CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 7 **CX/MAS 21/41/9**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

41st Session
Virtual, 17 – 25 May 2021

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

(Prepared by the EWG led by New Zealand and co-chaired by the United States of America)

Codex members and Observers wishing to submit comments at Step 3 on this document should do so as instructed in CL 2021/10/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 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.

EWG Registration (and first EWG consultation)

4. An email inviting registration to the EWG on the revised Guidelines was posted on the CCMAS EWG Forum on 26 August 2019. Registrations included 32 member countries and as well as observer organisations[2].

5. The EWG undertook a first round of consultation from 24 December 2019 to 7 February 2020. The CXG 50 was updated based on the comments submitted. References were removed to the e-book. The e-book containing sampling plan apps was proposed to sit outside of the revised CXG 50. Possibilities include publishing it as an information document.

6. Comments from this consultation resulted in updates to the revised CXG 50, or updates to be considered later. New Zealand published a summary of responses to the comments on the CCMAS EWG Forum on 20 April 2020[3].

Circular letter consultation (CL 2020/27/OCS-MAS)

7. The revised CXG 50 was then submitted as an agenda paper (CX/MAS 20/41/9) for CCMAS41. A Circular Letter (CL 2020/27/OCS-MAS) was posted on 31 May 2020 inviting members and observers to comment on the revised CXG 50, the e-book and the other documents (the New Zealand response, the USA comments and USA top-level response) ahead of, at that time, the scheduled CCMAS41.

8. With the onset of the COVID-19 pandemic and the consequential rescheduling of CCMAS41, the EWG was extended to continue this work.

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[1] Full discussion and decisions are in REP19/MAS, paras 67 - 80
[2] Argentina, Australia, Brazil, Canada, Chile, China, Denmark, Dominican Republic, Ecuador, Egypt, France, Germany, Hungary, India, Iran, Ireland, Japan, Kazakhstan, Korea, Mexico, Netherlands, New Zealand, Nigeria, Norway, Perú, Poland, South Africa, Switzerland, Thailand, United Kingdom, Uruguay, USA
[3] CCMAS40 Response to EWG comments on revised CXG 50 April 2020

9. Comments (CX/MAS 20/41/9 Add.1) were received from 14 member states and 3 observer organizations[4].

10. New Zealand prepared a summary report containing the comments received, along with responses and technical explanations where appropriate. This report was posted on the CCMAS EWG Forum on 14 September 2020[5]. The EWG was invited to note the report, and that it would be the basis for the revised draft guidelines. New Zealand also noted that the guiding principles for this work included trying to accommodate the different views unless there was widespread support for removal, but also taking account of scientific validity.

Webinar

11. A webinar to update members and observers on the work of CCMAS was held on 23–25 November 2020. Recordings and presentations are available on the CCMAS website. New Zealand gave a presentation on the progress of the revised CXG 50 as well as practical examples to help understanding of design of a sampling plan using the sampling plan app. This presentation, as well as responses to questions raised at the webinar were published on the CCMAS EWG Forum on 24 December 2020[6].

EWG Report for CCMAS 41

12. The EWG report for CCMAS 41 includes:

- Revised General Guidelines on Sampling (CXG 50-2004) (Appendix I)
- Information Document: Guide to the selection and design of sampling plans (Appendix II)
- Information Document: e-book (Codex Sampling) for General Guidelines on Sampling (CXG 50-2004) (Appendix III)
- List of EWG participants (Appendix IV).

13. The key features in the revised CXG 50 package are:

- A focus on acceptance sampling plans, to control the risks of accepting poor quality product (Consumer's Risk) and of rejecting product of good quality (Producer's Risk). Material relating to process control has been removed.

  The Producer's Risk Quality (PRQ) and Consumer's Risk Quality (CRQ), along with the allowable risks at those quality levels, are two fundamental inputs in the design of sampling plans; they define the stringency of the plan, the degree to which the sampling plan will control the producer's and consumer's risks. Allowable risks are expressed in terms of the probabilities of acceptance or rejection at those quality levels**.**

  a. Producer's Risk (PR) – the chance of rejection at the PRQ level (e.g. 5% chance of rejecting at PRQ of 1% nonconforming, or equivalently, 95% chance of acceptance at 1% nonconforming).

  b. Consumer's Risk (CR) – the chance of acceptance at the CRQ level (e.g. 10% chance of acceptance at a CRQ of 5% nonconforming.

  Once the PRQ and CRQ, along with their associated allowable probabilities of rejection (PR) and acceptance (CR) respectively are specified, **a sampling plan, allowing no more than those levels of risk, can be developed.**

- **Provision of a wider range of sampling plan options**. This enables different types of sampling plans to be designed and evaluated, providing wider consideration of cost and fairness as well as sampling, testing and a decision on acceptance or rejection of the lot.
- **Inclusion of material on measurement error adjustment**. Measurement error, in some situations, will impact on the acceptance or rejection of the lot. It may be 'simpler' to ignore It, but in international trade of food commodities where cost and fairness are as important as the decision, the impact of measurement error must be considered, and allowances made when required.
- **Ease of Use**. In many situations designers of sampling plans do not have access to statisticians to devise and interpret sampling plans. The use of the sampling plan apps included in the e-book means that users do not have to understand the statistical theory underlying the tools. However, there is still

[4] Australia, Canada, Chile, El Salvador, EuroChem, EU, IuFoST, Iraq, Japan, New Zealand, Mauritius, Mexico, Morocco, Norway, Peru, Thailand, USA
[5] Summary of responses to CL 2020_27_OCS-MAS CXG 50_September 2020.
[6] Responses to Chat Questions CCMAS Webinar November 2020

a need for understanding of the key concepts of sampling, such as Producer's and Consumer's risks and Operating Characteristic Curves.

- Utilising the revised CXG 50 to design and evaluate sampling plans is **simpler through the use of a sampling plan apps** for which links are provided in the supporting document **Codex sampling e-book'**. This e-book also contains more detail on the process involved, including for the most commonly used app for design and evaluation of attributes and variables sampling plans, a step-by-step procedure on how to use the app and interpret the sampling plan outcome.
- Inclusion of **information on other matters** related to sampling including physical sampling and the use of ISO sampling plans. Some general information is provided on sampling for inhomogeneous lots.

14. The outcome is a revised CXG 50 intended primarily for use by Codex commodity committees responsible for developing sampling plans for provisions in Codex standards, and by governments responsible for import or export inspection of foods. The Guidelines describe the design and evaluation of sampling plans for the international trade of food commodities.

Conclusions and recommendations

15. The revised *General Guidelines on Sampling* (CXG 50-2004) (presented in Appendix I) represents the work as outlined in the project document and the prioritization list to describe the design and evaluation of sampling plans for the international trade of food commodities. It is supported by an Information Document: guide to the selection and design of sampling plans (Appendix II) and an Information Document: e-book (Codex Sampling) (Appendix III).

16. The Committee is invited to::

1. To support the revised CXG 50 package (the revised CXG 50 and its supporting documents)
2. Agree to advance the proposed draft revised CXG 50 (Appendix I) to Step 5.
3. To re-establish the EWG to finalize CXG50 and to further develop the documents in support of CXG50 taking into account comments received to CL2021/10-MAS with intention that they are part of the CXG 50 package.

Appendix I

Proposed draft Revised *General Guidelines on Sampling* (CXG 50-2004)

(For comment at Step 3 through CL 2021/10/OCS-MAS)

1 Preamble

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

Foods are frequently sampled, throughout the supply chain from producers to consumers, for the purposes 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 has 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 level of quality acceptable to the customer and the rate of acceptance of compliant product, in terms of allowable risks for the consumer and the producer, 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 clear definition of sampling plans by Codex defines the quality objectives to be met and enables producers to devise appropriate control and inspection procedures to achieve them.

1.1 Scope

In Section 2, these Guidelines define general notions on food sampling, applicable in any situation. In Sections 3 to 5 they cover certain situations of statistical food control, in which certain sampling plans have been selected. Section 6 covers other matters relating to sampling and includes physical sampling as well as general information.

Most of the material in these Guidelines relates to homogenous lots. The following situations are covered:

- Sampling plans for the control of the percentage defective for homogeneous lots by attributes or by variables, for goods in bulk or individual items
- Sampling plans for the control of the mean content
- Adjustment for measurement error in cases where it is not negligible compared to sampling error.

Some general information is provided on sampling for inhomogeneous lots.

1.2 Definitions

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

Acceptance Sampling

Sampling after which decisions are made to accept or not to accept a lot, or other grouping of products, materials, or services, based on sample results

[SOURCE: ISO 3534:2]

Note:

- Also referred to as “Acceptance Sampling Inspection”
- In CXG50 and the e-book the term “Acceptance Sampling” and “Acceptance Sampling Inspection” are usually shortened to just “Sampling” or “Sampling Inspection”

Acceptance Sampling Plan

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

[SOURCE: ISO 3534:2]

Information note
An **Acceptance Sampling Plan, referred to as a “Sampling Plan” in CXG50 and the e-book,** intended for determining the acceptance or the rejection of a lot. The plan specifies:
- the number of samples to be taken and how those samples are to be taken from a lot
- how those samples will be tested, and
- the criterion, based on the test results obtained, used to determine whether the lot is accepted or rejected.

Confidence

The term ‘confidence’ is often used in conjunction with sampling plans. However, while it is a statistical term, in reality it has nothing to do with acceptance sampling. It is simpler to understand the correct approach to sampling to express risks in terms of probabilities of acceptance or rejection at specified levels of nonconforming product within a lot.

Confidence can be associated with consumer’s risk, for instance 95% confidence (that the lot is of satisfactory quality) means there is only 5% chance of acceptance.

However, confidence does not work well with producer’s risk.

Consumer and Producer

The terms ‘producer’ and ‘consumer’ are conventional and may apply to a range of different operators in the food chain, such as a grower, manufacturer, the manufacturer’s own quality control system, supplier, exporting country, processor, on-seller, or importing country.

Information note
The term ‘confidence’ is often used in conjunction with sampling plans. However, while it is a statistical term, in reality it has nothing to do with acceptance sampling. It is simpler to understand the correct approach to sampling to express risks in terms of probabilities of acceptance or rejection at specified levels of nonconforming product within a lot.
Confidence can be associated with consumer’s risk, for instance 95% confidence (that the lot is of satisfactory quality) means there is only 5% chance of acceptance.
However, confidence does not work well with producer’s risk.

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]

Information note
Consumer’s Risk is the probability of wrongly accepting a lot that is not of acceptable quality. It is a point on the OC curve corresponding to a predetermined and usually low probability of acceptance.

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]

Information note
Consumer's Risk Quality (CRQ) is the level nonconforming in a lot, specified in the design of a sampling plan, corresponding to a specified Consumer's Risk of accepting a lot of poor quality

Acceptance Sampling Inspection 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]

Information note
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.

Acceptance Sampling Inspection 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]

Information note
Inspection by Variables starts with selecting a sample of a number of items and measuring dimensions or characteristics so that information is available not only on whether a dimension, for example, is within certain limits but on the actual value of the dimension. The decision whether or not to accept a lot is made on the basis of calculations of the average and the variability of the measurements.
An inspection by variables sampling plan specifies the number of samples (**n**) and an acceptability constant (**k**). A lot is accepted against an upper specification limit if the acceptance criterion 'average result + **k** * the standard deviation of results' does not exceed the upper limit, and similarly for a lower limit. In other words, the acceptance criterion is based on the average value $\bar{\mathbf{x}}$ and the standard deviation of the results from the testing.
The values of **n** and **k** are worked out from the specified levels of allowable risk.

Lot

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

[SOURCE: ISO 3534:2]

Operating Characteristic Curve

The Operating Characteristic 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]

Information note
Producer's Risk is the probability of wrongly rejecting a lot that is of acceptable quality. It is a point on the OC curve corresponding to a predetermined and usually high probability of acceptance.

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]

Information note **Producer's Risk Quality** is the level nonconforming in a lot, specified in the design of a sampling plan, corresponding to a specified Producer's Risk (PR).

Provision, Characteristic, Standard

A **provision** is a requirement for a commodity that must be met in order that the commodity conforms to the standard.

A **characteristic** is the attribute in the commodity to which the provision relates

A **standard** is a set of provisions relating to a commodity, all of which must be met in order that the commodity conforms to the standard.

Example *Fat in WMP must exceed 26%* *Identified food or group of foods e.g. Milk powders and Cream Powders Codex Standard 207* *The attribute is the 'characteristic' in the commodity to which the provision relates e.g. fat* *Provision is the requirement that must be met e.g. must exceed 26%*

Quality Level

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

[SOURCE: ISO 3534:2]

A **sampling scheme** defines what data will be obtained and how. Precision and systematic sampling error are two principles that guide the choice of sampling scheme.

2 Acceptance Sampling - General Principles

2.1 Reasons for sampling

While various measures such as Hazard Analysis and Critical Control Point (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 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 are fully aware of the limitations and risks associated with using such a procedure and therefore most acceptance sampling procedures include provisions for dealing with non-conforming items found in lots that have been accepted by the sampling plan' .

Acceptance sampling is the process in which samples are taken from a lot and decisions are made concerning the disposition of that lot, whether the lot is accepted or rejected, based on the results from the testing or examination of those samples.

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 Approach to sampling

There are three possible approaches to sampling:

a. 100% inspection, involving inspection of all (i.e.100%) of the product

b. Sampling based on the principles of probability

c. Ad hoc inspection, that is, a sampling plan without a statistical basis.

The risks and costs associated with each of these three options can be considered:

For approach (a), it is clear that 100% sampling 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. In addition, the presence of measurement error means that it is still not possible to provide a 100% guarantee, even if all items in the lot are inspected.

Approach (b) has the disadvantage of higher risks as compared to approach (a), since some product will not be inspected. However, by using the probability approach the risks can be calculated and a sampling plan chosen that ensures these risks are controlled to desired levels. It also has the advantage of practicability and lower costs.

In the context of sampling, risk occurs when incorrect decisions are made about the status os the product.

There are two types of risks that can occur:

- Acceptance of product of unsatisfactory quality (consumer's risk) and
- Rejection of product of acceptable quality (producer's risk).

Sampling plans should be designed to control these risks to desired levels, i.e. they should take account of the principle of fitness for purpose. Such control provides assurance, over the longer term, across many lots (i.e. in terms of probability).

