 5.2.8)
	Minimum or maximum	Non-normal	Classification to attributes (Section 4.3.3)	Fractional nonconformance Plans (section 5.2.8)
Variables	Minimum or maximum	Compositional Proportions	Plans for compositional proportions (section 4.4.10)	Not included
	Average level	Not applicable	Plans for average level (section 4.3.5)	Not included
Inhomogeneous Lots (Bulk Materials)				
Attributes	Minimum or maximum	(blank)	Attributes plans (section 4.4.6)	
Variables	Minimum or maximum	(blank)	Variables plans (section 4.4.9)	
	Average level	Not applicable	Plans for average level (section 4.4.8)	

4.2 Inspection by Attributes Plans

4.2.1 Introduction

These plans are usually referred to as attributes sampling plans. They are the simplest type of single sampling plan because the inspection results are classified into two possible outcomes - conforming or nonconforming. Because they are applicable to all sampling situations, they have become the benchmark that all other sampling plans can be compared against.

The following diagram shows the process for the selection of attributes sampling plans as it depends on the type of data and nature of the lot.



4.2.2 Two-class attributes plans

Two-class attributes plans are defined by two numbers: the sample size ***n***, the number of items to be taken from the lot under inspection and the acceptance number ***c***, the maximum number of nonconforming items allowed in the sample for acceptance of the lot. If the number of nonconforming items in the sample is less than or equal to ***c*** then the lot can be accepted. If the number of nonconforming items found is greater than ***c*** then the lot is rejected. In their most general form, the number of samples ***n*** and the acceptance number ***c*** for these plans are determined from specifications of the allowable consumer's and producer's risks. It should be noted that ***c*** need not be zero (refer section 4.2.5).

These plans can be used for either isolated lots or a continuing series of lots that consist of either discrete items or are bulk materials.

4.2.3 ISO Standards - attributes plans

The ISO 2859 series of standards provides sampling plans that are indexed by either CRQ or PRQ. The lot size is an input to the sampling plans in these standards as the sample size depends on the lot size.

The ISO 2859-2 plans are indexed by CRQ and are intended for the inspection of homogeneous isolated lots consisting of discrete items. These plans are suitable for application in the field of food safety when it is not appropriate to explicitly control producer risks in the design of the plans.

Appendix II contains tables for Inspection by Attributes Plans from ISO 2859-1.

These plans are indexed by the PRQ.

4.2.4 Plans for small lots (based on the hypergeometric distribution)

If the sample size is large in relation to the lot size, some economy in the number of samples may be possible. As a rule, such economies are possible if the number of samples, calculated assuming an infinite lot size, exceeds 10% of the lot size. For conceptually infinite lots, sampling plans based on the hypergeometric distribution are the same as the general two-class plans based on the binomial distribution.

4.2.5 Zero-acceptance number plans

Zero-acceptance number (ZAN) plans are a special case of two-class plans in which the acceptance numbers are set to ***c*** = 0. They are used in more critical situations such as for pathogens or foreign matter where only consumer's risk is considered directly and acceptance of lots demands that nonconforming items are not found in the inspection.

However, just because nonconforming items have not been found does not mean that they are not present in lots that have passed inspection. One disadvantage of ZAN plans is that they have poor discrimination between lots of good and poor quality, so they may not be generally applicable. The low sample numbers generally employed for microbiological applications enable high levels of consumer protection to be provided because of the offsets between the limits used in those plans and levels of contamination at which food might become unsafe (refer section 3.2.4).

ZAN plans for finite lots can also be designed based on the hypergeometric distribution.

4.2.6 Three-class attribute plans

In these plans inspection results are classified into three classes, usually referred to as 'good', 'marginal' and 'poor' or 'unacceptable'. This type of plan is frequently used in microbiological assessments. They have an advantage, relative to two-class plans, of providing better discrimination between good and poor quality i.e., they have 'steeper' OC curves than two-class plans for the same number of samples.

Three-class plans are defined by four numbers (***n, c, m, M***) where:

- ***n*** is the number of samples to be taken
- ***c*** is the maximum number of 'marginal' samples allowed for acceptance of the lot
- ***m*** is the limit separating good quality from marginal quality samples
- ***M*** is the limit above which samples are classified as 'poor'
- Samples with results lying between the numbers ***m*** and ***M*** are classified as marginal.

Lots are accepted provided:

- None of the ***n*** samples is poor, having levels exceeding ***M***
- At most ***c*** of the samples are marginal, with levels between ***m*** and ***M***.

If ***m*** = ***M*** a three-class plan becomes a two-class plan.

Evaluation of these plans generally requires an assumption about the underlying distribution of the identified characteristic, such as the lognormal distribution for microbiological parameters. This might also apply to two-class plans, especially for microbiological plans.

Three class plans for finite lots can be designed based on the hypergeometric distribution.

4.2.7 Plans for variables data where an appropriate distribution is unknown

If the underlying distribution of a measured characteristic within a lot is not known and we are not prepared to assume that the characteristic can be adequately described by the normal or some other distribution, then the only recourse available is to classify the results as conforming or nonconforming with respect to the specification limit and to use attributes plans. Note that this approach should be used only when measurement uncertainty is negligible.

4.2.8 Attribute plans for multiple characteristics

Attributes plans can be easily applied to multiple characteristics by classifying inspected items as nonconforming if any of the individual characteristics are nonconforming.

Obviously, it makes sense to apply a plan to multiple characteristics only if the individual characteristics are of similar 'stringency', i.e., if the same or similar plans would be used if the characteristics were inspected individually. These plans have the advantage, compared to the use of individual plans, of allowing better control of producer's risk, of incorrectly rejecting lots of good quality.

4.3 Inspection by Variables Plans

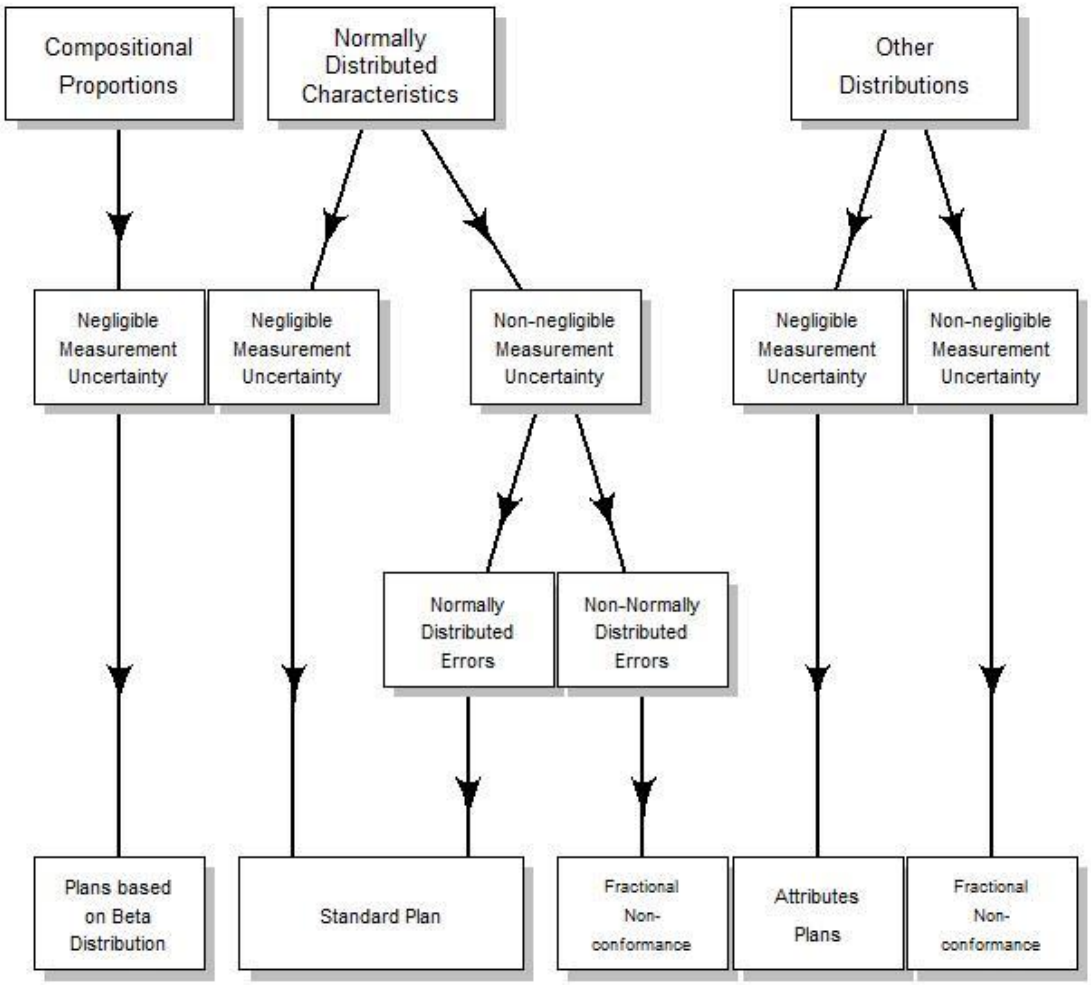
4.3.1 Introduction

If the underlying distribution of a measured characteristic is known, acceptance sampling can be performed directly on the measurements themselves. This often allows a considerable reduction in sample size.

For variables plans it is necessary to make an assumption regarding the distribution of the characteristic within the lot. While the normal (Gaussian) distribution is commonly adopted, for compositional proportions in bulk materials the beta distribution is more appropriate (though the normal distribution can serve as an approximation).

The following diagram shows the process for the selection of variables sampling plans:

Selection of Inspection by Variables Plans - Homogeneous Characteristics



4.3.2 Advantages and disadvantages of variables plans

The advantages of variables sampling plans are:

- they offer the same protection with a smaller sample size than that required for attributes plans
- there is feedback of data on the process which produced the units
- there is more information available in waiver situations
- the extent of conformity of each unit is taken into account in the application of the plan.

The disadvantages are:

- the outcome is dependent on the appropriateness of the underlying distribution, that the assumed statistical distribution provides a satisfactory description for the behaviour of the characteristic within the lot
- they are only applicable to one characteristic at a time
- there may be a higher inspection cost per unit
- a lot with no nonconforming units may be rejected by a variables plan, that occur when the average level lies too close to the specification limit, as measured in terms of the variation in the lot (lot standard deviation)

- there is a possibility that no nonconforming units are found to show to the producer after rejection.

4.3.3 Variables plans

Variables sampling plans are defined by two numbers: the sample size n, i.e., the number of items to be taken from the lot under inspection, and the acceptability constant ***k***, i.e., the multiplier of the lot standard deviation ***S*** in the acceptance criterion.

A lot is accepted if $\bar{X} + kS \leq U$ for an upper specification limit U or if $\bar{X} - kS \geq L$ for a lower limit L.

4.3.4 ISO Standards - variables plans

The ISO 3951 standards provide sampling plans that are indexed by either CRQ or PRQ. The lot size is an input to the sampling plans in these standards as the sample size depends on the lot size.

The ISO plans indexed by CRQ are intended for the inspection of homogeneous isolated lots consisting of discrete items. These plans are more suited for provisions relating to food safety when it is not appropriate to explicitly control producer risks in the design of the plans.

Appendix II contains tables for Inspection by Variables Plans from ISO 3951-1. These plans are indexed by the PRQ.

The ISO 3951-6 standard also contains procedures that deal with non-negligible measurement uncertainty. This is discussed in more detail in section 5.

4.3.5 Plans for the average level in the lot

In some cases, such as the net weight of packages, a limit applies to the average level, with the intention that the average level in the lot should not be less than the limit. In Codex, although an example of sampling plans for bulk materials, the plans for aflatoxins are also based on compliance of the average level. This is an example of the use of offsets (refer section 3.2.3).

It is usually assumed that the quality characteristic is normally distributed; the appropriateness of the distribution is less critical when compliance of the average level is being assessed. It is also usually assumed that there is a single specification limit, either a lower specification limit, ***L*** or an upper specification limit, ***U***.

When the lot standard deviation **σ** is known based on historical process data, the inspection plan for compliance of the average level to a minimum limit ***L*** is operated as follows:

1. Take a random sample of size n and obtain the sample mean
2. Calculate $A = L + k \times \sigma$
3. If the sample mean $\bar{x} > A$ accept the lot; otherwise reject the lot.

The parameters of the plan are ***n*** and ***k***. Note that ***k*** does not denote the same quantity as in the usual variables plans. When the lot standard deviation **σ** is unknown, it is replaced with the sample standard deviation ***s***. The OC curve for this plan is less discriminatory than the plan when the standard deviation **σ** is known, and a greater sample size will be required to provide equivalent discrimination to that provided when the standard deviation is known.

4.4 Sampling of Bulk Materials

4.4.1 Introduction

Bulk materials are continuous, consisting for example of particles of different densities and sizes. It is impossible to consider a lot of a bulk material as a set of discrete items because there is no way of selecting the items in a way that is not biased when using simple random sampling.

Some general objectives of bulk sampling are:

- acceptance on a lot-to-lot basis
- characterizing the material as to grade[12], any need for further processing, and its destination

[12] Foods and other materials are often ranked according to their quality, with the different quality levels are sometimes known as grades.

- control during processing
- determination of weight or content for purposes of payment
- determination of properties that must be known so that the end use will be appropriate
- experimentation and analysis to determine further sampling procedures and uses of the material.

Sampling units are created at the time of sampling by means of some kind of sampling device. The sampling units change depending on different factors such as how the device is employed, and the conditions that the device is used under.

In bulk sampling, a lot is seen as being composed of mutually exclusive segments.

Sometimes the segments are obvious, such as when the material comes in boxes or bags.

Other times the segments are not obvious, and so they have to be artificially created. One way of doing this is by superimposing imaginary grids over the material.

4.4.2 Theory of Sampling

The Theory of Sampling provides a comprehensive approach to the design of representative sampling, the aim of which is to obtain a sample for laboratory analysis whose composition is an unbiased estimate of the average level of a lot. However, this sample would not, by itself, be useful for assessing conformance of a lot to minimum or maximum specification limits as an additional allowance is required to compensate for variation in the lot to enable such assessments to be made.

4.4.3 Terminology

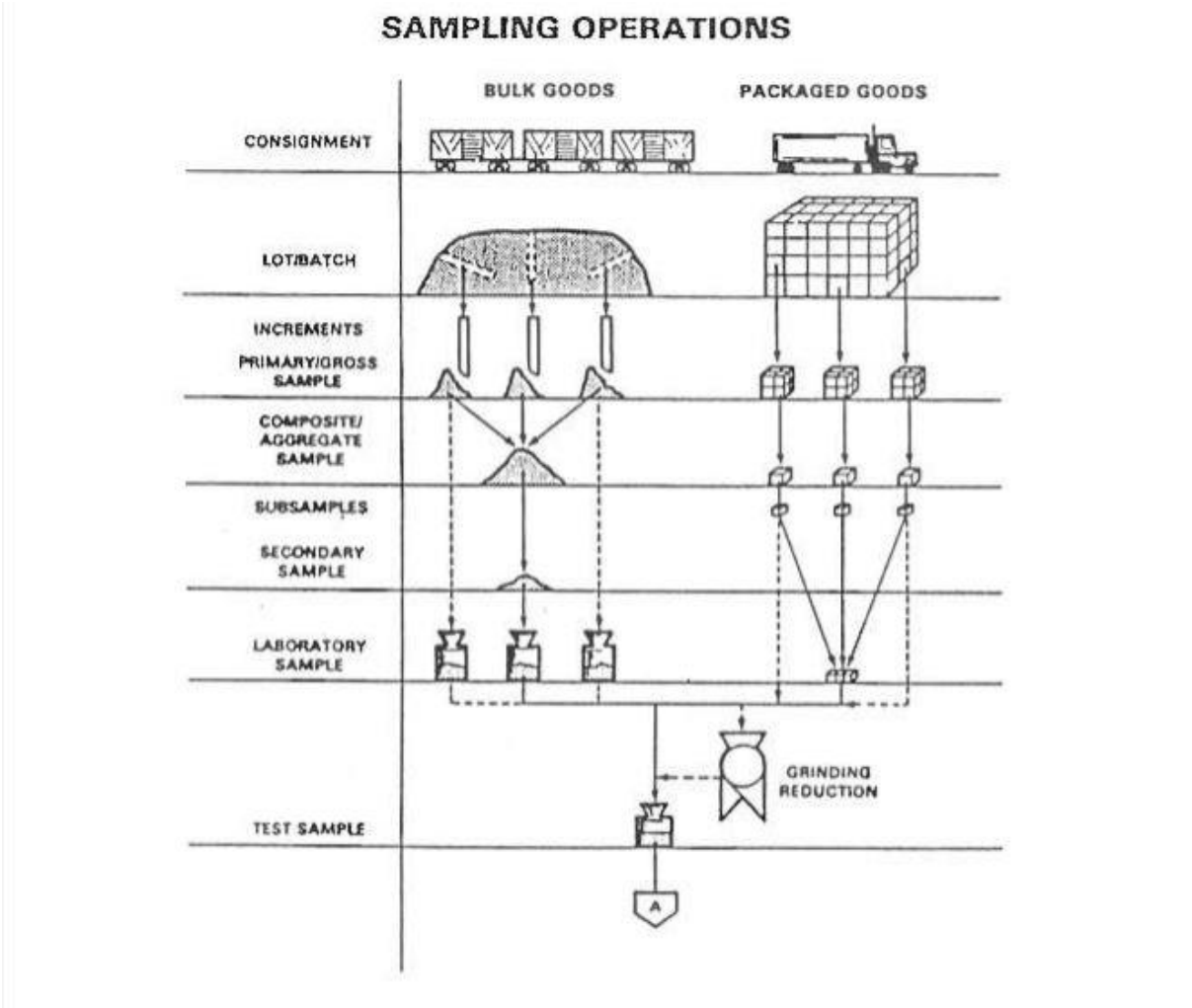
The special nature of sampling for bulk materials has led to the use of specific terminology, although this terminology varies between different fields, and between authors. Some of the commonly used terms are set out in the following table:

Table 3: Bulk material terminology for sampling plans

Term	**Meaning**
Lot	An identifiable quantity of a food commodity delivered at one time and determined to have common characteristics, such as origin, variety, type of packing, packer, consignor, or markings.
Segment	A portion of the lot to which inference will be made.
Increments	Randomly selected samples that represent the segment and may be used to form a composite sample.
Blending	The mixing or agglomerating of increments to form the composite sample.
Composite sample	A sample formed by blending a certain number of increments from specified segments of the lot.
Sub-sample	A portion of the composite sample that is sent to the laboratory. *Note: In CXG 54 and in the diagram that follows, this is called 'laboratory sample'.*
Laboratory sample	A portion of the sub-sample that is measured. *Note: In CXG 54 and in the diagram that follows, this is called 'test portion'.*

4.4.4 Illustration of terms

The following diagram shows how these definitions relate to the different aspects of the overall sampling process, from the sampling of the bulk material to obtaining laboratory samples for testing:



4.4.5 Design of general sampling plans for bulk materials

In the simplest case, such as the inspection of bulk materials of manufactured products, lots can often be considered homogeneous, allowing the standard attributes or variables plans to be used, with adjustment for analytical measurement uncertainty where appropriate.

On the other hand, some bulk materials, such as shipments of grains or other raw materials, cannot be considered homogeneous (refer section 3.2.7Special techniques are required for this situation, but the statistical methods are complex and only an overview is provided in these Guidelines.

Lot homogeneity is difficult to verify for bulk materials and generally requires large numbers of samples. Moreover, it is often difficult to perform random sampling from an entire lot of a bulk material. As a precaution, in cases where lot homogeneity can be neither assumed nor verified, lots should be treated as inhomogeneous.

The general approach to sampling inhomogeneous lots of bulk materials is that a lot is considered as a set of smaller segments (strata) each of which is more homogeneous than the entire lot. This allows the usual sampling procedures based on random sampling to be applied within each segment as inhomogeneity within each segment will have less effect.

The basic sampling and inspection procedure can be described as follows:

- segments, from which increments are to be taken are chosen at random
- several increments are chosen at random from each of the chosen segments
- the increments from each segment can sometime be combined to form a composite sample, which is thoroughly mixed
- one or more sub-samples are taken from each composite sample

- these sub-samples are tested
- acceptability of the lot is decided based on an acceptance criterion.

4.4.6 Attributes plans for bulk materials

The following points need to be considered in the design of attributes plans for bulk materials:

- inhomogeneity will be present and hence the standard attribute sampling plans for homogeneous lots will not be suitable as they do not provide adequate protection for consumers
- inhomogeneity can be overcome either by allowing for the correlation within the batch in the design of the sampling plan or, alternatively, by splitting the lot into more homogeneous segments, and using stratified sampling techniques. Either way, a preliminary study is needed to estimate the correlation and the variation between segments
- the proposed plans should be validated using different statistical models for the behaviour of the level nonconforming within the lot, to ensure robustness against different levels of correlation.

4.4.7 Variables plans for bulk materials

Typically, the total observed variation within a lot of bulk materials consists of several components due, for example, to variation between and within segments, due to sample preparation (e.g., including sub-sampling), testing and other causes.

Sampling plans for bulk materials, especially cost-optimal sampling plans, can be designed most effectively with prior knowledge of the different components of variation that exist within lots; it is desirable that a preliminary investigation of the variation is carried out prior to the development of any plans.

A minimum of 10 samples per segment is recommended to estimate the within lot variability, if the acceptance criterion involves averaging of multiple test results, laboratory samples should be tested at least in duplicate to allow estimation of the repeatability component of measurement uncertainty, unless an estimate is available from other sources such as a method validation study.

Example
The CXS 193-1995 shows the breakdown of the total variation for aflatoxins in tree-nuts, with a focus on sampling, sample preparation and testing; the variation due to sampling includes both between and within segment variation. It should be noted that provisions for aflatoxins are expressed in terms of the average levels in a lot.