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 unwarranted 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 on the basis of these plans except by mutual agreement of the consumer and producer based on an understanding of the risks.

In summary, the approach to sampling should be based on control of the levels of assurance provided and the costs to the parties involved in the transaction.

2.3 Sampling plan performance

2.3.1 Probability and what it means

Variation is present everywhere; raw materials vary in their composition, manufacturing process vary and, as a consequence, the products manufactured by those processes will also vary. Therefore, when we take a set of samples from a lot of product, we do not expect those samples to be of the same composition. Further, the presence of measurement error 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 to always be the same; there will be some variation of those results.

Variation causes uncertainty when we attempt to make decisions about the compliance of a lot to a specification limit; at any level nonconforming some lots might be accepted, and some might be rejected. However, if we describe the variation of the product and of the measurement process statistically, we can predict the expected outcome in any given situation, at any level nonconforming for any given sampling plan.

In acceptance sampling this expected outcome can be expressed as the average rate of acceptance (or success rate) over a long series of inspections of lots having the same level nonconforming. This average rate is more commonly known as the probability of acceptance and can lie between zero (lots with that level nonconforming are never accepted) and one (lots are always accepted).

In acceptance sampling the probability of acceptance for a particular plan depends on the level nonconforming in a lot, the decision criterion for that sampling plan and possibly, in the case of significant measurement error, on the bias and variation inherent in the measurement process. In practice, the level nonconforming in a lot is not known beforehand but it is possible to calculate the probability of acceptance for any assumed level nonconforming in a lot.

The relationship between the probabilities of acceptance and the assumed levels nonconforming for a sampling plan is described by the Operating Characteristic curve.

3 Design of Sampling Plans

3.1 Inputs to sampling plans

3.1.1 Producer's Risk Quality and Consumer's Risk Quality

The Producer's Risk Quality (PRQ) and Consumer's Risk Quality (CRQ) , along with the allowable risks at those quality levels, are two fundamental inputs in the design of sampling plans; they define the stringency of the plan, the degree to which the sampling plan will control the producer's and consumer's risks.

Allowable risks are expressed in terms of the probabilities of acceptance or rejection at those quality levels, for example:

- Producer's Risk (PR) – the chance of rejection at the PRQ level (e.g. 5% chance of rejecting at PRQ of 1% nonconforming, or equivalently, 95% chance of acceptance at 1% nonconforming)
- Consumer's Risk (CR) – the chance of acceptance at the CRQ level (e.g. 10% chance of acceptance at a CRQ of 5% nonconforming.

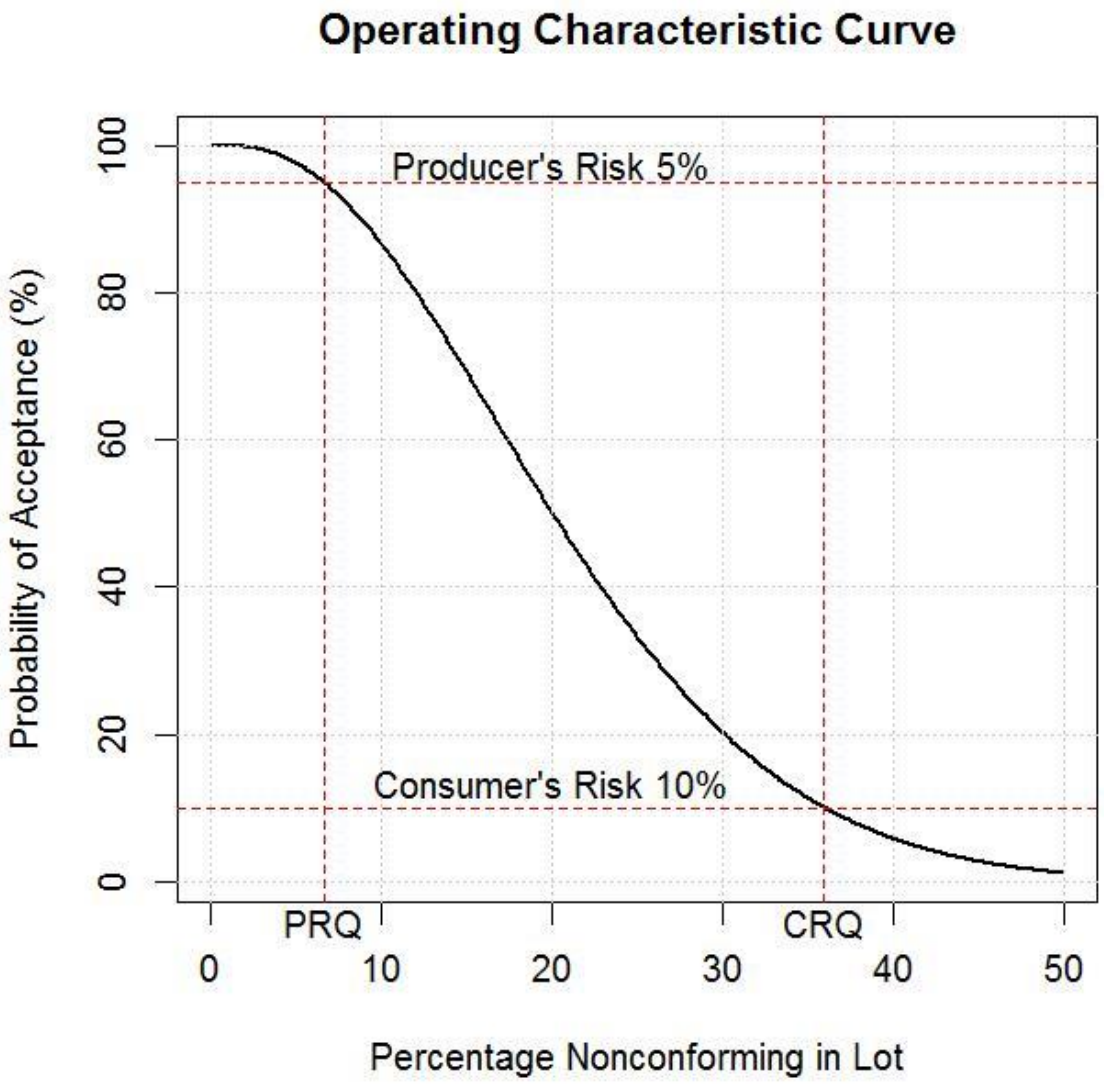
Once the PRQ and CRQ, along with their associated allowable probabilities of rejection (PR) and acceptance (CR) respectively are specified, a sampling plan, allowing no more than those levels of risk, can be developed. In some cases, such as where measurement error is significant, additional information may be required.

3.1.2 Operating Characteristic Curve (OC curve)

An Operating Characteristic curve (OC curve) for a sampling plan shows the probability of accepting (or rejecting) a lot in terms of the percentage nonconforming in the lot. The OC curve is calculated using the principles of probability.

Note that the Operating Characteristic does not say anything about the quality of a lot; it serves only to show the probability of accepting the lot at a particular quality level.

3.1.2.1 Figure 1: Operating Characteristic Curve

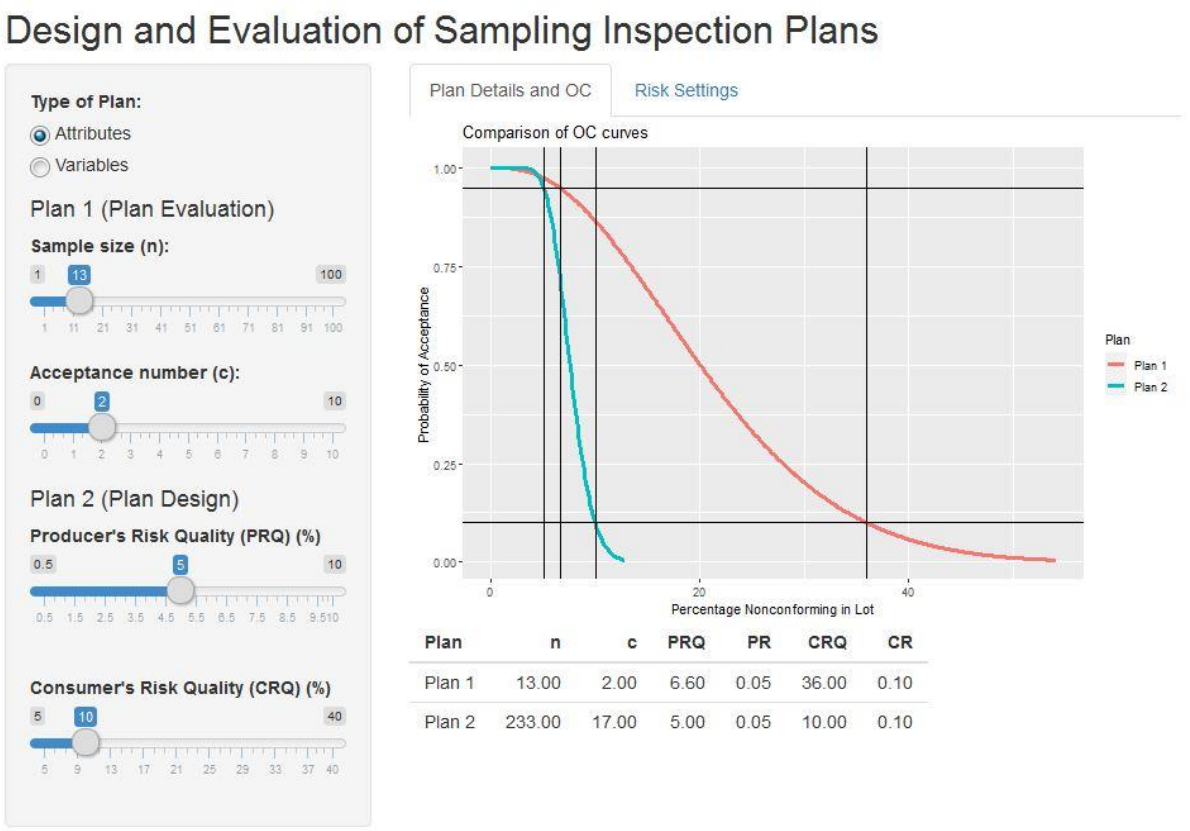


The diagram shows the points on the Operating Characteristic that are fundamental to the design of sampling plans.

3.1.3 Performance Criteria

Once the PRQ and CRQ, along with their associated probabilities of rejection (PR) and acceptance (CR) respectively are specified, a sampling plan, allowing no more than these levels of risk can be developed.

3.1.3.1 Figure 2: Design and Evaluation of Sampling Inspection Plans



Plan	n	c	PRQ	PR	CRQ	CR
Plan 1	13.00	2.00	6.60	0.05	36.00	0.10
Plan 2	233.00	17.00	5.00	0.05	10.00	0.10

3.1.4 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. When commodity committees have included sampling plans in provisions in a Codex commodity standard, these should be referred to the Codex Committee of Methods of Analysis and Sampling (CCMAS) for endorsement along with relevant information relating to the sampling plan.

Sampling plans should also be designed to control the risks to desired levels, i.e. they should take account of the principle of fitness for purpose.

The Principles for the Use of Sampling and Testing in International Food Trade (CXG 83-2013) states that sampling and testing procedures selected should be fit for their intended purposes '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'. .

In the wider context, fitness for purpose should consider the implications relating to cost, practicality, and fairness in the design of sampling plans.

Sampling plans can also be designed to specifically control the costs associated with acceptance of nonconforming lots and the rejection of compliant lots, but costs associated with sampling and testing, which are usually smaller, and other costs can also be taken into account.

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

- 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
- 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.

3.1.5 Fairness

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

- Sampling plans having inappropriate stringency, not commensurate with the application, for example, plans for assessment of composition that are more stringent than those for food safety
- High producer's or consumer's risks that may arise due to use of plans not based on appropriate specifications of allowable producer's and consumer's risks
- Plans not based on statistically valid principles, for example, failure to allow for or properly allow for either sampling or measurement errors or inappropriate allowances made for these errors
- Use of single sampling plans, including those chosen from sampling schemes, might be unfair, even though producer's and consumer's risks have been specified in their design, for example:

– there is always a chance that product of good quality may fail a consumer's inspection particularly when assessments are based on small sample numbers

– use of the same sampling plan by the producer in situations of deteriorating quality could result in increased consumer's risk (even if only product that passed the producer's assessments was received by the consumer).

Fairness 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. For example, designers of plans should ensure that producers are not exposed to unreasonable costs in terms of sampling and testing, loss of yields, or excessive rejection of their products in order to achieve compliance.

3.1.6 Stringency

In the interests of fairness, stringency should be in keeping with the perceived risks associated with failure and relativity among different characteristics. The following example shows an approach that could be used to set allowable levels of consumer's risks across different characteristics.

Example: Stringency

Risk rating	**Severe**	**Serious**	**Moderate**	**Indicator**	**Utility**
Level nonconforming	1%	5%	8%	10%	20%
Consumer's risk (allowable probability of acceptance)	1%	1%	5%	5%	5%

Each characteristic would be ranked according to the rating scale below and then the levels of allowable risk and associated levels nonconforming would be assigned. The process could be extended to also include producer's risk.

3.1.7 Nature of the Specification Limits

A specification may be expressed as a minimum or a maximum limit (or both) applied to either the overall distribution of the characteristic in the lot, i.e. the percentage nonconforming, or to the average level; the Codex Procedural Manual states that the following should be specified when sampling plans are included in Codex standards:

- Whether the specification applies to every item in a lot, or to the average in a lot, or the proportion nonconforming (inferences to be made to lots or processes)
- The appropriate acceptable quality levels to be used (levels of risk to be accepted)
- The acceptance conditions of a lot controlled, in relation to the qualitative/quantitative characteristic determined on a sample (decision rules).

In addition, Holst et al provides the following guidance 'It is sometimes seen that the measurement or sampling uncertainty has already been taken into account when formulating the specification limits. Such practice should, however, not be used. It is good current practice to formulate specification limits in such a way that the values to not depend on a specific measurement and sampling procedure or technology'. As a consequence, unless specified otherwise, specification limits should apply to the true values of the characteristics, not to the measurements themselves.

3.1.8 Nature of the Measurements

In some cases, such as where measurement error is significant, additional information may be required.

The options for sampling plans depend on whether the test results are measurements (variables data) or have nominal outcomes (attributes data), measured on a scale, including binary outcomes, for example, pass or fail, and measurements classified as binary outcomes. However, decisions on classifying measurements as binary outcomes should be made only after considering the sampling options available.

In the case of variables data, the assumed statistical distribution of the measurements must also be specified, whether the characteristic is normally distributed, a compositional proportion, or follows some other distribution or if it is not possible to define such a distribution. The nature of the measurements and their distribution will determine the choice of the plan.

However, it is not necessary that the characteristic follows the assumed distribution exactly (and in any case it is difficult to statistically verify conformance to a distribution using small samples), it is sufficient that the assumed distribution provides a satisfactory model for the behaviour of the characteristic in the lot.

3.1.9 Measurement and Inspection Errors

Measurement error refers to the difference between a measured value and the true value of what is being measured. On the other hand, inspection error refers to random errors of misclassifying conforming items as nonconforming and vice versa. The term 'measurement error' relates to variables data (measurements) whereas 'inspection error' relates to attributes data.

For attributes plans, details of the Type I and Type II error rates are needed. Refer to Section 5.2 for more details.

For variables plans, information about the measurement error, specifically the repeatability, reproducibility and possibly bias is required to enable the effect of measurement errors on the performance of sampling plans to be investigated and adjustments to be made if required. Refer to Section 5.3.

Information on the statistical distribution of the measurement errors is also needed when measurement error is significant, although it is common to assume measurement errors are normally distributed.

3.1.10 Lot Homogeneity

Sampling inspection plans usually assume that the lots to which they are applied are 'homogeneous', having the same quality throughout, and indeed, the international definition of a lot is 'a quantity of product produced under conditions presumed uniform'. Applying sampling inspection plans to a lot of varying quality can result in unjustified rejection of the lot as a whole, or the acceptance of the lot on an average basis, with parts of the lot containing product of possibly unsatisfactory quality.

In the statistical literature, heterogeneity usually refers to 'non-constant variation' with no reference to specification limits. However in sampling inspection, lot heterogeneity, such as short term process trends, is not particularly important and need not cause nonconformance provided there is an adequate offset between the average level of a lot and the specification limits to allow for the variation present. Hence it follows that in sampling inspection homogeneity must consider the proximity of results to the specification limits.

A lot (or essentially parts of a lot, which are termed as sublots) is called homogeneous when the quality within it is the same i.e. having the same probability nonconforming throughout with no particular part differing from any other part. This is equivalent to saying that a lot can be called homogeneous with respect to given specification limits, if the probability distributions of all sublots have the same fraction nonconforming. However, sublots should not be defined by test results from the lot.

The definition of any lot might differ according the characteristic inspected.

Section 4.4 discusses some of the issues concerning the inspection of inhomogeneous lots.

3.1.11 Lot Size

Lot size is not normally an input required for the design of sampling plans intended to control the consumer's and producer's risks in acceptance sampling. However, specification of the lot size is needed for attributes plans applied to small lots.

3.1.12 Other Inputs

For the purpose of the Guidelines, the context for the sampling plan should include consideration of the following points:

Inputs	Description
The identified food or group of foods	The sampling plan should relate to an identified food or group of foods.
Identified characteristic	The characteristic in the commodity to which the provision relates.
Provision in a Codex Standard	A requirement that a characteristic must meet, in order that the commodity conforms to the standard. The provision may specify a minimum or maximum limit relating to either the overall distribution or to the average level of the lot.
Use of food	Whether the food is intended for direct consumption or used as an ingredient, its content in the final food and the nature of any further processing steps.
Codex Procedural Manual	Information relating to the scope or field of application and the type of sampling (e.g. bulk or unit)

4 Sampling Plans

4.1 Selection of Sampling Plans

The following table provides references within these Guidelines.

4.1.1.1 Table 1: References to the selection of sampling plans in these Guidelines

Homogeneous lots				
Data Type	**Nature of Provision**	**Distribution**	**Negligible Measurement Error**	**Significant Measurement Error**
Attributes	Minimum or Maximum	Not applicable	Inspection by Attributes Plans	Retesting
			(Section 4.2)	(Section 5.2.1)
				Known Inspection Errors
				(Section 5.2.2)
Variables	Minimum or Maximum	Normal	Inspection by Variables Plans	Repeatability Error (1)
			(Section 4.2)	(Section 5.3.1)
				General Measurement Error (1)
				ISO3951-6
				Fractional Nonconformance Plans
				(Section 5.3.2)
	Minimum or Maximum	Non-normal	Classification to Attributes	Fractional Nonconformance Plans
			(Section 4.2.6)	(Section 5.3.2)
Variables	Minimum or Maximum	Compositional Proportions	Plans for Compositional Proportions	Not included
			(Section 4.3.1)	
	Average Level	Not applicable	Plans for Average Level	
			(Section 4.3.2)	
Inhomogeneous Lots (Bulk Materials)				
Attributes	Minimum or Maximum	(blank)	Attributes Plans	
			(Section 4.4.3)	
Variables	Minimum or Maximum	(blank)	Variables Plans	
			(Section 4.4.4)	
	Average Level	Not applicable	Plans for Average Level (Section 4.4.5)	

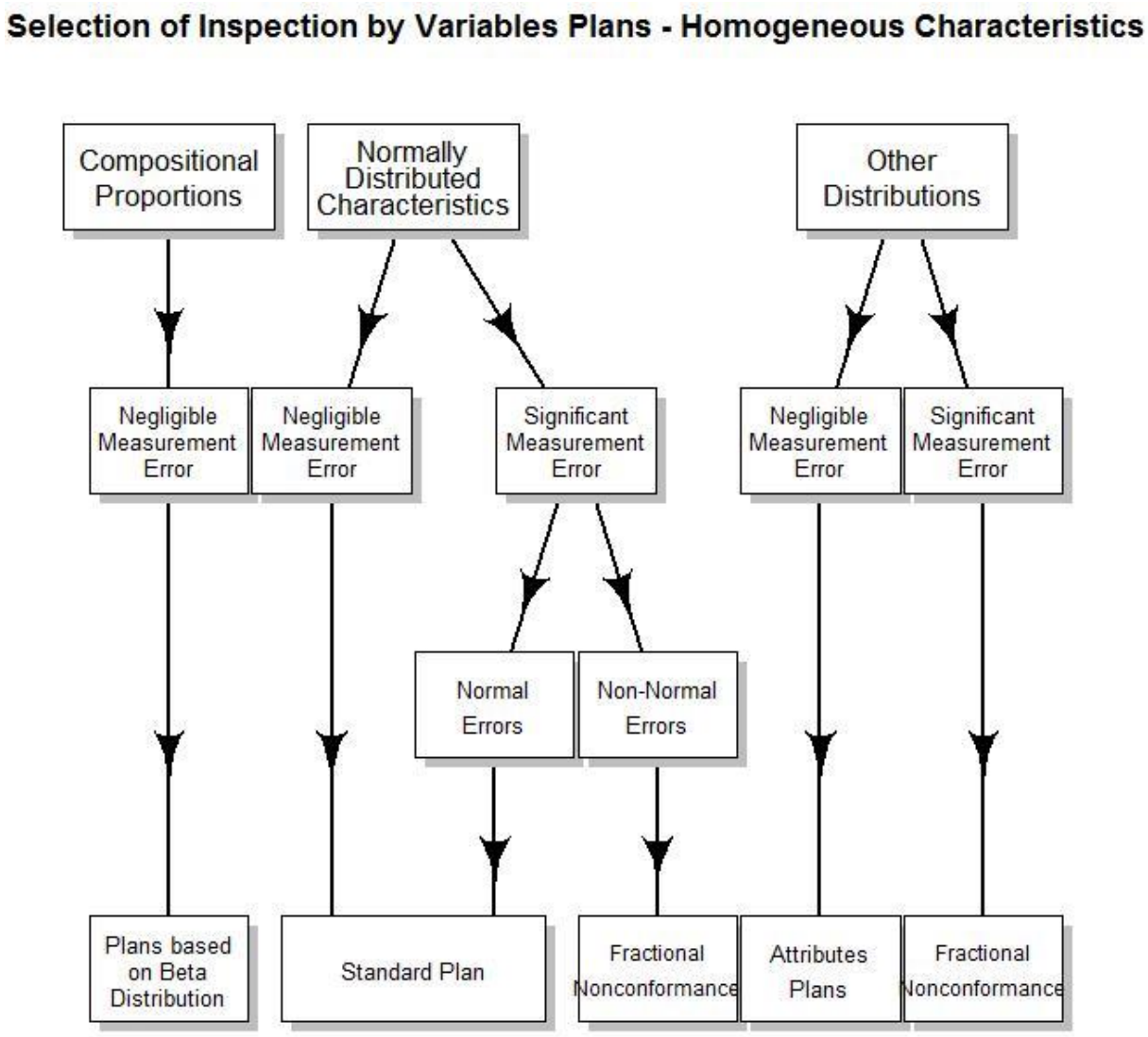
Note (1): In these cases measurement error is also assumed to be normally distributed

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.

4.2.1.1 Figure 3: Design of Attribute Plans



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.

4.2.3 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.

4.2.4 Zero-Acceptance Number Plans (including hypergeometric)

Zero-acceptance number plans (ZAN) 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 for 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, it should be noted that 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 good and poor quality lots, 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.

4.2.5 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 maximum limit for 'good' samples
- ***M*** is the microbiological 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, with levels exceeding ***M***
- 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 log-normal distribution for microbiological parameters. This might also apply to two-class plans, especially for microbiological plans.

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

4.2.6 Variables Plans (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 any 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 error is negligible.

4.2.7 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 product 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 saving in sample size, but we need to know the probability distribution of the characteristic within the lot; the Gaussian or normal distribution is commonly adopted. For compositional proportions in bulk materials, the beta distribution is more appropriate, but the normal distribution can serve as an approximation.

4.3.2 Advantages and Disadvantages of Plans

The advantages of variable sampling plans are:

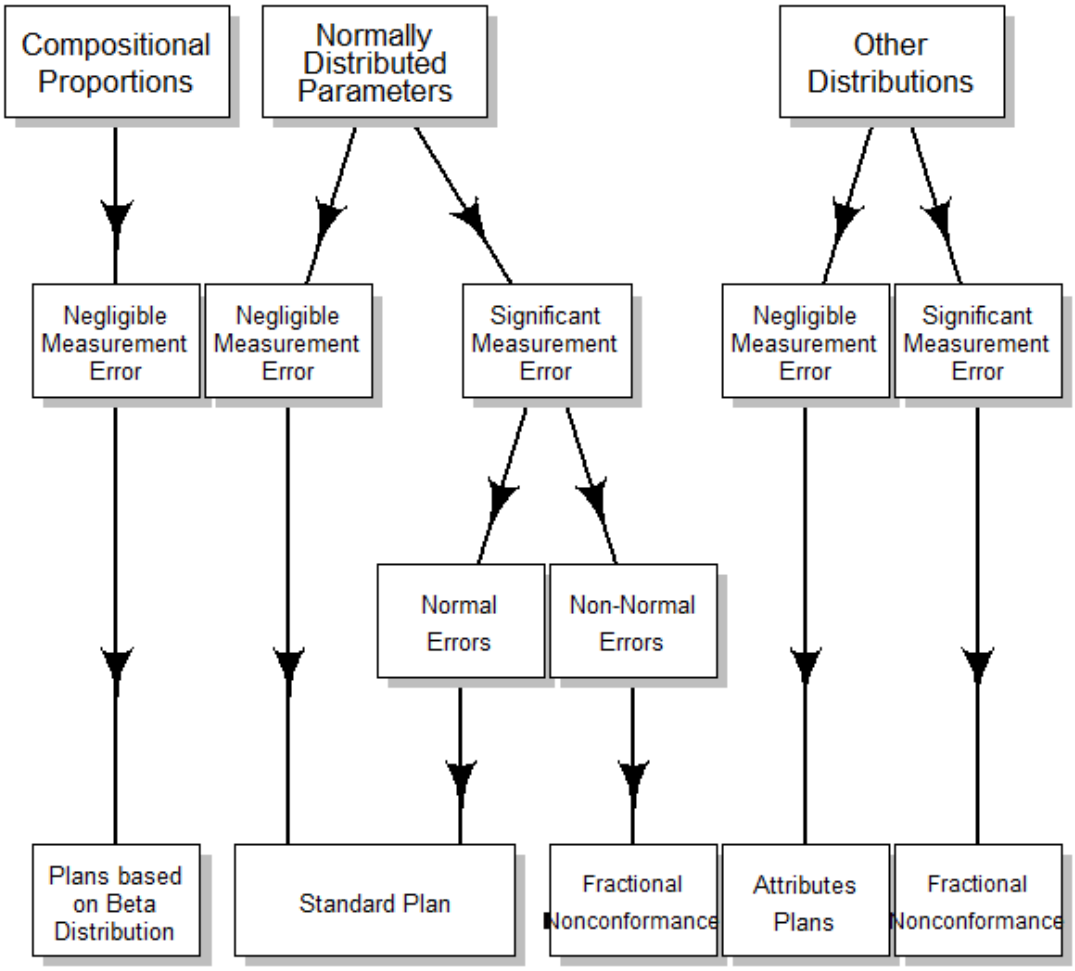
- They offer the same protection with a smaller sample size than that required for attributes plans
- There is feedback of data on the process which produced the units
- There is more information available in waiver situations
- The extent of conformity of each unit is taken into account in the application of the plan
- There is an increased likelihood that any errors in measurement will be detected.

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
- Variables sampling plans are only applicable to one characteristic at a time
- There may be a higher inspection cost per unit
- There may be higher clerical cost per unit due to the calculations involved
- A lot with no nonconforming units may be rejected by a variables plan, which can occur when the average level lies too close to the specification limit relative to the variation (standard deviation) present
- There is a possibility that no nonconforming units are found to show to the producer after rejection.

4.3.2.1 **Figure 4: Selection of Inspection by Variables Plans**

Selection of Inspection by Variables Plans - Homogeneous Characteristics



4.3.3 General Variables Plans

In variables plans, the mean ($\bar{X}$), is compared with the acceptance limit in a similar way to the attributes plans but, in order to allow for the variability in the lot, the sample standard deviation ***S*** is computed.

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

The numbers ***n*** and ***k*** can be found from a specification of two points on the intended OC curve, usually by a Producer's Risk Quality (PRQ) and a Consumer's Risk Quality (CRQ) and their associated probabilities of rejection and acceptance respectively.