Table 1. Variances[a] associated with the aflatoxin test procedure for each treenut

Test procedure	Almonds	Hazelnuts	Pistachios	Shelled Brazil nuts
Sampling[b,c]	S^2_s = (7 730/ns) $5.759C^{1.561}$	S^2_s = (10 000/ns) $4.291C^{1.609}$	S^2_s = 8 000/ns) $7.913C^{1.475}$	s_s^2 = (1 850/ns) $4.8616C^{1.889}$
Sample Prep[d]	S^2_{sp} = (100/nss) $0.170C^{1.646}$	S^2_{sp} = (50/nss) $0.021C^{1.545}$	S^2_{sp} = (25/nss) $2.334C^{1.522}$	s_{ss}^2 = (50/nss) $0.0306C^{0.632}$
Analytical[e]	S^2_a = (1/na) $0.0484C^{2.0}$	S^2_a = (1/na) $0.0484C^{2.0}$	S^2_a = (1/na) $0.0484C^{2.0}$	experimental s_a^2 = (1/n) $0.0164C^{1.117}$ or FAPAS s_a^2 = (1/n) $0.0484C^{2.0}$
Total variance	$S^2_s + S^2_{sp} + S^2_a$	$S^2_s + S^2_{sp} + S^2_a$	$S^2_s + S^2_{sp} + S^2_a$	$S^2_s + S^2_{sp} + S^2_a$

S_s^2, S_{sp}^2 and S_a^2, denote the variance associated with the sampling, sample preparation and analytical steps, respectively.

A sampling plan is defined in terms of laboratory sample size *ns*, test portion size *nss* and the number of aliquots *na* (i.e. the number of analytical samples taken from each subsample). The information in this table can be used to design an optimal sampling plan in terms of total cost for a specified consumer's risk at a given concentration *C*. Obviously, the costs associated with each step need to be known to derive a cost-optimal plan.

Since bulk materials are continuous, parts of each sample can be mixed to form a sample. This composite is then tested only once, rather than having to perform many tests on the individual samples. This is a physical way of creating a sample representing the average content per lot or segment. This averaging causes a reduction in the apparent variation meaning that adjustment of the acceptance criterion may be required for assessments against minimum or maximum limits.

Note however, that the use of composite sampling adds complexity to the design of a general sampling strategy due to the statistical complexity of modelling the mixing process; assuming that composites made up from many individual portions can be thoroughly mixed is possibly unrealistic.

4.4.8 Variables plans for the average level

Sampling plans for bulk materials are often used to assess compliance of the average level of a characteristic. In some cases, such as in the sampling plans for aflatoxins in CXS 193-1995[13], these plans are used in conjunction with offsets (refer section 3.2.3) to provide consumer protection.

Other procedures for the inspection of the average level of a lot such as those in ISO 10725 are available that consider costs to derive plans that are economical to apply, although these plans might not be suitable in cases where a more precise determination of the average level is required.

Plans for the average level might also be applicable where the product is homogenized through blending or further processing.

4.4.9 Variables plans for percentage nonconforming (minimum or maximum limits)

The strategy is similar to the design of variables plans for the average level except that an additional allowance must be made for variation within the lot, obtainable from the statistical analysis described in section 4.4.5. A simpler approach is to estimate within lot variation as the variation among the segments by taking one sample from each segment and testing those samples in duplicate to allow adjustment

[13] General standard for Contaminants and Toxins in food and feed (CXS 193-1995)

for measurement uncertainty, although this will not provide any information on other components of variation:

- the acceptance criterion has the same form as a conventional variables plan applied to homogeneous lots
- the number of samples n and the acceptability constant k can be found by trial and error, assessing the probabilities of acceptance against various alternative models for the behaviour of the characteristic in the lot. This should recognise that the formation of the segments might not reflect the disposition of nonconforming product within the lot.

4.4.10 Variables plans for compositional proportions (measurement uncertainty negligible)

Compositional characteristics are often quality measures for bulk materials. For example, the milkfat percentage with a minimum limit of 26 % is a primary quality measure for whole milk powders[14].

Compositional proportions, also referred to as mass fractions, are characterized by units of measure such as percent (of mass), mg/kg, µg/100g and the like, which are, strictly speaking, 'dimensionless' numbers lying between 0 and 1.

Compositional proportions can be modelled using the beta distribution. Variables sampling plans based on the normal distribution can only be approximate for compositional proportions and can lead to a higher consumer's risk than desired.

Sampling plans for compositional proportions are defined by two parameters, ***m***, the number of samples to be taken from the lot and ***k***, the acceptability constant defined in the same way as for the usual variables sampling plans. In order to design such plans, in addition to PRQ, CRQ etc., an estimate of the 'precision parameter' for the beta distribution, denoted by ***θ***, is required. This estimate can be obtained from the analysis of historical data.

When using these plans, the ***m*** samples are taken from the lot and can be tested individually or combined (blended, well mixed etc.) to form a composite sample that needs to be tested only once.

The average level ***P*** is taken as either the average of the ***m*** results from the testing of the individual samples or the single result from the testing of the composite sample.

A feature of the beta distribution is that its standard deviation depends on the average level, enabling an assessment to be conducted using a single test of a composite sample taken from the lot. The standard deviation is calculated using the formula:

$$s = \sqrt{P(1-P)/\theta}$$

where θ is the precision parameter for the beta distribution, estimated from historical data (see above).

The lot is accepted against an upper limit U provided $P + k \times s \leq U$ and similarly for a lower limit.

5 Inspection error and measurement uncertainty

Non-negligible analytical measurement uncertainty and inspection error have the potential to affect the probabilities of acceptance of a sampling plan. Accordingly, non-negligible analytical measurement uncertainty or inspection error must be taken into account in sampling inspection.

It has been shown theoretically that analytical measurement uncertainty and inspection errors affect the producer's risk more than they affect the consumer's risk, i.e. the increase in producer's risk (rejecting a lot of acceptable quality) exceeds the increase in consumer's risk (accepting a lot of unacceptable quality). Accordingly, in the interests of fairness, it is important that appropriate allowances are made for non-negligible measurement and inspection errors.

Acceptance sampling plans can be designed to allow for non-negligible analytical measurement uncertainty and inspection error.

5.1 Attributes Plans

In the context of attributes plans, 'inspection error' refers to random errors of misclassifying conforming items as nonconforming and vice versa.

[14] Standard for Milk Powders and Cream Powders (CXS 207-1999)

Inspection errors occur when testing an item for conformance and can be caused by human error, instrument error, or any other measurement related errors.

There are two types of inspection errors:

- Type I errors (***e₁***) occur when conforming items are classified as nonconforming
- Type II errors (***e₂***) are when nonconforming items are classified as conforming.

When inspection errors are present, they generally cause a greater increase in producer's risk than consumer's risk. For a single sampling plan, Type I errors (**e_1**) have a greater effect on the OC curve than Type II errors (**e_2**).

The true fraction nonconforming ***p*** and the observed fraction nonconforming ***p_e*** are related through the following equation:

$$p_e = e_1(1-p) + (1-e_2)p$$

The impact of inspection errors is particularly marked for zero acceptance number plans.

5.1.1 Known inspection errors

If the misclassification errors are known, i.e., if precise estimates of the misclassification errors are available, for example from a method validation study, the estimates of the Type I and Type II errors can be used to design a sampling plan to control producer's and consumer's risks to specified levels. This will inevitably lead to increased sample sizes.

5.2 Variables Plans

Measurement uncertainty provides information regarding the range of values that could reasonably be attributed to the measurand. As such, it constitutes an important measure of the quality or reliability of a test result.

For a more comprehensive discussion of measurement uncertainty, refer to the Guidelines on Measurement Uncertainty (CXG 54-2004).

It should be noted that the concept of measurement uncertainty as usually understood (and as discussed in the Guidelines on Measurement Uncertainty (CXG 54-2004)) relates to a single determination performed on a single sample. This is appropriate for conformity assessment, but not for acceptance sampling (refer section 2.2). The same holds for the procedure illustrated in Figure 1 in the Guidelines on Measurement Uncertainty (CXG 54-2004). In connection with acceptance sampling, it is important to take into account how the different measurement uncertainty components manifest themselves in the sampling and calculation procedures applied. This is discussed in section 5.2.4, below.

The terms 'negligible' and 'non-negligible'[15] are used to indicate whether or not allowances should be made for measurement uncertainty in acceptance sampling plans. In the ISO 3951 series, measurement uncertainty is considered non-negligible if it is greater than 10% of the *process* standard deviation (SD). In connection with the inspection of isolated lots, the same criterion can be applied, but replacing the *process* SD with the *lot* SD (refer section 3.2.6). However, the only definitive way to assess whether an adjustment for measurement uncertainty is required is to examine the OC curve for the proposed sampling plan in the presence of measurement uncertainty (refer section 2.3.1).

5.2.1 Measurement uncertainty

In order to clarify the role of measurement uncertainty in acceptance sampling, it is necessary to draw a distinction between *analytical* measurement uncertainty and the *sampling component* of (the total) measurement uncertainty. We start by reproducing the following definition from section 8 in CXG 54:

A laboratory sample is a sample as prepared (from the lot) for sending to the laboratory and intended for inspection or testing

Any sources which contribute to measurement uncertainty prior to the arrival of the laboratory sample in the laboratory can be considered components of sampling uncertainty:

- the sampling procedure

[15] The term 'significant' is also used

- the heterogeneity of the lot
- the person(s) performing the sampling
- subsampling steps (leading to the laboratory sample)
- contributions due to storage and transportation conditions (prior to the arrival of the laboratory sample in the laboratory).

Any sources which contribute to uncertainty within the laboratory can be considered components of analytical measurement uncertainty, for example:

- subsampling steps performed on the basis of the laboratory sample, such as taking a test sample, test portion, etc.
- sample preparation
- contributions due to storage conditions (in the laboratory)
- analytical steps
- laboratory technician.

In determining measurement uncertainty, it is important to take account of all relevant contributions, including all sampling and analytical sources.

Role of measurement uncertainty in acceptance sampling

The lot standard deviation represents variation of the characteristic across items in the lot under inspection. Accordingly, it can be said that the *sampling* component of measurement uncertainty is *represented* by the lot standard deviation, even though, conceptually, sampling uncertainty is not the same as the lot standard deviation[16]. Accordingly, the question is whether *analytical* measurement uncertainty sources affect the calculation of the lot standard deviation[17].

If the quality level is expressed in terms of the proportion of items nonconforming, then the central question is how to obtain a reliable estimate for the lot standard deviation net of any analytical measurement uncertainty. The question thus arises: *which analytical measurement uncertainty sources might inflate the estimate of the lot standard deviation?*

In many cases, an estimate of analytical measurement uncertainty is available in the form of a reproducibility precision standard deviation consisting of a repeatability component (random within-lab variability) and a between-laboratory component (lab bias). In connection with acceptance sampling, these two components do not affect the estimation of the lot standard deviation in the same way and must be treated differently. For example, if we can assume that laboratory bias is negligible, then it is only necessary to take the repeatability component into account.

In summary, in connection with the calculation of the lot standard deviation in acceptance sampling:

- Only the possible impact of analytical components of measurement uncertainty on the calculation of the lot standard deviation need be considered
- Different components of analytical measurement uncertainty are treated differently; indeed, some may not be taken into consideration at all.

It is necessary to correct the lot standard deviation *only if analytical measurement uncertainty is non-negligible*. In order to determine whether analytical measurement uncertainty is non-negligible, the ratio of the analytical measurement uncertainty and the lot standard deviation is considered. Analytical measurement uncertainty is considered non-negligible if it is greater than or equal to 10% of the lot standard deviation.