4.3.4 Sampling Plans for Compositional Proportions (measurement error negligible)

Compositional characteristics are often quality measures for bulk materials. For example, the percentage fat with a minimum limit of 26% is a primary quality measure for milk powders. Compositional proportions, also referred to as mass fractions, are characterized by units of measure such as percentages (by mass), mg/kg, µg/100g and the like, which are, strictly speaking, 'dimensionless' numbers lying between 0 and 1.

Compositional fractions 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 higher consumer's risks 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 addition to the PRQ, CRQ etc. to design these plans we also need an estimate of the 'precision parameter' for the beta distribution, denoted by ***θ***, which 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 (and 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 below).

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

4.3.5 Plans for the Average in the Lot

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***.

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***, although the values of ***n*** and ***k*** are not the same as the those 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. This is where a different methodology is introduced, which brings with it sampling bias and non-representativeness.

Some general objectives of bulk sampling are:

- Acceptance on a lot-to-lot basis
- Characterise the material as to grade, any need for further processing, and its destination
- 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, the lots of bulk material are 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 (TOS)

The Theory of Sampling[7] (TOS) 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

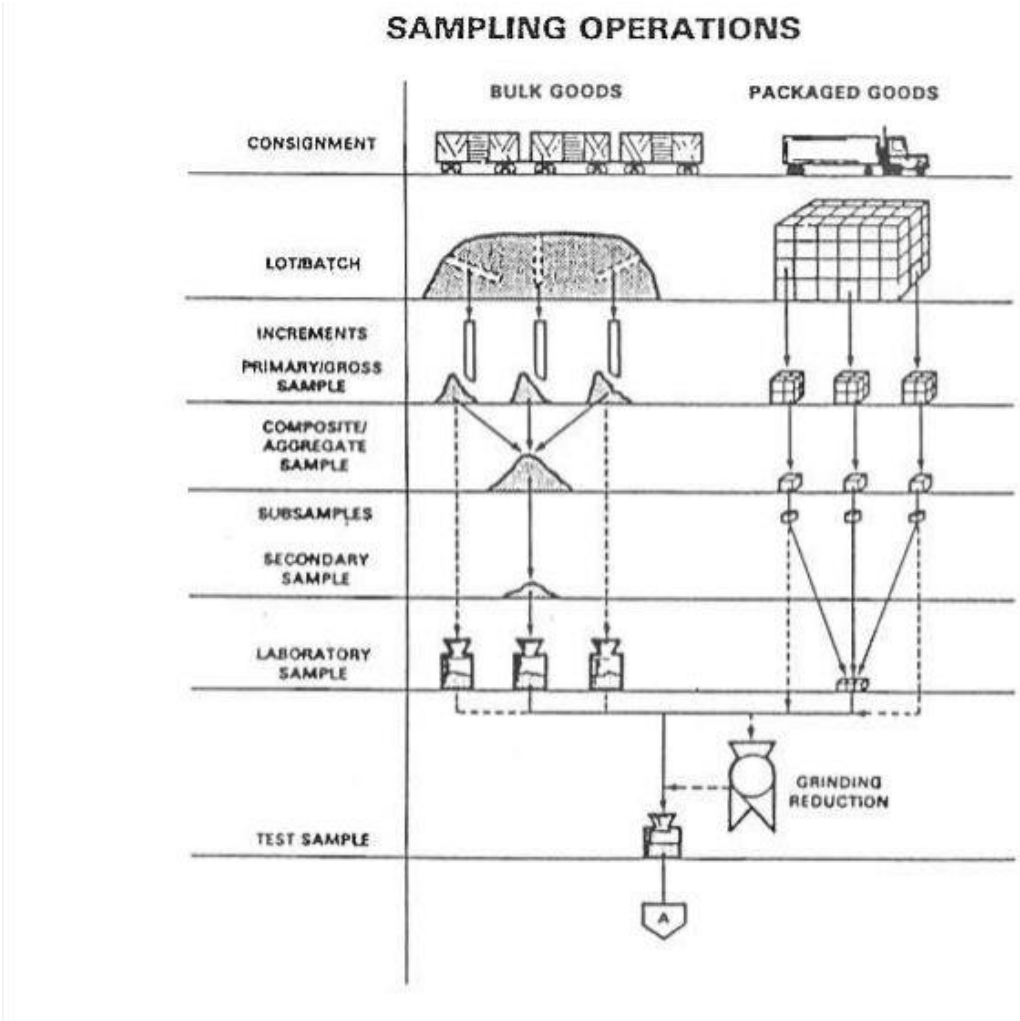
The special nature of sampling for bulk materials has led to the use of specific terminology, although this terminology varies between different fields, and between authors. Some of the commonly used terms are:

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.
Laboratory sample	A portion of the sub-sample that is measured.

4.4.4 Illustration of Terms [reference NMKL]

This diagram, from NMKL Procedure 12, 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.

[7] Esbensen, Kim & Wagner, Cooper. (2015). Theory of sampling (TOS) - Fundamental definitions and concepts. 27. 22-25



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 measurement error where appropriate.

On the other hand, some bulk materials, such as shipments of grains or other raw materials, cannot be considered homogeneous - the variation of a characteristic within a lot can often not be satisfactorily described by a single distribution. Special techniques are required for this situation, but the statistical methods are complex and only an overview is provided in these Guidelines – see Sections 4.4.6 and 4.4.7.

Lot homogeneity is difficult to verify for bulk materials, generally requiring large numbers of samples, and it is difficult to take proper random samples from an entire lot of a bulk material. As a precaution lots should be treated as inhomogeneous as insurance against such possible heterogeneity.

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 heterogeneity within each segment will have less effect. The basic sampling and inspection procedure can be described as follows:

- Segments are chosen at random using simple random sampling
- Several increments are chosen at random from each segment
- 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:

- Heterogeneity 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
- Heterogeneity 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
- Measurement error can be allowed for by performing multiple tests on each laboratory sample, with an initial recommendation that each sample should be tested at least three times. Under this scheme a sample would be declared 'conforming' if the majority of results (i.e. at least two out of three test results complying with the limit) passed rather than requiring 'no test samples failing'
- Lot resubmission and repeat testing should be allowed to guard against measurement system failures that might also include errors incurred by taking primary samples as grab samples.

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 ten (10) lots and ten individual subsamples per segment is needed to estimate the within segment variation to allow design of a sampling plan. Laboratory samples must be tested at least in duplicate to allow estimation of the component of variation due to measurement error, unless estimates are available from other sources such as test method validation.

Example
Codex Standard 193 shows the breakdown of the total variation for aflatoxins in tree-nuts, with a focus on the sample preparation and testing; the variation due to sampling includes both between and within segment variation. It is 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	$S^2_s + S^2_{sp} + S^2_a$	$S^2_s + S^2_{sp} + S^2_a$	$S^2_s + S^2_{sp} + S^2_a$	$S^2_s + S^2_{sp} + S^2_a$

A sampling plan is defined in terms of the numbers 'ns', the number of samples, 'nss', the number of subsamples taken from each sample and 'na', the number of analytical samples taken from each subsample. The information in this table can be used to design an optimal sampling plan, optimal in terms of total cost for a specified consumer's risk at any given concentration 'C'. Obviously, the costs associated with each step need to be known to derive a cost optimal plan.

Any sampling plan derived from the design process should be validated against a range of statistical models for the behaviour of the characteristic within the lot.

Since bulk materials are continuous, parts of each sample can be mixed together to form a composite. 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 composite sample representing the average content of 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 unrealistic.

4.4.8 Variables Plans for the Average Level

Many sampling plans for bulk materials are used to assess compliance of the average level of a characteristic, as in the sampling plans for aflatoxins. Other procedures for the inspection of the average level of a lot are available that consider costs to derive plans that are economical to apply, although these plans might not be suitable in cases where more precise determination of the average level is required.

Plans for the average level might also be applicable where 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 above. 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 for measurement error, although this will not provide any information on other components of variation:

- The acceptance criterion has the same form as a conventional inspection by variables plan applied to homogeneous lots
- The number of samples ***n*** and the acceptability constant ***k*** can be found by a trial and error process, assessing the probabilities of acceptance against various alternative models for the

behaviour of the characteristic in the lot. This exercise should recognises that the formation of the segments might not reflect the disposition of nonconforming product within the lot.

5 Inspection and Measurement Errors

5.1.1 Introduction

Measurement error refers to the difference between a measured value and the true value of what is being measured (the measurand). On the other hand, **inspection error** refers to random errors of misclassifying conforming items as nonconforming and vice versa. The term 'measurement error' relates to variables data (measurements) whereas 'inspection error' relates to attributes data.

Significant measurement and inspection errors have the potential to affect the probabilities of acceptance of a sampling plan. It has been shown that measurement and inspection errors affect producer's risk more than they affect consumer's risk i.e. the increase in producer's risk, of incorrectly rejecting product of good quality, exceeds the increase in consumer's risk, of accepting product of poor quality. On this basis it might be unfair not to allow for measurement error in sampling inspection.

Sampling inspection plans can be designed to allow for measurement and random misclassification errors.

Sampling is also cost-optimal in the presence of significant measurement error.

5.1.2 Measurement Uncertainty and Measurement Error

Although the terms 'measurement uncertainty' and 'measurement error' both reflect the uncertainty associated with measurements and are often used interchangeably in a less formal sense, they are defined differently, formulated differently and used differently.

The term 'measurement error', defined as 'error' in the *Guidelines on Analytical Terminology* (CXG 72-009) as 'Measured quantity value minus a reference quantity value', is more conceptual, and reflects the effect of both bias and random errors. On the other hand, while also used conceptually, 'measurement uncertainty' refers specifically to a parameter characterizing the dispersion of values attributed to the measurand.

The key difference between these two concepts lies in their usage. 'Measurement uncertainty' is used in the evaluation of conformity ('conformity assessment'), whether the true value of the entity, i.e. the sample inspected, conforms to the specification when measurement errors are present. 'Conformity assessment' is used to make declarations of conformity about an inspected item but is not intended to serve as a lot assessment procedure, as it would offer poor protection to consumers.

On the other hand, 'sampling inspection' is used '*when goods are transferred between two parties, to provide unambiguous rules for releasing a product after inspection of only a limited sample. Both parties are fully aware of the limitations and risks associated with using such a procedure and therefore most acceptance sampling procedures include provisions for dealing with non-conforming items found in lots that have been accepted by the sampling plan*'[8].

The aim of acceptance sampling inspection is to make good decisions about a lot given when measurement errors are present whereas the purpose of conformity assessment is to say something about the true values of the samples tested, allowing for measurement uncertainty.

The design and evaluation of sampling inspection plans requires that separate allowances are made for biases and random errors as they affect the operating characteristic differently. In addition, the construction of an OC curve demands that random errors are described in terms of the variation about the true values of measurands, i.e. that they are Type A components in measurement uncertainty terms.

In the estimation of 'measurement uncertainty', biases are treated as Type B components, i.e. as the outcomes of random variables following assumed distributions around their observed values, to allow their inclusion in the overall measurement uncertainty. The overall uncertainty might also include other Type B components based on the 'degree of belief' that the possible values of a component follow an assumed distribution.

[8] Holst et al

5.2 Attributes Plans

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

Inspection errors occur when testing a unit for conformance and can be caused by human error, instrument error, or any other measurement related errors:

- Type I errors (***e₁***) occur when true conforming units are classified as apparently nonconforming
- Type II errors (***e₂***) are when true nonconforming units are placed as apparently 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 ***pₑ*** are related through the following equation:

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

where

e₁ is the probability of classifying a conforming item as nonconforming and
e₂ is the probability of classifying a nonconforming item as conforming.

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

5.2.1 Retesting

Retesting can be used to mitigate the impact of inspection errors. It can be used with either attributes or variables plans. If an item is found to be nonconforming, it can be tested again. Since a smaller proportion of nonconforming units is expected, retesting will be required only occasionally. Retesting conforming units is often not beneficial for economic reasons.

In addition, because inspection errors increase producer's risk more than they increase consumer's risks, it is more important to control Type I errors (conforming items classified as nonconforming). Therefore, it makes more sense to retest only the items that are apparently nonconforming.

Retesting of an item can be done up to a maximum of ***m*** times, with the value of ***m*** to be decided. This means that each sampled item will have a maximum of ***m*** chances to achieve conformance. Retesting relies on the assumption that testing will not degrade the quality of the item. If a sample is of a non-discrete type physical material such as powder, then it is assumed that ***m*** homogeneous sub-samples can be made for every unit of the sample.

If misclassification errors are large, retesting of nonconforming items is necessary to reduce the adverse impact on the producer's risk. Inspection errors do affect the consumer's risks, but the effect is small compared to the effect of producer's risks and it can be compensated for by adjusting the sample size. Such adjustments are likely to be small.

5.2.2 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.

5.3 Variables Plans

Measurement error is the difference between a measured value and the true value of what is being measured (the 'measurand'). Measurement errors can be either random or systematic.

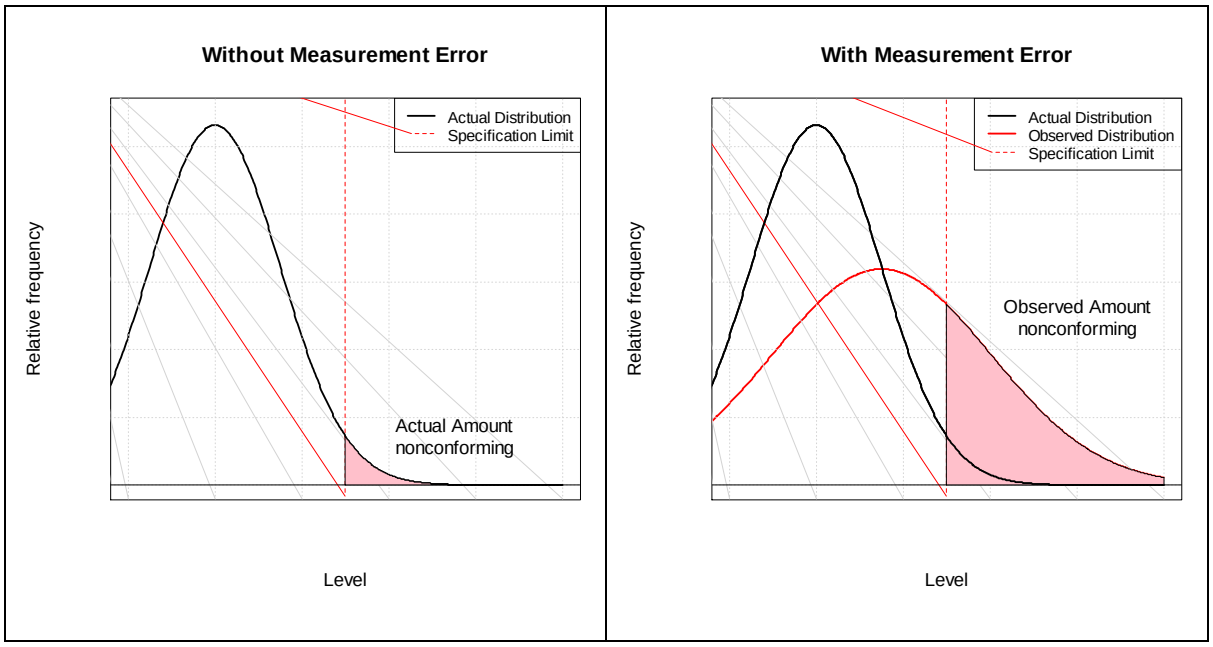
'Random errors' are uncorrelated, but they affect the results of repeated measurements. Random errors are characterised by measures such as the repeatability, reproducibility, and stability.

'Systematic errors' such as biases affect all measurements in the same way and can be identified when the random errors are small. Systematic errors can be described in terms of accuracy, bias, and drift. In general, adjustment for biases can be made by subtracting the bias from the actual measurements

and then applying the variables plan as usual. Any uncertainty arising from the estimation of the bias would need to be allowed for as an additional random error.

The following diagrams show the effect of measurement error on the observed level nonconforming in a lot and unless suitably accounted for, on its probability of acceptance.

5.3.1.1 Figure 5: Effect of Measurement Error



The terms 'significant' and 'negligible' are often used as the basis to decide whether allowances should be made for measurement error in sampling. 'Significant measurement error' means that the measurement error is large in relation to sampling error, assessed using the 'error-variance' ratio, the ratio of the measurement error variance to the variance representing the variation of the true levels of the characteristic in the lot, where the variance is the square of the standard deviation. Adjustment for measurement error is usually deemed necessary if the error-variance ratio exceeds 10%. However, this rule is somewhat subjective and the only definitive way to assess whether adjustment for measurement errors is required is to examine the OC curves for the proposed sampling plan in the presence of the measurement error.

5.3.2 Significant Repeatability Measurement Error (no bias)

If the characteristic follows a normal distribution in the lot under inspection and the measurement error is also normally distributed, a variables plan allowing for repeatability error will have the same acceptability constant (k-value) as the 'error free' plan, but a larger sample size will be required to provide the same control of producer's and consumer's risks. The number of samples depends on the 'erro-variance ratio', described above. However, in other respects these plans are the same as those for error free variables plans, with the acceptance of lots based on criteria such as $\bar{X} + kS \leq U$ for an upper specification limit ***U*** where, in this case, $\bar{X}$ is the average of the measurements and S is their standard deviation.

5.3.2.1 Hahn's Approach[9]

Hahn suggested a simple method of adjusting data to adjust for the effect of measurement error in the observed data. This involves adjusting the observed standard deviation by 'subtracting' the standard deviation representing the repeatability component of measurement error.

This adjustment is made by subtracting the repeatability variance from the observed variance (the variance is the square of the standard deviation):

[9] Hahn, G. J. 1982. Removing Measurement Error in Assessing Conformance to Specifications'. Journal of Quality Technology 14: 117–21.

$$s_{adj}^2 = s_{obs}^2 - s_r^2$$

where s_{adj}, s_{obs} and s_r are the adjusted, observed and repeatability standard deviations respectively. It is possible that the repeatability standard deviation is greater than the observed standard deviation, in which case the adjusted standard deviation is assumed to be zero. In general, the acceptability constant will be smaller for plans based on adjusted standard deviations.

5.3.3 Significant General Measurement Error

In this context, measurement error refers to reproducibility. This situation is dealt with in ISO3951-6. It is assumed that repeatability and reproducibility, as well as the identified characteristic, are normally distributed. While the acceptance criterion is of exactly the same form as the other 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 risk in the manner intended

5.3.4 Fractional Nonconformance

If the characteristic does not follow a normal distribution in the lot [i.e. it is not appropriate to assume that the characteristic follows a normal distribution, refer to Section 3.1.6], plans based on Fractional Nonconformance (FNC) can be used for measurement error adjustment (FNC plans can also be used if the characteristic is normally distributed).

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 error 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 other types of plan, by considering the allowable risks at the producer's and consumer's quality levels. Additional information on the 'error-variance' ratio 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…n).

The main advantage of FNC inspection plans is that they can be used even when the underlying quality characteristic is not normally distributed, unlike variables plans they do not require the underlying assumptions about the distribution of the characteristic to be met.

The use of FNC adjustment is preferred over approaches based on measurement uncertainty in which samples are classified as conforming or non-conforming using the 'beyond reasonable doubt' principle. This approach will be less economical in terms of sample numbers and might not be optimal in terms of controlling producer's and consumer's risks as the conformity assessment approach based on measurement uncertainty is conservative; individual samples are classified non-compliant only under a reasonable worst case measurement scenario. As measurement uncertainty has the potential to affect both producer's and consumer's risks it is necessary to consider both measurement and sampling uncertainty in the design of sampling plans.

6 Other Matters Relating to Sampling

6.1 Physical Sampling

- Physical sampling, including sample handling, is a significant area in itself.
- A single sample taken from the product is a minimum amount to allow the laboratory testing in accordance with the requirements of the test method noting there could be more than one test applied to a single, larger sample.
- In some cases, a larger sample might be taken from a lot and one or more sub-samples taken from that sample after it has been thoroughly mixed.

The Theory of Sampling (TOS) (Section 4.4.2) relies on procedures due to Gy[10] that represent best practice for physical sampling from a lot in an unbiased manner. 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 sampling inspection plans. Reference should be made to product 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 heterogeneity 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 nearby and convenient to sample. It is a non-probability sampling and sometimes used in pilot testing.

It is an *ad hoc* method of sampling that is readily available, and often used due to low cost.

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 ISO Sampling Plans

6.2.1 Introduction

The two standards ISO 2859 Sampling procedures for inspection by attributes and ISO 3951 Sampling procedures for inspection by variables are the two principal ISO standards dealing with sampling inspection. These standards are based on the following principles and assumptions:

- They are applicable to lots consisting of discrete items
- The sample size is determined according to the lot size

[10] P.M. Gy, Sampling of Particulate Material, Theory and Practise, Elsevier, Amsterdam, 1992.

- The standards describe sampling schemes, i.e. sets for sampling plans, for normal, tightened, and reduced inspection, with switching rules based on recent quality history to swap between those inspection levels
- The sampling schemes are designed to specifically control either the producer's risk, or the consumer's risk, but not both
- It is assumed that measurement error is negligible in the construction of most of these schemes although ISO3951 does contain some information relating to adjustment for measurement error.

6.2.2 Lot Size vs Sample Size

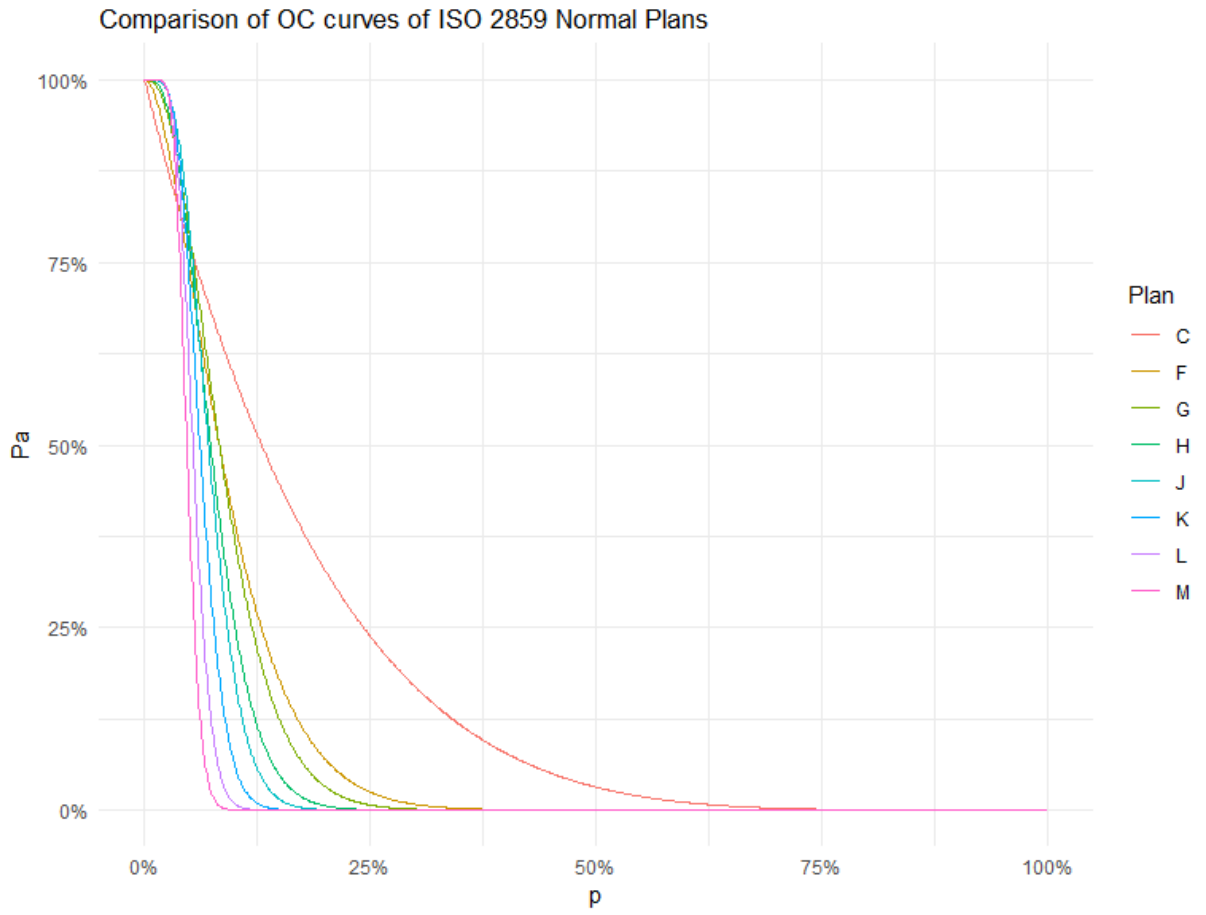
Statistically, the lot size itself does not have an important role in determining protection to consumer and producer whereas changes in sample size do affect on the protection afforded by any plan.

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, and has been changed over time, 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.

To achieve this, the designers of the ISO plans have chosen not to explicitly control both the producer's or consumer's risks in the design of these plans, plans are based either on control of producer's risk or control of the consumer's risk; sampling plans indexed by PRQ do not fix the consumer's risk at a constant level such as 5% and the consumer's risk will decrease only for large lot sizes.

The following table and graph shows the OC curves of the single sampling plans for normal inspection from ISO 2859, for a PRQ of 2.5% (Level II General Inspection). The consumer's risks differ significantly for these plans and varies according to the lot size.

Lot size range	**Sample Code**	**(*n* , *c*)**	**Producer's Risk**		**Consumer's Risk**	
			Level nonconforming (PRQ)	**Probability of Rejection**	**Level nonconforming (CRQ)**	**Probability of Acceptance**
16-25	C	(5,0)	2.5%	0.119	36.9%	0.10
91-150	F	(20,1)	2.5%	0.088	18.1%	0.10
151-280	G	(32,2)	2.5%	0.045	15.8%	0.10
281-500	H	(50,3)	2.5%	0.036	12.9%	0.10
501-1200	J	(80,5)	2.5%	0.015	11.3%	0.10
1201-3200	K	(125, 7)	2.5%	0.014	9.2%	0.10
3201-10000	L	(200, 10)	2.5%	0.013	7.6%	0.10
10001-35000	M	(315, 14)	2.5%	0.014	6.3%	0.10



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.

6.2.3 Sampling Schemes

ISO standards employ sampling schemes, sets of sampling plans with different levels of inspection to ensure quality is effectively controlled. Sampling schemes also contain 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.

Sampling schemes provide more comprehensive assurance compared to sampling plans.

Normal inspection is used when the process is considered to be operating at, or slightly better than, the PRQ.

Tightened inspection uses stricter acceptance criteria 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.

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 an equivalent [single] sampling plan that controls the producer's and consumer's risks to the same levels as an overall sampling scheme.

6.3 Reinspection

Sampling inspection plans usually assume that a random sample is taken from the lot. When random sampling of prepackaged commodities from large containers is difficult, physical sampling may be done

poorly. Hence it is natural for the producers or consumers to occasionally suspect or dispute the sampling done. The use of sampling plans based on relatively small sample sizes can result in high risks of making incorrect decisions, so reinspection plans should be used in the interests of fairness.

When the original inspection is considered suspect due to sampling or measurement issues, lot reinspection can be carried out, in which the lot is resubmitted for inspection with a new sample taken to make a decision. This process can be repeated; the design of the sampling plan used for each reinspection depends on the number of reinspections allowed.

Reinspection schemes are particularly useful for zero acceptance number sampling plans. It is well known that the zero-acceptance number plans generally involve a higher risks to producers. Hence use of reinspection allows producers to opt for reinspection of a lot when there is good process history to believe that the quality of the lot is indeed good but the lot may have been rejected due to poor sampling or problems with measurement. Variables sampling plans employing small sample sizes and large ***k*** values such as ***k***= 2 can also be harsh on producers.

6.4 Inhomogeneous Lots

Section 3.1.8 on Lot Homogeneity deals with homogeneity in general, and this section with how to handle isolated heterogeneity should it occur. Section 4.4 discussed issues concerning fundamental heterogeneity of lots in the context of plans for the inspection of bulk materials.

Acceptance inspection 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.

Most sampling plans are based on the assumption that the lots are homogeneous. Use of these plans in the presence of lot heterogeneity will usually increase producer's and consumer's risks, so that consumer protection may be compromised when an inspection lot is not homogeneous.