[16] The lot standard deviation is not a component of measurement uncertainty, whereas sampling uncertainty is.
[17] In statistical terms, this point can be made as follows: If the distribution of the property of interest in the lot follows a normal distribution, and if the sampling procedure is adequate (meaning that the noncentral *t*-distribution can be applied), then the calculation of the probability of acceptance takes into account the sampling uncertainty (the statistical uncertainty of the estimate of the lot standard deviation).

Various methods of adjustment or allowance for analytical measurement uncertainty are discussed in the following sections.

Within Item Variation

For the case of lots consisting of discrete items, one uncertainty source deserves special attention: **within-item variation**. Typically, one measurement value is obtained per item, and the lot standard deviation is calculated on the basis of these item-specific values. Each measurement value is intended to represent the mean concentration of the given item. However, the lot standard deviation calculated in this manner may be inflated by within-item variation. There are two cases to consider.

Case 1 – subsampling prior to the arrival of the sample in the laboratory

In this scenario, there is a sub-sampling step between item selection and the arrival of the laboratory sample in the laboratory, and this sub-sampling step causes non-negligible deviations between laboratory samples from one and the same item (if several laboratory samples were taken from the same item). Note that in this case, the lot standard deviation will be inflated by a sampling (rather than an analytical) component of measurement uncertainty. Accordingly, this case represents an exception to what has been repeatedly stated: namely, that in acceptance sampling, it is only the analytical (and not the sampling) components of measurement uncertainty which may need to be taken into consideration. A correction for this type of overestimation of the lot standard deviation presents practicability issues and is not typically contemplated. This case is mentioned here merely for the sake of completeness.

Case 2 – subsampling within the laboratory

In this scenario, sub-sampling inside the laboratory causes non-negligible deviations between test portions taken from the same laboratory sample. While the source of this measurement uncertainty is analytical, it is not typically reflected in estimates of measurement uncertainty. An estimate of this type of within-item variation can be obtained via a 'duplicate' experimental design, where two test portions per laboratory sample are analyzed.

5.2.2 General discussion of bias

Measurement uncertainty consists, on the one hand, of components that reflect random effects (varying randomly with each test result) and, on the other hand, of components that reflect systematic effects (remaining constant across test results).

A systematic effect is commonly referred to as a bias.

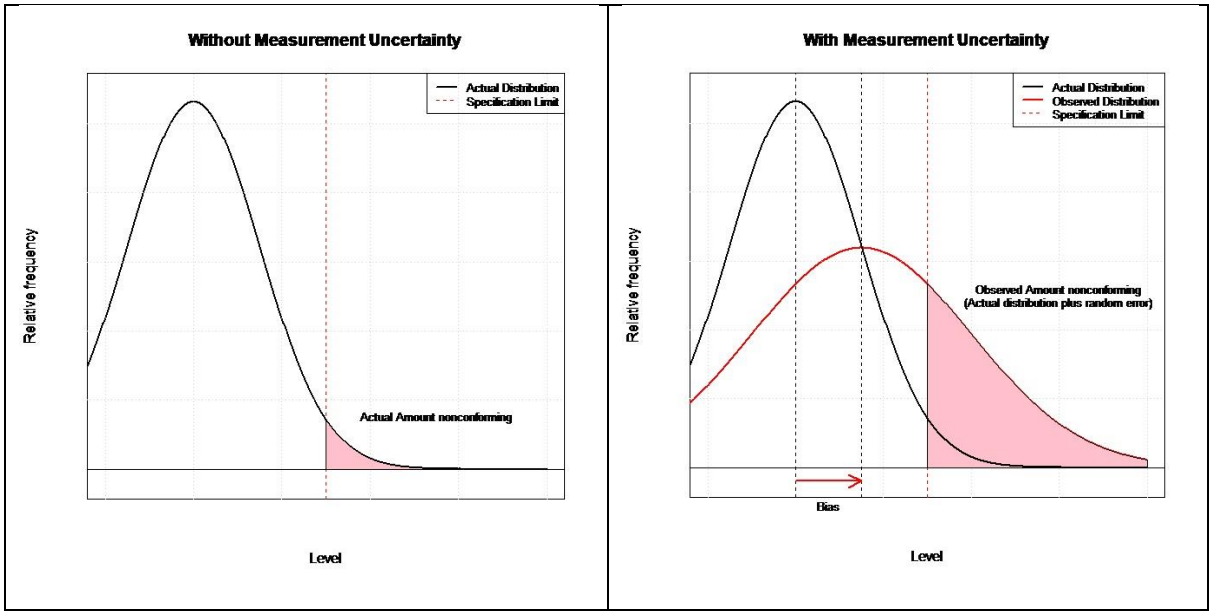
In principle, if a bias is observed, it is corrected for; and it is the *uncertainty of the bias correction* which is taken into account in the measurement uncertainty.

In practice, a bias may affect test results even after a *bias correction* is performed. This is the case, for example, if the bias correction is adequate for a given matrix, but not for another.

There may be various sources of bias. The analytical method itself may have a bias. In addition, the method bias may vary from one matrix to the next. In this sense, matrix effects (or a 'matrix bias') may be observed. Finally, the method bias may vary from one laboratory to the next. In the sense, laboratory effects (or a 'laboratory bias') may be observed.

It is often possible to obtain an estimate of the magnitude of a bias even in the absence of information regarding the 'true value'. For instance, the 'between-laboratory' component of reproducibility precision, calculated on the basis of data from a collaborative study, characterizes the magnitude of the laboratory bias. Similarly, there are procedures for estimating laboratory bias on the basis of Quality Control data or Proficiency Test results which can be used to characterize the magnitude of the laboratory bias.

The following diagram shows the distribution and the percent nonconforming in a lot in the case that there are neither random effects nor bias (referred to as an 'error free' plan), and the effect which random effects and bias can have on the observed distribution and the apparent percentage nonconforming in a lot. This diagram thus shows the effect that random effects and bias can have on the probability of acceptance of a lot, unless such effects are adequately accounted for.



5.2.3 Top-down approach: the ISO 5725-2 model

In many cases, an estimate of measurement uncertainty is supported by precision data from an inter-laboratory method validation study (collaborative study) calculated on the basis of the simple design from the ISO 5725-1 and ISO 5725-2 standards. This design allows two precision components to be calculated:

- one component reflecting *random effects* under near identical conditions within a given laboratory, referred to as the repeatability component
- one component reflecting *laboratory bias*, referred to as the between-laboratory component.

Though this model is not the most general model[18], it will be used as the basis for the discussion of the adjustment for measurement uncertainty in variables sampling plans.

The term '*between-laboratory*' component in ISO 5725-2 characterizes the range of laboratory bias under repeatability conditions. It should be noted however, that the laboratory bias includes intermediate precision effects (different technicians, pieces of equipment, batches of reagents or points in time within the same laboratory). The between-laboratory variation as estimated in ISO 5725-2 thus consists of both the intermediate components and a residual laboratory bias that remains constant across different measurement conditions or points in time in a given laboratory.

Note: The method component of bias could also be taken into consideration. In other words: the determination of measurement uncertainty could take into account not only precision, but trueness as well.

Note: A proper consideration of laboratory and method bias requires the availability of precision data from an inter-laboratory collaborative study. In particular, data from an in-house study are not sufficient to support an estimate of measurement uncertainty.

Note: The revised ISO 5725-3 describes factorial designs which allow a reliable estimation of precision parameters even with relatively few participating laboratories. The manner in which different components of precision should be taken into account in acceptance sampling depends on the experimental design of the study in which said components were obtained.

5.2.4 The acceptance criterion

The acceptance criterion in a variables plan takes the form:

$$\bar{x} + k \cdot s \leq USL,$$

[18] For a more general model, see the Guidelines on Measurement Uncertainty (CXG 54-20004)

where $\bar{x}$ is the average value of the test results obtained from the inspection, s is their standard deviation and USL denotes the upper specification limit.

The standard deviation s characterizes the total variation, including:

- variation of the characteristic in the lot (the lot standard deviation)
- random components of measurement uncertainty
- additional measurement uncertainty components such as the uncertainty of bias correction or the range of lab bias.

The mean value $\bar{x}$ is calculated from several test results. When taking measurement uncertainty into account, it is thus necessary to consider how averaging affects:

- the different measurement uncertainty components
- the uncertainty due to sampling as characterized by the lot standard deviation.

In general, taking the mean value across n test results will not reduce the measurement uncertainty by a factor of $1/\sqrt{n}$.

As far as the two components from the ISO 5725-2 model discussed above:

- averaging across n test results will reduce the repeatability component by a factor of $1/\sqrt{n}$
- however, averaging across n test results will not reduce the between-laboratory component.

The uncertainty of bias correction is not reduced by averaging over several test results.

Averaging across n test results, each obtained from a different item, will reduce the contribution of the lot standard deviation to total variation by a factor of $1/\sqrt{n}$.

In the absence of fundamental variability, the lot standard deviation from a *single* test result obtained from a *well-mixed* composite sample obtained from n increments is reduced by a factor of $1/\sqrt{n}$.

5.2.5 Laboratory bias in acceptance sampling

In connection with acceptance sampling, the following should be noted:

- if information regarding laboratory bias is available in the form of a between-laboratory standard deviation from an interlaboratory study conducted according to ISO 5725-2, then measurements during lot inspection should be performed under repeatability conditions, with the bias, represented by the between-laboratory standard deviation, taken into account in the sampling plan. As mentioned above, in the context of ISO 5725-2, the so-called between-laboratory SD includes both within-laboratory and between-laboratory components.
- matrix effects (variation of bias across matrices within the scope of the method) can affect the test results differently in different laboratories (see the Guidelines on Measurement Uncertainty (CXG 54-2004), sections 10, 12 and 15). This means that an estimate of the between-laboratory variation may be valid for a given matrix, but not for another. An estimate of the bias across different matrices can be obtained by means of an in-house experiment. If such an estimate is available, it should be taken into account in the sampling plan

if an estimate of the between-laboratory standard deviation is available, it is important to consider whether it constitutes a reliable characterization of the variation of laboratory bias, in the sense that the estimate was obtained on the basis of data from a sufficiently large number of laboratories (see the Guidelines on Measurement Uncertainty (CXG 54-2004), sections 16, 17 and 18).

5.2.6 Absence of laboratory bias:

If it can be assumed that:

- there is negligible bias
- the characteristic follows a normal distribution in the lot under inspection
- the random components of measurement uncertainty (i.e. repeatability component) follow a normal distribution

then the following approach can be applied.

This involves adjusting the observed standard deviation s by 'subtracting' the standard deviation representing the repeatability component of measurement uncertainty u:

$s_{adj}^2 = s^2 - u^2$. The adjusted standard deviation is then used in the acceptance criterion:

$\bar{x} + ks_{adj} \leq USL$. If the measurement uncertainty is greater than the observed standard deviation, the adjusted standard deviation is set equal to zero. In general, the acceptability constant will be smaller for plans based on adjusted standard deviations:

- this approach is preferred to the other commonly used approach in which the observed standard deviation (that includes random components of analytical measurement uncertainty) is used directly, as the alternative method leads to higher sample sizes according to the ratio of the lot standard deviation of the analytical component of measurement uncertainty to the lot standard deviation
- often, as described in section 5.2.1, samples taken from the lot are subsampled prior to testing. If the within-sample, i.e. between subsample (within the same sample), variation is non-negligible then the lot standard deviation, that should represent the between-sample variation, will be inflated.