If a lot is fundamentally inhomogeneous, as in lots consisting of bulk materials, those plans should be used.

Inhomogeneous lots might occur because inspection lots differ from manufacturing lots or for other reasons; one approach may be to split that lot into sublots in line with production lots or other standardised 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 be used for the entire lot, if that lot was homogeneous. However, lots should not be split into sublots on the basis of results obtained from earlier testing.

Appendix II

Revised General Guidelines on Sampling (CXG 50-2004)
Guide to the selection and design of sampling plans

(for comment through CL2021/10/OCS-MAS)

This guide is intended to be used in conjunction with the *General Guidelines on Sampling* (CXG 50-2004). It provides a step-by-step procedure to identify appropriate options for sampling plans, appropriate to the context for which the sampling plan is required. Once suitable options have been identified, specific sampling plans, e.g. the number of samples and the acceptance number in the case of attributes plans, can be determined from specifications of the PRQ and CRQ, and their associated allowable risks, the probabilities of rejection (PR) and acceptance (CR), respectively, at those levels.

A. Determine Sampling Plan Options

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

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

3. Attributes data

Is the inspection error negligible or significant?

Negligible	CXG50 4.2	App1 (attributes)	
Significant	CXG50 5.2.1	App4	Retesting
	CXG50 5.2.2	App7	Known errors

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

5. Variables plans, normally distributed characteristics

Is measurement error negligible or significant?			
Negligible	CXG50 4.2	App1 (Variables)	
Significant	Go to step 6		

6. Variables plans, normally distributed characteristics, significant measurement error

Is the measurement error normally distributed or does it follow some other distribution?			
Normally distributed	CXG50 5.3.1	App7	ISO3951-1 Annex O (repeatability)
	CXG50 5.3.2		ISO3951-6 (general error)
	CXG50 5.3.2	App16	Fractional nonconformance plans
Some other distribution	CXG50 5.3.2	App16	Fractional nonconformance plans

7. Compositional Proportions

Is measurement error negligible or significant?			
Negligible	CXG50 4.3.1	App10	
Significant	Go to step 6		use normal approximation

8. Characteristic neither normally distributed nor a compositional proportion

Is the measurement error negligible or significant?			
Negligible	CXG50 4.2.6	App1	Classify to attributes
Significant	CXG50 5.3.2	App16	Fractional Nonconformance Plans

9. Provision expressed in terms of the average level in a lot

Is the measurement error negligible or significant?			
Negligible	CXG50 4.3.2	App3	Plans for the average level
Significant			

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

Consumer's Risk Quality level (CRQ)

What percentage nonconforming would need to be present in lots that we would want to reject most of the time?	
How often would you want to accept such lots (default = 10%)?	10%

Producer's Risk Quality level (PRQ)

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

Appendix III

Revised General Guidelines on Sampling (CXG 50-2004): e-book (Codex Sampling) for General Guidelines on Sampling (CXG 50-2004)

(for comment through CL2021/10/OCS-MAS)

This e-book is to sit alongside the General Guidelines on Sampling (CXG 50-2004). It provides additional information on sampling, as well as apps for the design and evaluation of sampling plans.
For technical and other reasons, the e-book cannot be issued electronically at this time.
References mentioned in the text are listed at the end of the document.

The previous version of the e-book can be viewed here: GL50 e-book v1.

1 Introduction

Acceptance sampling is the methodology giving the procedures by which decisions to accept or not accept (a lot, or a series of lots usually) are based. Acceptance sampling depends on the results of the inspection of samples.

Acceptance sampling is preferred when: testing is destructive, the cost and time for 100% inspection are high, or there are limitations of the work force.

There are some disadvantages of acceptance sampling. These include the risk of accepting bad lots or rejecting good lots. Acceptance sampling does not provide any direct form of quality improvement, it simply accepts or rejects lots.

The Codex Procedural Manual and the Principles for the Use of Sampling and Testing in International Food Trade' (CXG 83-2013) (CXG 83) state that 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'.*

Fairness can only be established by consideration of both the consumer's and the producer's risks.

This revised CXG 50 has sections covering:

- General Principles
- Design of Sampling Plans
- Sampling Plans (attributes, variables, bulk materials)
- Inspection and Measurement Errors
- Other matters relating to Sampling.

The sampling plan tool (refer 2.3.1) allows **for control of *both* consumer's and producer's risks** as part of the design. This tool will also produce an Operating Characteristic (OC) curve. The OC curve is an important component of sampling plan design as it is used to gauge the protection to the consumers and producers. The Codex Procedural Manual says *'a commodity committee should, whenever possible, provide information to CCMAS for each sampling plan relating to the scope or field of application, the type of sampling (e.g. bulk or unit), sample sizes, decision rules, details of plans (e.g. Operating Characteristic curves), inferences to be made to lots or processes, levels of risk to be accepted and pertinent supportive data'.*

Codex commodity committees are responsible for developing Codex provisions – and need to be aware of how sampling plans will perform in regard to Codex provisions. The sampling plan tools can be used to demonstrate the OC curve that comes from selection of a combination of Producer's Risk Quality (PRQ) and Consumer's Risk Quality (CRQ), the number of samples ***n***, the acceptance number ***c*** or the acceptability constant ***k***, and the resulting consumer's and producer's risks.

1.1 Reference table

The following table provides references within the Guidelines on Sampling (CXG 50-2004) and this Information Document.

			Negligible Measurement Error		Significant Measurement Error	
Data Type	**Nature of Provision**	**Distribution**	**CXG50 reference**	**e-book reference**	**CXG50 reference**	**e-book reference**
Attributes	Minimum or Maximum*	Not applicable	Inspection by Attributes Plans (Section 4.2)	Section 4.2 App1	Retesting (Section 5.2.1)	Section 8.4 App4
					Known Inspection Errors (Section 5.2.2)	Section 8.3 App7
Variables	Minimum or Maximum	Normal	Inspection by Variables Plans (Section 4.2)	Section 4.3 App1	Significant Repeatability Error (1) (Section 5.3.1)	Section 8.2 App15
					General Measurement Error (1) ISO3951-6	
					Fractional Nonconformance Plans (Section 5.3.2)	Section 8.5 App16
	Minimum or Maximum	Non-normal	Classification to Attributes (Section 4.2.6)	Section 4.2 App1	Fractional Nonconformance Plans (Section 5.3.2)	Section 8.5 App16

			Negligible Measurement Error		Significant Measurement Error	
Data Type	**Nature of Provision**	**Distribution**	**CXG50 reference**	**e-book reference**	**CXG50 reference**	**e-book reference**
Variables	Minimum or Maximum	Compositional Proportions	Plans for Compositional Proportions (Section 4.3.1)	Section 7.2 App10	-	-
	Average Level	Not applicable	Plans for Average Level (Section 4.3.2)	Section 6.1 App3	-	-

Note (1) In these cases measurement error is also assumed to be normally distributed.

Other material
In addition, the following apps are provided:
- App2 to demonstrate the effect of lot size on sample size (e-book Section 5.1)
- App5 to demonstrate the effect of lot heterogeneity on the probability of acceptance (e-book Section 5.4)

2 Concepts of Sampling

2.1 The Purpose of Sampling

The main aims of sampling inspection is to ensure that the customer receives product of the required quality, and to ensure that products are safe, while remembering that financial resources are limited and the cost of the product must also reflect any costs associated with sampling and testing.

In addition, the Codex Procedural Manual and the *Principles for the Use of Sampling and Testing in International Food Trade'* (CXG 83-2013) state that 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'.*

The choice of sampling plan depends on the level of protection against poor quality products to be provided to the consumer, whilst also ensuring suitable fairness to producers, in recognition of fair practices in food trade and the nature of measurements associated with the testing for the provision.

2.1.1 What are the ways that sampling inspection can be carried out?

There are three possible ways that sampling inspection can be carried out:

- 100% inspection
- Sampling design based on probability, application on statistics
- Ad hoc inspection, that is, a sampling plan without a statistical basis.

For **Approach (a)**, 100% sampling is not feasible due to the prohibitive cost of testing and in addition, there might not be any product left to sell. Also, the presence of measurement error means that it is still not possible to provide a 100% guarantee, even if all items in the lot are inspected.

Approach (b) has the disadvantage of higher risks as compared to approach (a), some product might not be inspected. However, by using the probability approach, the risks can be calculated, and a sampling plan can be chosen to ensure these risks are controlled to the desired levels. It also has the advantage of practicability and lower costs. Another important point is to be realistic about the level we wish to control risks if it is to be achievable.

Approach (c) is often 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 or rejection of foods. The probabilities associated with such plans should be evaluated where possible. Decisions on acceptance or rejection should not be made solely on the basis of these plans.

Approach (b) - the probability approach

Clearly an intended 100% guarantee cannot be provided when sampling methods are used, as not all the product will be inspected. This means that there are two types of risks that can occur:

- The risk that product of unsatisfactory quality will be accepted (Consumer's Risk)
- The risk that good quality product will be rejected (Producer's Risk).

However, if we specify how we want to control these risks, we can design a sampling plan that ensures these risks are not exceeded.

In practice, the producer's and consumer's risks are specified in terms of the Producer's Risk Quality (PRQ) and the Consumer's Risk Quality (CRQ) respectively. Once these are specified, along with their associated probabilities of rejection and acceptance respectively, a sampling plan, allowing no more than these levels of risk can be developed.

2.1.2 Definitions

Acceptance Sampling

Sampling after which decisions are made to accept or not to accept a lot, or other grouping of products, materials, or services, based on sample results

[SOURCE: ISO 3534:2]
Note:

- Also referred to as "Acceptance Sampling Inspection"

- In CXG50 and the e-book the term “Acceptance Sampling” and “Acceptance Sampling Inspection” are usually shortened to just “Sampling” or “Sampling Inspection”

Acceptance Sampling Plan
Plan which states the sample size (s) to be used and the associated criteria for lot acceptance.
[SOURCE: ISO 3534:2]

Information note
An **Acceptance Sampling Plan, referred to as a “Sampling Plan” in CXG50 and the e-book,** intended for determining the acceptance or the rejection of a lot. The plan specifies:
- the number of samples to be taken and how those samples are to be taken from a lot
- how those samples will be tested, and
- the criterion, based on the test results obtained, used to determine whether the lot is accepted or rejected.

Consumer and Producer

The terms ‘producer’ and ‘consumer’ are conventional and may apply to a range of different operators in the food chain, such as a grower, manufacturer, the manufacturer’s own quality control system, supplier, exporting country, processor, on-seller, or importing country.

Information note
The term ‘confidence’ is often used in conjunction with sampling plans. However, while it is a statistical term, in reality it has nothing to do with acceptance sampling. It is simpler to understand the correct approach to sampling to express risks in terms of probabilities of acceptance or rejection at specified levels of nonconforming product within a lot.
Confidence can be associated with consumer’s risk, for instance 95% confidence (that the lot is of satisfactory quality) means there is only 5% chance of acceptance.
However, confidence does not work well with producer’s risk.

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]

Information note
Consumer’s Risk is the probability of wrongly accepting a lot that is not of acceptable quality. It is a point on the OC curve corresponding to a predetermined and usually low probability of acceptance.

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]

Information note
Consumer’s Risk Quality (CRQ) is the level nonconforming in a lot, specified in the design of a sampling plan, corresponding to a specified Consumer’s Risk of accepting a lot of poor quality

Acceptance Sampling Inspection 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]

Information note
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.

Acceptance Sampling Inspection 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]

Information note
Inspection by Variables starts with selecting a sample of a number of items and measuring dimensions or characteristics so that information is available not only on whether a dimension, for example, is within certain limits but on the actual value of the dimension. The decision whether or not to accept a lot is made on the basis of calculations of the average and the variability of the measurements.
An inspection by variables sampling plan specifies the number of samples (**n**) and an acceptability constant (**k**). A lot is accepted against an upper specification limit if the acceptance criterion 'average result + **k** * the standard deviation of results' does not exceed the upper limit, and similarly for a lower limit. In other words, the acceptance criterion is based on the average value $\bar{\mathbf{x}}$ and the standard deviation of the results from the testing.
The values of **n** and **k** are worked out from the specified levels of allowable risk.

Lot

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

[SOURCE: ISO 3534:2]

Operating Characteristic Curve

The Operating Characteristic 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]

Information note
Producer's Risk is the probability of wrongly rejecting a lot that is of acceptable quality. It is a point on the OC curve corresponding to a predetermined and usually high probability of acceptance.

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]

Information note
Producer's Risk Quality is the level nonconforming in a lot, specified in the design of a sampling plan, corresponding to a specified Producer's Risk (PR).

Provision, Characteristic, Standard

A **provision** is a requirement for a commodity that must be met in order that the commodity conforms to the standard.

A **characteristic** is the attribute in the commodity to which the provision relates

A **standard** is a set of provisions relating to a commodity, all of which must be met in order that the commodity conforms to the standard.

Example
Fat in WMP must exceed 26%
Identified food or group of foods e.g. Milk powders and Cream Powders Codex Standard 207
The attribute is the 'characteristic' in the commodity to which the provision relates e.g. fat

Provision is the requirement that must be met e.g. must exceed 26%

Quality Level

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

[SOURCE: ISO 3534:2]

A **sampling scheme** defines what data will be obtained and how. Precision and systematic sampling error are two principles that guide the choice of sampling scheme.

2.2 Statistical texts & references

These references provide for more detail on statistical concepts referred in the CXG 50.

Author	Name
Bicking, C.A. 1967	"The Sampling of Bulk Materials." Materials Research and Standards 7 (2): 95–116.
Bicking, C.A. 1978	"Principles and Methods of Sampling." In Treatise on Analytical Chemistry, second edition, 1:299–359. John Wiley & Sons, New York.
Bray D, Lyon D, Burr I (1973)	Three Class Attributes Plans in Acceptance Sampling. Technometrics, 15(3), 575–585.
	This is the original paper proposing the use of three-class attributes sampling plans, widely used in microbiological assessments. The paper contains tables for the selection of plans based on control of producer's and consumer's risks.
Esbensen, Kim & Wagner, Claas (2015)	Theory of sampling (TOS) - fundamental definitions and concepts. Spectroscopy Europe VOL. 27 22-25.
Eugene L. Grant and Richard S.Leavenworth	Statistical Quality Control, seventh edition, McGraw-Hill, 1996.
Govindaraju, K., and S. Ganesalingam. 1997	"Sampling Inspection for Resubmitted Lots." Communication in Statistics-Simulation and Computation 26 (3): 1163–76.
Govindaraju, K., & Jones, G. (2015).	Fractional acceptance numbers for lot quality assurance. In S. Knoth, & W. Schmid (Vol. Eds.), Frontiers in statistical quality control: Vol. 11, (pp. 271–286). Springer.
	The published paper proposing the Fractional Nonconformance method for measurement error adjustment in sampling.
Gy, P.M. 1992.	Sampling of Particulate Material, Theory and Practice, Elsevier, Amsterdam.
Hahn, G. J.	"Removing Measurement Error in Assessing Conformance to Specifications." Journal of Quality Technology (1982) 14: 117–21.
Hamaker, H. C. 1960.	"Attribute Sampling in Operation." Bulletin of the International Statistical Institute 37 (2): 265–81.
Holst, Thyregod & Wilrich	"On Conformity Testing and the Use of Two Stage Procedures." International Statistical Review 69: 419–32.
J. M. Juran and A. Blanton Godfrey, 1999	Juran's Quality Control Handbook, fifth edition, McGraw-Hill.
Montgomery DC, 2013	Introduction to Statistical Quality Control John Wiley & Sons.
Kilsby D.C, Aspinall L.J. and Baird-Parker A.C. (1978)	A System for Setting Numerical Microbiological Specifications for Foods. J. Appl. Bacteriology, 46, 591-599.
	Paper by Kilsby, Aspinall and Baird-Parker proposing use of variables plans for assessment of microbiological parameters, employing the use of inner and outer limits.

Owen, D. B., and Youn-Min Chou. 1983	"Effect of Measurement Error and Instrument Bias on Operating Characteristics for Variables Sampling Plans." Journal of Quality Technology 15: 107–17.
Vaden T.J. (1990)	Balanced Risk Sampling. ASQC Quality Congress Transactions – San Francisco, 1078-1083.
	Discusses the use of the plans based on the Indifference Quality Level, which favour neither the producer nor the consumer, mentioned in Section 3.1.2 of CXG 50, as a way to achieve more manageable sample sizes.
Wetherill BG 1977	Sampling Inspection and Quality Control Chapman & Hall.

2.2.1 More Advanced Material

Author	Name
Guenther WC, 1977	Sampling Inspection in Statistical Quality Control. Charles Griffin and Company
Hald A, 1981	Statistical Theory of Sampling Inspection by Attributes. Academic Press.
Johnson NL, Kotz S, Wu X, 1991	Inspection Errors for Attributes in Quality Control. Chapman & Hall.
Kiermeier A 2008	"Visualising and Assessing Acceptance Sampling Plans: The R Package AcceptanceSampling." Journal of Statistical Software, 26(6). URL http://www.jstatsoft.org/v26/i06/.
	Documentation relating to the R package AcceptanceSampling, written by Andreas Kiermeier who was a member of the team who published the FAO/WHO Guideline Statistical Aspects of Microbiological Criteria Related to Foods. A Risk Manager's Guide.
Schilling EG & Neubauer DV 2017	Acceptance Sampling in Quality Control Third Edition CRC Press.

2.3 Different Sampling Plan Design Approaches

There is no one-size-fits-all sampling plan design that applies. What is important is that the approach used is science-based, with sound statistical backing. In practice, sampling plans may be based on industry practice. However, the choice of plans and endorsement of those plans should still be made with knowledge of the associated risks, bearing in mind that the main purpose of sampling is to ensure that the customer receives product of satisfactory quality.

2.4 Endorsement by CCMAS of Sampling Plans from Different Sources

The Codex Procedural Manual 'General instructions for the Selection of Methods of Sampling' says that sampling methods described in CXG 50, or elaborated by international organisations are preferred, and provides as guidance, different types of sampling plans and procedures.

The Codex Procedural Manual also says *'a commodity committee should, whenever possible, provide information to CCMAS for each sampling plan relating to the scope or field of application, the type of sampling (e.g. bulk or unit), sample sizes, decision rules, details of plans (e.g. Operating Characteristic curves), inferences to be made to lots or processes, levels of risk to be accepted and pertinent supportive data'*

CCMAS endorsement of sampling plans is based on the information provided, and expertise to judge the validity of the plan. Commodity committee design of a sampling plan is also based on criteria for the design, as well as expertise to apply the criteria to a suitable sampling plan.

To aid the design of a sampling plan by the commodity committee, and to help with the provision of the basis for sampling plans, the OC curve can be used. The sampling plan tools we have developed provide an opportunity for commodity committees to compare different sampling plan criteria, based on the requirements of commodity standards.

CCMAS will be in a position to endorse sampling plans whether the plan is sourced from CXG 50, ISO or another source, so long as the plans meet the requirements of the commodity committee and it can be shown the plan satisfies the principles adopted by Codex, that *'fair and valid sampling procedures are used when food is being tested for compliance with a particular Codex commodity standard'*.

2.4.1 Apps to demonstrate acceptance sampling

There are 14 apps currently available in the `R` package called `nzcodex`. This R package can be launched in RStudio environment.

The `nzcodex R` package containing all the apps and sampling inspection tool documentation can be downloaded at the following link.

nzcodex

The package will launch shiny applications (apps) or tools. Some apps are intended for demonstrating risk assessment principles while other apps are to design sampling inspection plans on statistical risk assessment principles. Click on the link nzcodex to download the zip file containing the package – following this the packaged can be installed in R or Rstudio.

Some of the apps in the package have been removed from the e-book as they were not relevant to sampling.

App1 is about design and evaluation of sampling plans. This app can be used to examine the OC curves before creating and using a sampling plan as the different curves can be compared. The app can be used to investigate either attributes sampling plans or variables plans. In the attributes sampling plan, there is the option to change the sample size and the acceptance number for plan 1 (the purposive plan). For plan 2 (the designed plan), the PRQ, CRQ, producer's risk, and consumer's risk are all to be entered. Once the parameters are chosen, the two OC curves can be compared. Variables sampling plans are similar except there is a *k*-constant instead of an acceptance number. There is also an additional parameter, which is whether the standard deviation is known or unknown. The two OC curves can again be compared for the variables sampling plan.

App2 demonstrates the effect of lot size. This app allows you to see the impact that lot size and sample size have on the OC curves. There are two curves, for finite and infinite lots. The OC curve for the infinite lot does not change, but the finite lot OC curve changes depending on the plan parameters. The sample size, acceptance number, lot size and producer's and consumer's risks can be altered to see what effect the changes have on the OC curves.

App3 demonstrates variables plan for averages. There are different parameters that can be selected. These include whether the standard deviation is known, whether the specification limit is upper or lower, and what this particular specification limit is. If the standard deviation is known, its value is entered. The sample size and *k*-constant are also selected, along with the producer's and consumer's risks. The OC curves will be different depending on whether the standard deviation was known or not, and these curves can be compared.

App4 is about repeat testing (retesting) as a way of overcoming the effect of inspection error. It is designed for users to be able to explore the effect of repeat testing. Only items which are classified as nonconforming are able to be re-tested. There are two OC curves, one for repeat testing and the other for single testing. When the plan parameters: sample size, acceptance number, maximum number of tests and the chances of misclassification (percentage conforming as nonconforming, and percentage nonconforming as conforming) are altered, these OC curves change and can be compared. The producer's and consumer's risks can also be selected. It can be seen what effect repeat testing has on the PRQ and CRQ levels, in order to determine its impact.

App5 explores the effect of lot heterogeneity, expressed in terms of a correlation. The sample size, acceptance number and correlation parameter are all chosen. In addition, the producer's and consumer's risks can be chosen. When these inputs are changed, the graph of the OC curves will change. There are separate curves for homogeneous and heterogeneous cases which can be compared. In order to compensate for lack of homogeneity (non-zero correlation), the sample size can be increased to reduce the consumer's risk in general.

App6 is about resampling, used when the outcome of an inspection is disputed, and further sampling is used to resolve the dispute. This app allows you to select either an attributes or a variables plan. For the attributes plan the sample size, the number of reinspection's to be carried out, and the acceptance number can be changed. For variables plans the sample size, number of reinspection's,

and the *k*-constant can be altered, along with whether the standard deviation is known or not. Once these are decided upon, the OC curve changes. The OC curve plot shows the difference between a single inspection, and what the resampling scheme would look like, given by the two different curves on the plot. The producer's risk and consumer's risk are also detailed. Therefore, this app can be used to explore what impact a resampling inspection scheme has.

App7 relates to the effect of inspection errors on risks for attributes plans. The sample size and acceptance number are chosen for the attributes plan, along with the producer's and consumer's risks. Then the chance of misclassifying conforming as nonconforming, and nonconforming as conforming is also selected. The OC curve is given dependent on what is selected for these variables. There are two OC curves, one for with inspection error, and the other for no inspection error. Both of these curves can be compared as the parameter values change to see what effect the inspection error has on risks.

App9 is about conformity testing, i.e. whether the true value of the sample tested complies with a limit. This app looks at the probability of declaring conformity for both the FNC and ISO methods. A sample size, the significance levels for the limiting value (LV) and FNC and the variance ratio each need to be selected. Plots are then displayed which show the probability of conformity and nonconformity for ISO two-stage and FNC testing procedures to compare. It is assumed that both these conformity testing procedures have equal samples that are tested.

App10 is about sampling plans for compositional proportions. This app allows the user to change the PRQ and CRQ levels, along with the *U* or *L* (upper or lower specification limit) and theta value (the 'precision parameter' describing the variation for the beta distribution). Changing these inputs allows users to see what will happen to the OC Curves (which is a way of describing the behaviour of a sampling plan). OC curves for plans based on both the beta and normal distributions are shown and can be compared.

App15 enables the user to design a variables sampling inspection plan that is adjusted for the repeatability SD of measurement errors. This app particularly shows that the acceptability constant *k* constant must be smaller depending on the size of the repeatability SD.

App16 compares the Fractional Nonconformance (FNC) based inspection plans for measurement adjustment with the variables plans adjusted for repeatability type measurement error. FNC inspection plans are particularly useful when the normal distribution does not hold for the underlying quality characteristic.

Supplementary technical notes and examples are also given in the apps.

2.4.2 Additional ideas for Apps:

- Upgraded App1 to include plans based on the hypergeometric distribution for finite lots
- Design of Fractional Nonconformance Plans
- Design and Evaluation of Three class Attribute Plans
- Extend App3 to allow the effect of measurement error to be investigated
- New: Design of plans for heterogeneous contamination for presence/absence parameters.

3 Design of Sampling Plans

Sampling inspection plans are usually designed to protect the interests of the producer and the consumer. This is accomplished by specifying quality levels and the associated risks of acceptance and rejection. The most popular indices for the design of a plan are the PRQ, CRQ and the associated producer's risk (PR) and consumer's risk (CR).

3.1 Broader Issues

Bicking (1967) gives a guideline on the broader issues that need to be considered in sampling inspection.

1. Clarify the purpose of sampling
   - What population will the sample be taken from?
   - What information is needed about the population?
   - What are the criteria that lot acceptance will be based on?

2. Specify the population and investigate the history of a lot
   - Does the process that produced the lot come from a state of control?
   - Does the lot size agree with the expectations of the producer and the consumer?
   - Are the methods of handling and storage being considered properly when the lot size is determined?
3. Look at the measurement error
   - Separate the measurement error and sampling error
   - Compare these two sources of error
4. Think about what the within-lots and between-lots variances due to different processes are
5. List the instructions for sampling, ensuring to protect against the following issues:
   - Any lack of clarity in the purpose of sampling
   - Any lack of instructions that are not specific enough
   - Not providing methods that check sampling error, reliability, and bias
   - Methods that would be unsuitable when handling the sample
6. Control the sampling operation.
   - Make sure the samplers are well trained
   - Do check samples to control the operation of the plan
7. Ensure that the sampling instructions are reviewed and alter any changes that are required for the process

The sampling inspection plan then needs to be agreed upon and passed on to whoever is responsible to apply the plan. In order for this acceptance sampling plan to be effective, it involves more than just selecting and applying rules. Inspection should also include: good data, quick information, and incentives for the producer to provide quality at satisfactory levels.

3.2 Administration of Sampling Plans

An acceptance sampling plan is an important aspect to the overall approach of maximising the quality at a minimum cost. Acceptance sampling plans need to change in order to consider current results, and any history of inspections that have been performed. This process is known as acceptance control because it involves selection, application, and modification of the acceptance sampling procedures in order to adapt to a changing inspection environment. Inspection results allow users to accept or reject individual lots as they are found, but they are also beneficial for any future production planning for the producer. This is because it can be decided whether the process needs any alterations in order to eliminate any issues.

Before a sampling plan is used, the quality levels need to be determined. The consumer seeks to try minimising the total cost of purchase, inspection, assembly, and the eventual service. It is not reasonable for the consumer to expect quality levels that are higher than the previous quality levels in the industry. The producer needs to select an acceptable level that is suitable for all intended customers at the prices they are willing to pay, rather than setting individual quality levels for each customer. Both the consumer and the producer need to understand the quality levels. Then the producer is responsible to carry out inspection that is sufficient to assure conformance.

Process data should be analysed over a long enough period of time to assess the overall level of performance. This is used to set the Producer's Risk Quality (PRQ). There are some instances where the PRQ will differ from the state-of-the-art process average. Some of these instances include (i) handling a class of nonconformities instead of a single quality characteristic, or (ii) there is an urgency of demand for a product. In the end, the quality levels are often decided by economic considerations.

The basic principle of administration of sampling inspection is that there is a need for simplicity and practicality. Methods and procedures need to be safe, sure, swift, and simple. In order to be successfully used in industry, acceptance sampling and all forms of administration need to be as uncomplicated as possible.

The text by Schilling and Neubauer (2008) may be consulted for more details on the administration of acceptance sampling.

3.3 Design of Sampling Plans and Risk Management

The phrase 'designing a plan` means determining the parameters of the sampling plan such as the sample size *n* and acceptance number *c* so that the plan is fit for purpose. In designing a sampling plan, one has to accomplish a number of different purposes. Hamaker (1960) has listed the following purposes as the important ones:

1. To strike a proper balance between the consumer's requirements, the producer's capabilities, and the inspector's capacity.
2. To separate bad lots from good.
3. Simplicity of procedures and administration.
4. Economy in number of observations.
5. To reduce the risk of wrong decisions with increasing lot size.
6. To use accumulated sample data as a valuable source of information.
7. To exert pressure on the producer or supplier when the quality of the lots received is unreliable or not up to standard.
8. To reduce sampling when the quality is reliable and satisfactory.