A similar approach can also be used to adjust the observed lot standard deviation for non-negligible between-subsample variation. This adjustment will occur automatically if one uses an estimate of the repeatability component obtained using the 'duplicates method'.

In the situation where every sample in the inspection is tested in duplicate, an adjustment for measurement uncertainty can be made for both subsampling variation and measurement uncertainty, using a slightly different procedure. In this case the observed standard deviation *s* calculated from all the data is adjusted by subtracting the quantity $½u^2$ where *u* is the standard deviation of the differences between the results for each pair of duplicate samples:

$$s_{adj}^2 = s^2 - ½u^2.$$

5.2.7 Presence of laboratory bias

The presence of bias means that an estimate of between-laboratory variation is available.

This estimate is considered a measure of laboratory bias and is taken into account in the sampling plan.

If the laboratory bias is relatively small allowance can be made using the techniques described in Annex B of ISO 3951-6. It is assumed that repeatability and laboratory-bias effects, as well as the characteristic, are normally distributed. While the acceptance criterion is of the same form as in the 'error-free' variables plans, in some circumstances it might not be possible to find a sampling plan (the number of samples ***n*** and the acceptability constant ***k***) that controls producer's and consumer's risks in the manner intended.

If the laboratory bias (i.e., the estimate of between-laboratory variation) is too large to apply the procedure from ISO 3951-6, then an adjusted specification limit USL_{adj} should be calculated as $USL_{adj} = USL - q \cdot s_L$, where s_L denotes the estimate of between-laboratory variation (standard deviation). If an estimate of the variation of bias across matrices s_{matrix} is available, then the adjusted specification limit should be calculated as

$USL_{adj} = USL - q \cdot \sqrt{{s_L}^2 + {s_{matrix}}^2}$, where q denotes the appropriate quantile.

5.2.8 Fractional nonconformance

If the characteristic does not follow a normal distribution (refer section 3.2.5), plans based on Fractional Nonconformance (FNC) can be used to allow for analytical measurement uncertainty.

The FNC for a sample can be thought of as the probability that the true value of the sample exceeds the specification limit, allowing for any measurement uncertainty present.

A sampling plan based on the FNC adjustment principle is defined by two numbers, ***n***, the number of samples to be taken and ***Ac***, the maximum acceptance limit for acceptance of the lot. These two numbers are determined in the same manner as for other types of plans, namely, by considering the allowable risks at PRQ and CRQ. Additional information on the ratio between measurement uncertainty and lot SD is also required for the design of these plans.

A lot is accepted provided the sum of the individual sample FNC values does not exceed the maximum acceptance limit.

$$\sum_{i=1}^{n} FNC_i \leq Ac$$

where FNC_i is the FNC value for the i^{th} sample ($i = 1 \ldots n$).

The use of FNC adjustment is preferred over approaches in which samples are classified as conforming or non-conforming against a specification limit or on a 'beyond reasonable doubt' basis taking measurement uncertainty in account. Such approaches are less economical in terms of sample numbers and might not be optimal in terms of controlling producer's and consumer's risks and need to be evaluated.

6 Other Matters Relating to Sampling

6.1 Physical Sampling

The Theory of Sampling (refer section 4.4.2) relies on procedures that represent best practice for unbiased physical sampling from a lot. These sampling procedures should be observed with respect to each individual sample taken from a lot, and for any subsequent mixing and sub-sampling etc., noting that usually more than a single sample is required in acceptance sampling plans. Reference should be made to material-specific ISO or other standards for details of sampling procedures for different commodities. Adherence to specified sampling procedures might be a legislative or regulatory requirement for some commodities in some jurisdictions.

6.1.1 Random sampling

For lots consisting of discrete items, random sampling means that each item has an equal chance of being selected in the sample. The assumption of random sampling allows the Operating Characteristic to be calculated; deviating from random sampling might mean that the plan does not control the producer's or consumer's risks as might have been intended. In many cases systematic sampling, taking samples at regularly spaced intervals throughout a lot, will suffice as a substitute for true random sampling.

It is common for lots to be 'layered', individual items might (say) be packed in cartons, there might be several (but the same number) of these smaller cartons packed into a larger carton, and several (but the same number) of the larger cartons packed on a pallet. Selecting a random sample of size ***n*** items would proceed as follows:

- select ***n*** pallets from the number of pallets in the lot (the same pallet can be selected more than once)
- select a random larger carton from the cartons on each side of the selected pallets
- select a smaller carton from each of the larger cartons that have been selected
- finally, select an individual item from each of these smaller cartons – these constitute the sample which will be tested or examined.

For bulk materials taking a random sample is more difficult. Many lots of bulk materials can be considered as a collection of segments; stratified random sampling is used in which, in the simplest case, segments are selected at random from the total number of segments, then within each segment that has been chosen a random sample of increments is taken.

This is discussed in more detail in section 4.4.

In principle there is no need for random sampling for well-mixed fluids or bulk products; however random sampling might still be used as a precaution against inhomogeneity or for procedural reasons.

6.1.2 Convenience sampling

Convenience sampling is often referred to as pragmatic sampling. It involves taking samples, and sometimes only a single sample, from a part of a population that is convenient to sample and is often used due to low cost. It is a form of *ad hoc* sampling that is sometimes used in pilot testing.

There are usually more disadvantages than advantages with convenience sampling. There is a possibility of sampling error and lack of adequate representation of the population, and furthermore, use of convenience sampling might lead to disputes as it is neither a fair nor a valid procedure.

6.2 Reinspection

When the results of the original inspection of a given lot are considered suspect due to sampling, lot reinspection can be carried out. Reinspection is therefore a possible option that could be used for the resolution of disputes. It is important, if possible, to rule out other causes before concluding that faulty sampling is the cause.

The Guidelines for Settling Disputes on Analytical (Test) Results (CXG 70-2009) provide the following advice:

'Possible reasons for disagreement may include one or several causes such as: the existence, appropriateness and statistical validity of the sampling plan used to assess the product; the allowances made for normal measurement error and within-lot product variation; differences in physical sampling

procedures; differences in composition of the samples tested due to product in homogeneity or changes occurring during storage and/or transport of the product'.

Reinspection involves the lot being resubmitted for inspection, with the decision regarding acceptance or rejection based on a new sample. This process can be repeated; the design of the sampling plan used for each new reinspection depends on the number of reinspections allowed.

There may be perfectly legitimate reasons to raise doubts concerning the results of the original inspection results:

- acceptance sampling plans assume lot homogeneity, which, in turn, often requires random sampling (refer section 3.2.7). Since random sampling of pre-packaged commodities from large containers is difficult, it is natural for the producers or consumers to occasionally distrust or dispute the sampling procedure
- the use of sampling plans based on relatively small sample sizes can result in high risks of incorrect acceptance or rejection.

Accordingly, there are situations in which reinspection should be performed in the interest of fairness. However, if an appropriate sampling procedure has been properly applied then evidence should be brought forth to justify the need for reinspection.

Reinspection schemes are particularly useful for zero acceptance number sampling plans or for variables plans with small sample sizes and large k values such as k= 2. It is well known that such plans generally involve higher risks to producers. Hence, the use of reinspection allows producers to opt for reinspection of a lot when:

- the lot may have been rejected due to an appropriate sampling procedure or poor sampling practice, or
- there is good process history to believe that the quality of the lot is indeed good.

6.3 Inhomogeneous lots

While section 3.2.4 discusses the *conditions under which* a lot can be considered homogeneous, this section addresses the question *how to handle* cases of inhomogeneous lots consisting of discrete items. For more information on sampling of inhomogeneous lots consisting of bulk materials, refer to section 4.4.

Most sampling plans are based on the assumption that the lots are homogeneous. Use of these plans with inhomogeneous lots will usually increase producer's risks and consumer's risks, so that consumer protection may be compromised.

Lots may be inhomogeneous because inspection lots differ from manufacturing lots. Accordingly, one approach may be to split a given inhomogeneous inspection lot into sublots in line with production lots or other standardized manufacturing processes. Each of the sublots might then be sufficiently homogeneous to be inspected using standard attributes or variables sampling plans, inspecting each sublot with the same plan that would have been used for the entire lot, had it been homogeneous. However, lots should not be split into sublots based on results obtained from earlier testing.

APPENDIX I
GUIDE TO THE SELECTION AND DESIGN OF SAMPLING PLANS

1 Introduction

This section provides a high level summary of the principles relating to the design of sampling plans and to the various types of sampling plans discussed in the main document.

It has been structured in a way that allows users to follow the process for the design of a sampling plan from first principles to quickly identify options for sampling plans that are relevant to a particular situation in which sampling is to be undertaken.

Links are provided that allow users to quickly access further information about particular sampling options in the main document.

1.1 Selection of Options for Sampling Plans

A. Determine Sampling Plan Options

1. Type of data

Are the test results expressed as pass/fail outcomes (or equivalent) or are they measurements?

Pass/Fail (or equivalent) outcomes (Attributes)	Go to step 2
Measurements (Variables)	Go to Step 3

Help on attributes data
Help on variables data

2. Attributes data

Is the inspection error negligible or non-negligible?

Negligible	CXG50 4.2	PR & CR	ISO2859
	CXG50 4.2.3	CR only	-2
	CXG50 Appendix II	PR only	ISO2859 -1
Non-negligible	CXG50 5.1.1	Known Inspection errors	

Help on Design of Attributes Plans

3. Variables data

Does the provision relate to compliance of the distribution or to the average level of the characteristic?

3.a. Plans to assess compliance of the distribution

Is the characteristic normally distributed, a compositional characteristic or does it follow some other distribution?

Normally distributed	Go to step 4
Compositional Proportion	Go to step 6
Some other distribution	Go to step 7

Help on Design of Variables Plans

3.b. Plans for the average level

Plans for the Average level	Go to step 8

Help on provision
Help on average level

4. Variables plans, normally distributed characteristics

Is measurement uncertainty negligible or non-negligible?

Negligible	CXG50 4.3.3	PR & CR	
	CXG50 4.3.4	CR only	ISO3951-6
	CXG50 Appendix 2	PR only	ISO3951-1
Non-negligible	Go to step 5		

5. Variables plans, normally distributed characteristics, non-negligible measurement uncertainty

Is the measurement uncertainty normally distributed or does it follow some other distribution?

Normally distributed	CXG50 5.2.7	PR & CR	
	CXG50 5.2.5	CR only	ISO3951-6
Some other distribution	CXG50 5.2.8	PR & CR	

6. Compositional Proportions

Is measurement uncertainty negligible or non-negligible?

Negligible	CXG50 4.4.10	PR & CR
Non-negligible	Go to step 5	

7. Characteristic is neither normally distributed nor a compositional proportion

Is the measurement uncertainty negligible or non-negligible?

Negligible	CXG50 4.2.7	PR & CR
Non-negligible	CXG50 5.2.8	PR & CR

8. Provision is expressed in terms of the average level in a lot

Is the measurement uncertainty negligible or non-negligible?

Negligible	CXG50 4.4.8	PR & CR
Non-negligible		
[no information provided]		

B. Specify Stringency for the Sampling Plan (plans to assess compliance to minimum or maximum levels)

Consumer's Risk Quality level (CRQ) Help on CRQ

What percentage nonconforming (quality level?) would you allow in lots that you would want to reject most of the time?	6.5%

Consumer's Risk (CR) Help on CR

What consumer's risk are you prepared to allow, i.e., how often would you want to accept lots containing 6.5% nonconforming?	10%

If the characteristic is a 'serious' food safety (or other) concern
- It might not be appropriate to control producer's risks explicitly
- Use ISO plans (or alternatives) that control only the consumer's risk

If the characteristic is not a 'serious' food safety or other concern, it is appropriate to also control the producer's risk

Producer's Risk Quality level (PRQ) Help on PRQ

What percentage nonconforming (quality level?) would need to be present in lots that you would want to accept most of the time?	5.0%

Producer's Risk (PR) Help on PR

What producer's risk are you prepared to allow, i.e., how often would you want to reject lots containing 5.0% nonconforming?	5%

C. Evaluate Plan to Determine Plan Parameters and Calculate Operating Characteristic

Determine the number of samples and the acceptance number (attributes plans) or the acceptability constant (variables plans)

1.1.1 Attributes sampling plan example

Using Codex Standard CXS 207-1999 for Milk and Cream Powders as an example.

These examples are hypothetical, some of the scenarios are artificial and may not reflect reality.

Example 1: Scorched particles in wholemilk powder

The characteristic scorched particles is included in CXS 207-1999 as an additional quality factor. The standard says that a sample is considered to conform if it is assessed as being 'Disc B' at a maximum.

1. Nature of the Provision

Does the provision apply to the overall distribution (most of the lot must comply) or to the average level?

Overall Distribution	Go to step 2
Average Level	Go to Step 9

This parameter applies to the overall distribution of the product.

2. Type of data

Are the test results expressed as pass/fail outcomes (or equivalent) or are they measurements?

Pass/Fail outcomes (Attributes)	Go to step 3
Measurements (Variables)	Go to Step 4

Scorched particle 'scores' are attributes data, being either 'Less than or equal to Disc B' or exceeding 'Disc B'.

3. Attributes data

Is the inspection error negligible or significant?

Negligible	CXG50 4.2
Significant	CXG50 5.1.1

It is assumed that measurement error is negligible for this example.

Specify Stringency for the Sampling Plan

(plans to assess compliance to minimum or maximum levels)

The last step is the decide on the required stringency for the sampling plan, how we want the sampling plan to control the producer's and consumer's risks.
This can be done by answering the following questions. In most cases the default values of 10% for the probabilities of wrongly accepting product at the consumer's quality level and 5% for the probability of wrongly rejecting product at the producer's risk quality can be used so it is necessary to specify only the consumer's and producer's risk levels.
Note the questions are expressed the other way round.

Noting that scorched particles is an additional quality factor (characteristic), for the purposes of this example it is assumed that it is of lesser importance than the compositional characteristics so that the consumer's risk quality level could be set at 15%, and the producer's risk quality level at 5%.

Consumer's Risk Quality level (CRQ)

What percentage nonconforming would you allow in lots that you would want to reject most of the time?	15%
How often would you want to accept such lots?	10%

Producer's Risk Quality level (PRQ)

What percentage nonconforming would need to be present in lots that you would want to accept most of the time?	4%
How often would you want to reject such lots?	5%

The following image is an output from a sampling design app. In this example the only inputs required are selection of:
- the 'attributes' option for the type of plan
- the producer's risk quality level of 4%
- the consumer's risk quality of 15%
- (the default producer's and consumer's risks are 5% and 10% respectively).

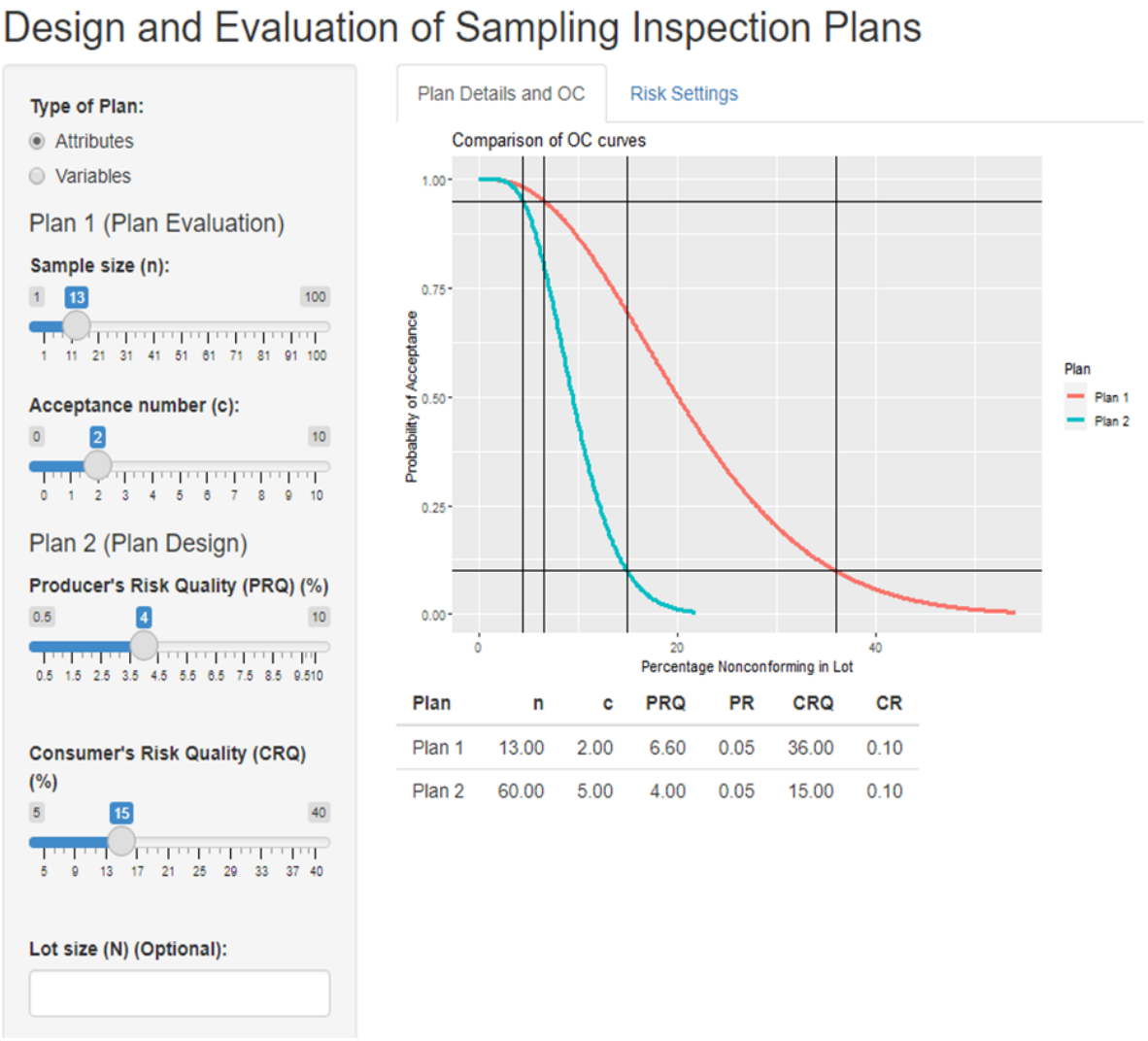
The required sampling plan to control the risks to these levels can be read from the table below the plot as (n = 60, c = 5), i.e., 60 samples need to be taken from the lot and tested, with the lot accepted provided no more than five of those 60 samples were found to be nonconforming, rated at more than 'Disc B'.
However, this plan might be excessive from a practical point of view, considering that testing for scorched particles is manually intensive. Several options are available:

- Re-design the plan using different settings for the producer's risks and consumer's risks
- Use an 'off the shelf' plan, such as a plan from an ISO Standard
- Decide not to carry out assessments of scorched particles

The image below shows the Operating Characteristic for the plan (n=13, c=2) taken from the ISO Standard.
The table below the plot shows the producer's risk quality (PRQ) level of 6.6% and a consumer's risk quality (CRQ) of 36% so that there would be a 10% chance of accepting lots in which 36% of the product is nonconforming.

A decision needs to be made whether this plan is suitable.

This shows that it is important that 'off the shelf' sampling plans are evaluated prior to use to ensure that they will control the producer's and particularly the consumer's risk to satisfactory levels.



1.1.2 Variables sampling plan example

Using Codex Standard CXS 207-1999 for Milk and Cream Powders as an example.
These examples are hypothetical, some of the scenarios are artificial and may not reflect reality.

Example 2: Moisture in wholemilk powder

The provision states that moisture should not exceed a maximum of 5%.

In this example it is assumed that measurement uncertainty is negligible compared to the lot standard deviation, more details are given below.

1. Nature of the Provision

Does the provision apply to the overall distribution (most of the lot must comply) or to the average level?

Overall Distribution	Go to step 2
Average Level	Go to Step 9

The provision is a maximum limit, so applies to the overall distribution of moisture within a lot.

2. Type of data

Are the test results expressed as pass/fail outcomes (or equivalent) or are they measurements?

Pass/Fail outcomes (Attributes)	Go to step 3
Measurements (Variables)	Go to Step 4

Moisture is a measured parameter, so variables plans are the natural choice. Attributes plans could also be used since measurement uncertainty is negligible, although those plans would be less economical in terms of the number of samples required to be tested.

3. Attributes data

Is the inspection error negligible or significant?

Negligible	CXG50 4.2
Significant	CXG50 5.2.1 CXG50 5.2.2

As above measurement uncertainty is assumed to be negligible.

4. Variables data

Is the characteristic normally distributed, a compositional characteristic or does it follow some other distribution?

Normally distributed	Go to step 5
Compositional Proportion	Go to step 7
Some other distribution	Go to step 8

For the purposes of this example and generally, it is assumed that moisture within a lot is normally distributed

5. Variables plans, normally distributed characteristics

Is measurement uncertainty negligible or significant?

Negligible	CXG50 4.2 Go to step 6
Significant	

Measurement uncertainty is assumed to be negligible.

Specify Stringency for the Sampling Plan

(plans to assess compliance to minimum or maximum levels)

The last step is to decide on the required stringency for the sampling plan, how we want the sampling plan to control the producer's and consumer's risks.

This can be done by answering the following questions. In most cases the default values of 10% for the probabilities of wrongly accepting product at the consumer's quality level and 5% for the probability of wrongly rejecting product at the producer's risk quality can be used so it is necessary to specify only the consumer's and producer's risk levels.
Note the questions are expressed the other way round, e.g., the CRQ question relates to rejection, rather than to acceptance.
In this example it is assumed that the consumer's risk quality level is 10%, possibly reflecting the milkpowders are a commodity product and the producer's risk quality level is 2½%.

Consumer's Risk Quality level (CRQ)

What percentage nonconforming would you allow in lots that you would want to reject most of the time?	10%
How often would you want to accept such lots?	10%

Producer's Risk Quality level (PRQ)

What percentage nonconforming would need to be present in lots that you would want to accept most of the time?	2.5 %
How often would you want to reject such lots?	5%

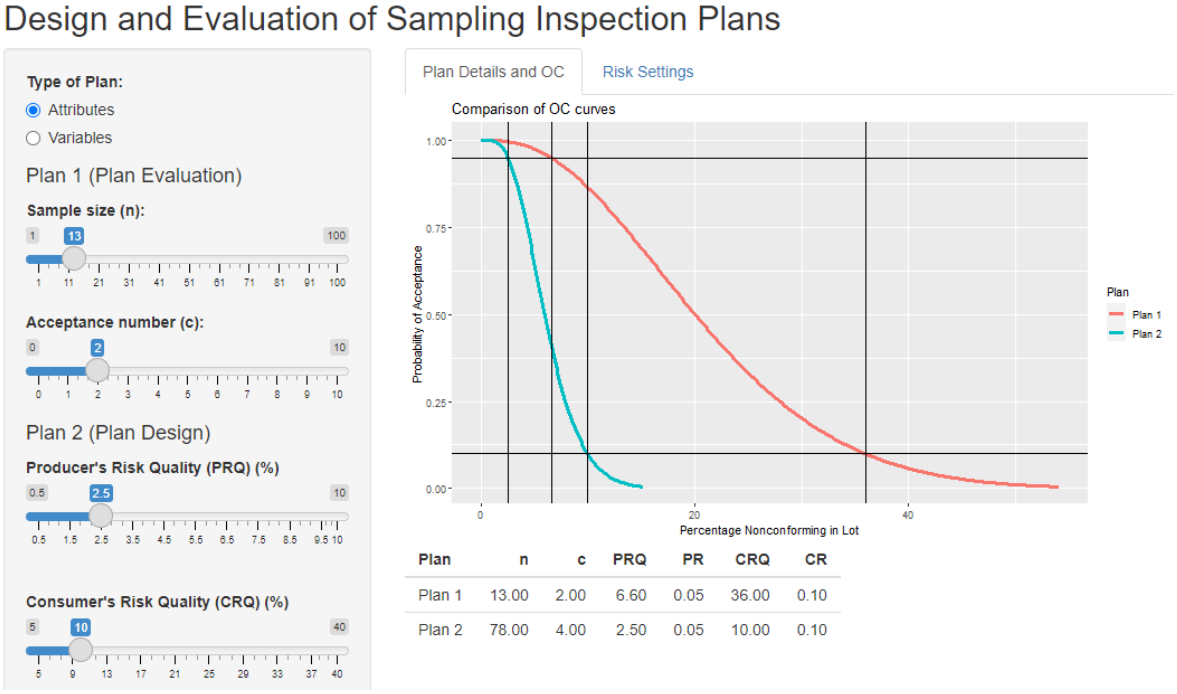
Plan Design
As measurement uncertainty is negligible, the sampling plans can be designed using an app.

1. Attributes Plans

The following shows an image of the output from the app. In this example the only inputs required are selection of:

- the 'attributes' option for the type of plan
- the producer's risk quality level of 2.5%
- the consumer's risk quality of 10%
- the default producer's risks and consumer's risks are 5% and 10% respectively.

The required sampling plan to control the risks to these levels can be read from the table below the plot as (n = 78, c =4), i.e., 78 samples need to be taken from the lot and tested, with the lot accepted provided no more than four of those 78 samples was found to be nonconforming, having results greater than 5%.

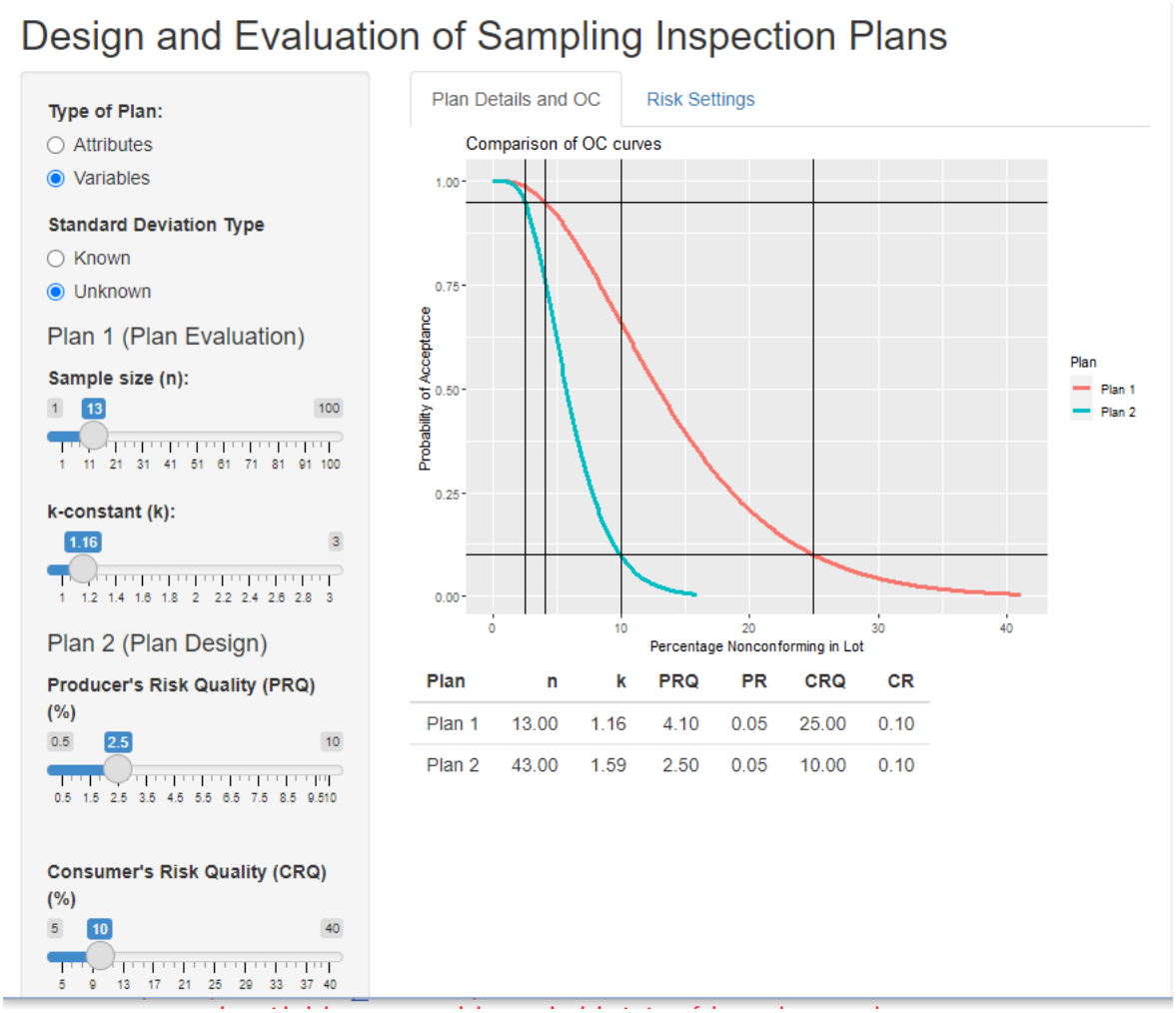


2. Variables Plans

The following shows an image of the output from the app. In this example the only inputs required are selection of:

- the 'Variables' option for the type of plan
- the producer's risk quality level of 2.5%
- the consumer's risk quality of 10%
- the default producer's risks and consumer's risks are 5% and 10% respectively.

We need to also specify whether the true standard deviation (sd) for the process that produced the batch is known or whether it is unknown and is estimated from the data obtained from sampling the lot, but it would be more usual for standard deviations to be unknown in inspections carried out by 'consumers'.



The required sampling plan to control the risks to these levels can be read from the table below the plot as (n = 43, c = 1.59), i.e., 43 samples need to be taken from the lot and tested, with the lot accepted provided the average and the standard deviation of the results meets the acceptance criterion:

$$\bar{x} + 1.59s \leq 5$$

Where $\bar{x}$ is the average of the 43 individual results and 's' is their standard deviation. It is assumed that the measurements are expressed as a percentage e.g., moisture of 5% on a weight/weight basis, rather than as a decimal (0.05).

1.1.3 Supporting material

Context	Term	Explanation
Nature of the provision	Provision	A provision is a requirement for a commodity that must be met in order that the commodity conforms to the standard.
Nature of the provision	Overall distribution	Specification limits may be expressed as a minimum or a maximum limit (or both) applied to either the overall distribution of the characteristic in the lot, e.g., the percentage nonconforming quality level, or to the average level

Nature of the provision	Average level	In some cases, such as the net weight of packages, a limit is set on the average level, with the intention that the average level in the batch should not be less than the limit. In Codex, although an example of sampling plans for bulk materials, the plans for aflatoxins are also based on compliance of the average level, to ensure that there is a small chance that the average level in a lot exceeds the maximum limit. It is usually assumed that the quality characteristic is normally distributed; the appropriateness of the distribution is less critical when compliance of the average level is being assessed. It is also usually assumed that there is a single specification limit, either a lower specification limit, L or an upper specification limit, U.
Types of data	Attributes	Data for which the test results have nominal outcomes or are measured on a scale, particularly binary outcomes such as pass or fail, and measurements classified as binary outcomes.
Types of data	Variables	Inspection by Variables means that the outcomes of the measurements on each sample is a number, usually a decimal number. This is in contrast to attributes data where pass/fail outcomes are obtained or on a scale (sometimes described numerically, e.g. 1-5).
Type of sampling plan	Attributes Plan	Inspection by Attributes consists of examining an item, or characteristics of an item, and classifying the item as 'conforming' or 'nonconforming'. The action to be taken is decided by counting the number of nonconforming items or the number of nonconformities found in a random sample. An inspection by attributes sampling plan specifies the number of samples (n) and the maximum number of nonconforming items, referred to as the acceptance constant (c), for the lot to be accepted. The values of n and c are worked out from the specified levels of allowable risk.
Type of sampling plan	Variables Plan	Inspection by Variables plans use means and standard deviations calculated from the measurements (variables data) to make a decision about the acceptance of a lot. These plans are specified by the number of samples required to be taken (n) and an acceptability constant (k).
Measurement uncertainty		Parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand (i.e. the quantity intended to be measured). Measurement can consist of random and systematic components.
Lot standard deviation		A parameter, usually expressed as a standard deviation, describing the variation of a characteristic within a lot.
Negligible measurement uncertainty		The situation where the measurement uncertainty is small in relation to the lot standard deviation and does not need to be taken into account in the design of a sampling plan. Typically, MU is considered negligible if the standard deviation representing the MU is less than 10% of the lot standard deviation.
Non-negligible measurement uncertainty		Refers to cases where the measurement uncertainty is NOT negligible.
Standard deviation		Standard deviation is a measure of the amount of variation or dispersion in a set of values

Known (true) standard deviation		Conceptually, the standard deviation that would be found, for example, if every item in a lot was measured. In practice, standard deviations can be considered known if calculated using a reasonably large number of test results, typically 100-200. For a standard deviation representing the longer-term variation of a process to be considered known, the process must be stable (consistent) over time.
Estimated (sample) standard deviation		A standard deviation calculated from a smaller amount of data than required for the standard deviation to be considered known.
Normal distribution		A statistical distribution commonly used in many branches of statistics to describe the variation of a measurement method under certain conditions or of a characteristic within a lot. A normal distribution is described by its mean (i.e. average level) and standard deviation and follows a characteristic 'bell-shaped' curve.
Compositional proportion		A characteristic whose concentration within a lot can be expressed as a 'mass fraction', a number taking values between zero and one. Strictly speaking compositional proportions are dimensionless, and do not have proper units of measure, although it is common to express then using units such as percentages, parts-per-million (ppm) etc.
Producer's risk	PR	In general terms, producer's risk is the risk that a lot of good quality will be rejected. More specifically, in the design of acceptance sampling plans, producer's risk is the probability of rejecting a lot that has a quality level equal to the producer's risk quality (PRQ) level.
Producer's risk quality level	PRQ	The quality level (percentage nonconforming in the lot) at which the probability of rejecting the lot is equal to the specified producer's risk (PR)
Consumer's risk	CR	Consumer's risk is the risk that a lot of poor quality will be accepted. More specifically, in the design of acceptance sampling plans, consumer's risk is the probability of accepting a lot that has a quality level equal to the consumer's risk quality (CRQ) level.
Consumer's risk quality level	CRQ	The quality level (percentage nonconforming in the lot) at which the probability of accepting the lot is equal to the specified consumer's risk (CR)

APPENDIX II
ISO INSPECTION PLANS INDEXED BY PRODUCER'S RISK

1 ISO Inspection plans indexed by producer's risk – Introduction/Background

As noted in sections 4.2.3 and 4.3.4, the sampling plans included in the ISO 2859 and ISO 3951 standards differ from plans discussed elsewhere in these guidelines in that they have been designed to explicitly control either the producer's or the consumer's risk, but not both, and use a lot size relationship to determine the required sample size.

1.1 Lot Size vs Sample Size

Statistically, the lot size does not have an important role in determining protection to consumers and producers whereas changes in the sample size does affect the protection afforded by any plan.

However, despite this, a lot size versus sample size relationship has been built into the design of the sampling plans appearing in the ISO standards. This relationship is arbitrary, although it has the general effect of reducing the risks of making incorrect decisions for larger lots, where the costs incurred from incorrect decisions will be greater. This relationship means that the ISO standards are applicable only to lots that consist of discrete items.

As a consequence of employing the sample size versus lot size relationship, ISO has designated that sampling plans indexed by PRQ, explicitly controlling the producer's risk, are intended for the inspection of a continuing series of lots and plans indexed by CRQ, explicitly controlling consumer's risk, as being suitable for the inspection of isolated lots. However, this distinction is no longer relevant if both types of risk are considered in the design of plans.

1.2 Sampling Schemes

The ISO standards indexed by PRQ employ sampling schemes, sets of sampling plans with different levels of inspection to ensure quality is effectively controlled. Sampling schemes employ switching rules for changing between inspection levels based on recent quality history. Typically, and in ISO standards, switching occurs between normal, tightened, and reduced inspection plans within each sampling scheme:

- normal inspection is used when the process is considered to be operating at, or slightly better than, the PRQ
- tightened inspection uses stricter decision rules than those used in normal inspection. The main objective of using tightened inspection is to exert pressure on the producer when the quality is poorer than the PRQ by introducing a higher rate of rejection
- reduced inspection permits smaller sample sizes than those used in normal inspection. When the level of the submitted quality is sufficiently good, reduced inspection offers sampling economy.

Sampling schemes provide more comprehensive assurance than the use of individual sampling plans. However, switching rules are considered too complex to apply in international trade, and from a consumer's point of view in general, although it is possible to design a sampling plan that controls the producer's and consumer's risks to the same levels as an overall sampling scheme.

1.3 Table: Inspection by Attributes Plans from ISO 2859-1

Lot size (Number of items)	**AQL**	**Reduced (n, c)**	**Normal (n, c)**	**Tightened (reduced inspection) (n, c)**
2-8	0.65%	(2 ,0)	(2 ,0)	(3 ,0)
	2.50%	(2 ,0)	(2 ,0)	(3 ,0)
	6.50%	(2 ,0)	(2 ,0)	(3 ,0)
9-15	0.65%	(2 ,0)	(3 ,0)	(5 ,0)
	2.50%	(2 ,0)	(3 ,0)	(5 ,0)
	6.50%	(2 ,0)	(3 ,0)	(5 ,1)

Lot size (Number of items)	AQL	Reduced (n, c)	Normal (n, c)	Tightened (reduced inspection) (n, c)
16-25	0.65%	(2 ,0)	(5 ,0)	(8 ,0)
	2.50%	(2 ,0)	(5 ,0)	(8 ,0)
	6.50%	(2 ,0)	(5 ,1)	(8 ,1)
26-50	0.65%	(2 ,0)	(8 ,0)	(13 ,0)
	2.50%	(2 ,0)	(8 ,0)	(13 ,1)
	6.50%	(2 ,0)	(8 ,1)	(13 ,1)
51 - 90	0.65%	(2 ,0)	(13 ,0)	(20 ,0)
	2.50%	(2 ,0)	(13 ,1)	(20 ,1)
	6.50%	(2 ,0)	(13 ,2)	(20 ,2)
91 - 150	0.65%	(3 ,0)	(20 ,0)	(32 ,0)
	2.50%	(3 ,0)	(20 ,1)	(32 ,1)
	6.50%	(3 ,0)	(20 ,3)	(32 ,3)
151 - 280	0.65%	(5 ,0)	(32 ,0)	(50 ,1)
	2.50%	(5 ,0)	(32 ,2)	(50 ,2)
	6.50%	(5 ,1)	(32 ,5)	(50 ,5)
281 - 500	0.65%	(8 ,0)	(50 ,1)	(80 ,1)
	2.50%	(8 ,0)	(50 ,3)	(80 ,3)
	6.50%	(8 ,1)	(50 ,7)	(80 ,8)
501 - 1 200	0.65%	(13 ,0)	(80 ,1)	(125 ,1)
	2.50%	(13 ,1)	(80 ,5)	(125 ,5)
	6.50%	(13 ,2)	(80 ,10)	(125 ,12)
1 201 – 1 320	0.65%	(20 ,1)	(125 ,2)	(200 ,2)
	2.50%	(20 ,1)	(125 ,7)	(200 ,8)
	6.50%	(20 ,3)	(125 ,14)	(200 ,18)
1 321 – 10 000	0.65%	(32 ,0)	(200 ,3)	(315 ,3)
	2.50%	(32 ,2)	(200 ,10)	(315 ,12)
	6.50%	(32 ,5)	(200 ,21)	(315 ,18)
10 001 – 35 000	0.65%	(50 ,1)	(315 ,5)	(500 ,5)
	2.50%	(50 ,3)	(315 ,14)	(500 ,18)
	6.50%	(50 ,7)	(315 ,21)	(500 ,18)
35 001 - 150 000	0.65%	(80 ,1)	(500 ,7)	(800 ,8)
	2.50%	(80 ,5)	(500 ,21)	(800 ,18)

Lot size (Number of items)	**AQL**	**Reduced (n, c)**	**Normal (n, c)**	**Tightened (reduced inspection) (n, c)**
	6.50%	(80 ,10)	(500 ,21)	(800 ,18)
150 001 -	0.65%	(125 ,2)	(800 ,10)	(1 250 ,12)
500 000	2.50%	(125 ,7)	(800 ,21)	(1 250 ,18)
	6.50%	(125 ,12)	(800 ,21)	(1 250 ,18)
500 001 and over	0.65%	(200 ,3)	(1 250 ,14)	(2 000 ,18)
	2.50%	(200 ,10)	(1 250 ,21)	(2 000 ,18)
	6.50%	(200 ,12)	(1 250 ,21)	(2 000 ,18)

1.4 Table: Inspection by Variables Plans from ISO 3951-1 (lot standard deviation unknown)

Lot size (Number of items)	AQL	Reduced (n, k)	Normal (n, k)	Tightened inspection (n, k)
2 - 8	0.65%	(3, 1.45)	(3, 1.45)	(4, 1.45)
	2.50%	(3, 0.958)	(3, 0.958)	(4, 0.958)
	6.50%	(3, 0.566)	(3, 0.566)	(4, 0.566)
9 - 15	0.65%	(3, 1.45)	(3, 1.45)	(5, 1.45)
	2.50%	(3, 0.958)	(3, 0.958)	(5, 0.958)
	6.50%	(3, 0.566)	(3, 0.566)	(5, 0.566)
16 - 25	0.65%	(3, 1.45)	(4, 1.45)	(7, 1.45)
	2.50%	(3, 0.958)	(4, 0.958)	(7, 0.958)
	6.50%	(3, 0.566)	(4, 0.566)	(7, 0.566)
26 - 50	0.65%	(3, 1.45)	(5, 1.45)	(10, 1.45)
	2.50%	(3, 0.958)	(5, 0.958)	(10, 0.958)
	6.50%	(3, 0.566)	(5, 0.566)	(10, 0.566)
51 - 90	0.65%	(3, 1.45)	(7, 1.45)	(15, 1.45)
	2.50%	(3, 0.958)	(7, 0.958)	(15, 0.958)
	6.50%	(3, 0.566)	(7, 0.566)	(15, 0.566)
91 - 150	0.65%	(3, 1.45)	(10, 1.45)	(20, 1.45)
	2.50%	(3, 0.958)	(10, 0.958)	(20, 0.958)
	6.50%	(3, 0.566)	(10, 0.566)	(20, 0.566)
151 - 280	0.65%	(4, 1.45)	(15, 1.45)	(25, 1.45)
	2.50%	(4, 1.01)	(15, 1.01)	(25, 1.01)
	6.50%	(4, 0.617)	(15, 0.617)	(25, 0.617)
281 - 500	0.65%	(5, 1.53)	(20, 1.53)	(35, 1.53)
	2.50%	(5, 1.07)	(20, 1.07)	(35, 1.07)
	6.50%	(5, 0.675)	(20, 0.675)	(35, 0.675)
501 – 1 200	0.65%	(7, 1.62)	(35, 1.62)	(50, 1.62)
	2.50%	(7, 1.15)	(35, 1.15)	(50, 1.15)
	6.50%	(7, 0.755)	(35, 0.755)	(50, 0.755)
1 201 – 1 320	0.65%	(10, 1.72)	(50, 1.72)	(75, 1.72)
	2.50%	(10, 1.23)	(50, 1.23)	(75, 1.23)
	6.50%	(10, 0.828)	(50, 0.828)	(75, 0.828)
1 321 - 10 000	0.65%	(15, 1.79)	(75, 1.79)	(100, 1.79)

Lot size (Number of items)	AQL	Reduced (n, k)	Normal (n, k)	Tightened inspection (n, k)
	2.50%	(15, 1.30)	(75, 1.30)	(100, 1.30)
	6.50%	(15, 0.886)	(75, 0.886)	(100, 0.886)
10 001 - 35 000	0.65%	(20, 1.82)	(100, 1.82)	(150, 1.82)
	2.50%	(20, 1.33)	(100, 1.33)	(150, 1.33)
	6.50%	(20, 0.917)	(100, 0.917)	(150, 0.917)
35 001 - 150 000	0.65%	(25, 185)	(150, 185)	(200, 185)
	2.50%	(25, 135)	(150, 135)	(200, 135)
	6.50%	(25, 936)	(150, 936)	(200, 936)
150 001 - 500 000	0.65%	(35, 189)	(200, 189)	(200, 189)
	2.50%	(35, 139)	(200, 139)	(200, 139)
	6.50%	(35, 969)	(200, 969)	(200, 969)
500 001 -	0.65%	(50, 193)	(200, 193)	(200, 193)
	2.50%	(50, 142)	(200, 142)	(200, 142)
	6.50%	(50, 100)	(200, 100)	(200, 100)

Appendix II

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