Hamaker cautioned that the above aims are partly conflicting and not all of them can be simultaneously realized.

The first four purposes are particularly critical. The designed sampling plan must explicitly quantify the producer's and consumer's risks. Some of the published sampling inspection procedures such as those in ISO 3951 place more emphasis on reducing the producer's risk with increasing lot size. This is to encourage large scale production and lot formation. For international trade and particularly for food products, consumer's risk control is particularly important in addition to simplicity of operation and transparency, and fairness in reducing the risks to both producers and consumers.

4 Routine Attributes and Variables Sampling Plans

4.1 What Information is Needed to Design the Sampling Plan?

We have developed a toolbox of apps for the design of attributes and variables sampling plans for routine inspection. This tool will assist commodity committees with the design of a sampling plan to ensure fair practices in food trade. The tool can be enhanced for example, to allow for measurement error.

The guidance for the selection or design of suitable sampling plans is based in statistical theory. Use of these tools allows for the statistics to sit in the background.

These tools help guide the design of appropriate sampling plans by showing the operating characteristic (OC) curve to demonstrate the performance of the plan. The tool also allows the plan to be designed from the Producer's Risk Quality (PRQ) and Consumer's Risk Quality (CRQ). The OC curve shows the probability of accepting a lot versus the fraction nonconforming in that lot for a given sample size and acceptance number.

The tools for the design of plans can be used by specifying both the PRQ and CRQ, from which they will work out the number of samples ***n*** and the acceptance number ***c*** for attribute plans, or the ***n*** and the acceptability constant ***k*** for variables plans. This means the Consumer's Risk Quality and Producer's Risk Quality must be specified as part of the plan design.

The tools also provides the option to move away from the usual approach in which it is assumed that the PRQ and CRQ are associated with probabilities of acceptance of 95% and 10% respectively. The tool allows the probabilities of acceptance, or levels out of specification corresponding to specified levels of acceptance, to be calculated. In general, you need to specify any two points on the operating characteristic, i.e. two quality levels and the associated probability of acceptance or rejection at those levels, in order to determine ***n*** and ***c*** (or ***k***). However 95% acceptance is usually associated with good quality and 10% acceptance with poor quality so it seems easier to specify levels representing what is

good quality that should be accepted most of the time and what is poor quality that should be rejected most of the time.

4.2 Single Sampling Plans for Attributes

The simplest single sampling plan is one done by attributes. This is because the inspection results are classified into only two classes of outcomes. Because it is applicable to all sampling situations, it has become the benchmark that all other sampling plans can be compared against. It can be used in different ways in inspection. This includes: counting the number of nonconforming items found in a sample (Poisson distribution), evaluating the proportions nonconforming from large lots (binomial distribution), or from individual small lots (hypergeometric distribution).

Only the binomial is available in the current apps, but the hypergeometric is in the upgraded app1.

It is relatively simple to implement attributes sampling plans. A random sample of size ***n*** is taken from a lot of size ***N***, which can be very large or infinite. The number of nonconforming items found is compared to the acceptance number ***c***. If the number of nonconforming items is less than or equal to ***c***, then the lot can be accepted. However, if the number of nonconforming items found is greater than ***c***, then the lot is rejected.

There are many different charts and tables that can be used to determine a single-sampling attributes plan. Chapter 5 in Schilling and Neubauer (2008) contains explanations of many of these and demonstrates how they can be implemented.

4.3 Single Sampling Plan for Variables

If the underlying distribution of individual measurements is known, acceptance sampling can be performed directly on the measurements themselves. This often allows a considerable saving in sample size, but we need to know the probability distribution of the underlying measurements. The Gaussian or normal distribution is commonly adopted as the distribution of the measurements. For compositional proportions in bulk material, the beta distribution is more appropriate, but the normal distribution can often serve as an approximation.

In variables plans, the mean $\bar{x}$ is compared with the acceptance limit in a similar way to the number of nonconforming units, ***d***, being compared to an acceptance number, ***c***, in the attributes plans. In order to adjust for the variability in the lot, the sample standard deviation ***S*** is computed. The quantity $\bar{x} \pm kS$ is then compared with the lower, *L* or upper, *U* specification limits. The lot acceptance criterion is $\bar{x} + kS \leq U$ or $\bar{x} - kS \geq L$. This method of operation of variables plan is known as the *k*-method to control the fraction nonconforming *p*. The variables plan can be selected for a given PRQ level, producer's risk, CRQ level, and consumer's risk.

Schilling and Neubauer (2008) explains some of the advantages and disadvantages of variables sampling plans.

The advantages of variable sampling plans are:

1. It offers the same protection with a smaller sample size than what is required for attributes
2. There is feedback of data on the process which produced the units
3. There is more data available in waiver situations
4. There is the extent of conformity of each unit given weight in application of the plan
5. There is an increased likelihood that any errors in measurement will be detected

The disadvantages are:

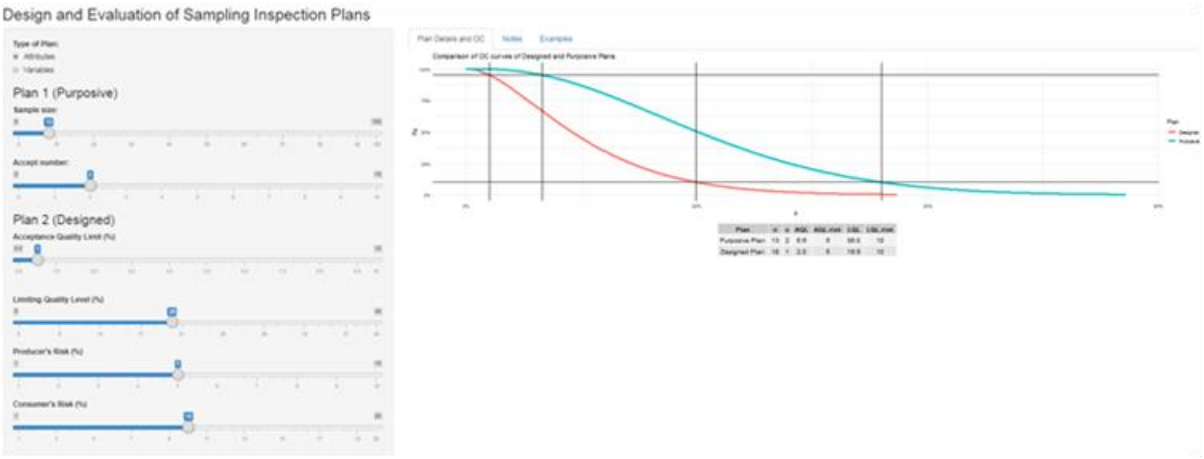
1. The results are dependent on the underlying distribution of measurements assumption being correct
2. Variables sampling plans are only applicable to one characteristic at a time
3. There is a higher inspection cost per unit
4. There is a higher clerical cost per unit
5. There is a possibility of no nonconforming units being found to show to the producer after rejection

Unfortunately, a lot with no nonconforming units may be rejected by a variables plan.

For more details on variables sampling plans, consult Chapter 10 of Schilling and Neubauer (2008).

4.3.1 App implementing attributes and variables sampling plans

This app can be accessed via the link: App1



4.3.2 Examples

4.3.2.1 Attribute Inspection Plans

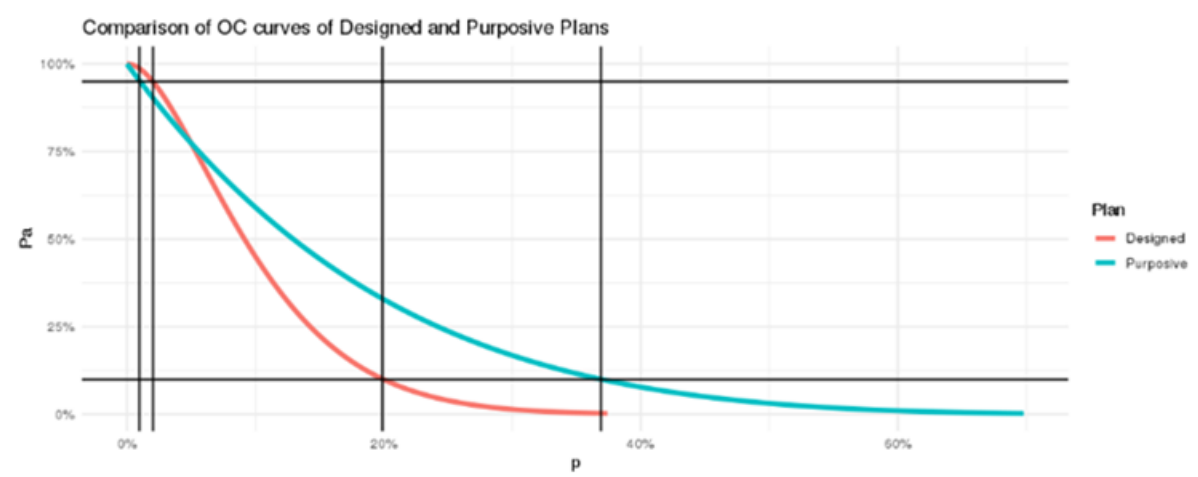
Assume that a sampling plan with sample size *n=5* and accept number *c=0* is used to inspect a lot of button type mushrooms. The button style be defined as whole mushrooms, with attached stems not exceeding 5mm in length, measured from the bottom of the veil.

A number of quality measures are inspected after opening randomly sampled five cans from the lot.

These measures often include-

1. Flavour (normal flavour and odour but free from other flavours or odours foreign to the product).
2. Texture and Character (based on mushroom units with detached caps or stems etc.)
3. and other quality characteristics listed in the appropriate Codex Standard.

For this *(n=5, c=0)* plan, the consumer's risk is about 40% when about 17% of the mushrooms in a lot are nonconforming. Using the app, a better balance between producer's and consumer's risk can be achieved. The designed plan *(n=18, c=1)* plan is able to discriminate well between a good and poor-quality lot. Many other sampling inspection plans can be obtained so that consumer's risk is lower than the risk under *(n=5, c=0)* plan.



Plan	n	c	AQL	AQL.risk	LQL	LQL.risk
Purposive Plan	5	0	1	5	36.9	10
Designed Plan	18	1	2	5	19.9	10

4.3.2.2 Variables Inspection Plans

Solubility is an important quality characteristic for Instant coffee. An upper specification limit *U=30* seconds is set for the time to dissolve instant coffee readily in boiling water with moderate stirring.

Assume that currently a variables sampling plan with *n=10* and *k=1.5* is employed in order to reduce the consumer's risk as well as improve the discrimination, the sample size can be increased to *n=13* and *k* is adjusted to *k=1.638* using the app by trial and error.

Suppose however we assume a lot size *n* of 8000, and we want a sampling plan with Producer's Risk Quality PRQ = 2.5% and that the standard deviation is unknown, i.e. it is not known from historical data but will be estimated from the results obtained from the sampling and testing. Assume also, for the purposes of this example, that measurement error is negligible.

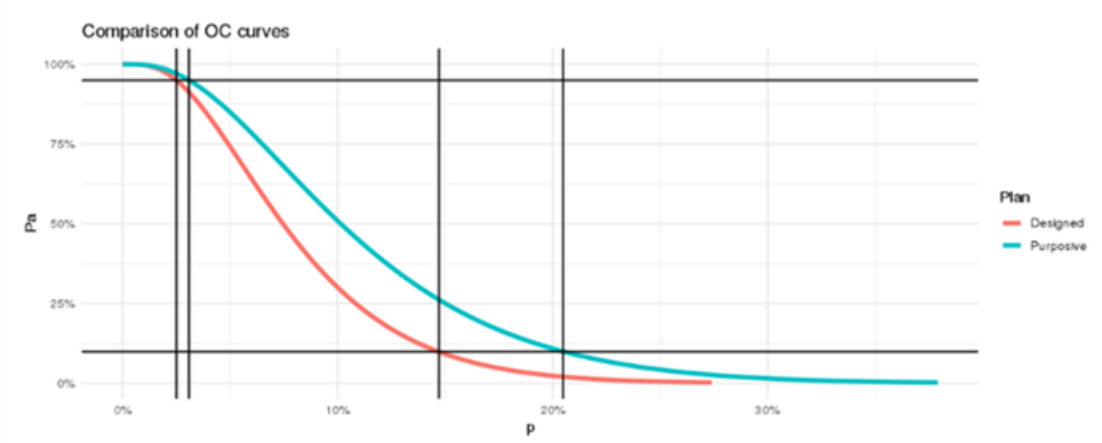
The variables inspection plan currently employed for the quality assurance of calls for taking n = 15 samples and fixes the acceptability constant k = 1.30. The Producer's Risk Quality level for this plan is 2.5%. This variables plan is operated as follows:

1. Obtain the solubility time in seconds for each of the 15 samples taken.
2. The lot would be accepted against an upper specification limit (USL) as long as

$$\bar{x} + kS \leq USL$$

where $\bar{x}$ is the average of the test results, *S* is their standard deviation and k = 1.30.

The performance of this plan for various nonconforming levels of solubility can be assessed using the OC curve displayed in the app. Using the tool, we can specifically evaluate the consumer's risk. Note that in this example the PRQ and the sample size (*n*) have been specified so that the Consumer's Risk Quality (CRQ), indicating the level of Consumer's Risk, is intrinsically determined. The following screenshot shows the OC curve of the current purposive plan along with a new designed plan with *n=22* and *k=1.463*.



Plan	n	k	AQL	AQL.risk	LQL	LQL.risk
Purposive Plan	15	1.300	3.1	5	20.5	10
Designed Plan	22	1.463	2.5	5	14.7	10

The designed plan has a lower CRQ of about 15% instead of the CRQ of about 20% for the current plan. The new plan is more discriminatory at other solubility quality levels, having lower probabilities of acceptance at higher levels nonconforming.

5 Some Issues of Routine Inspection

In this section, some of the commonly encountered issues such as the relationship between sample size and lot size are discussed. Resampling and retesting (not the same thing) are also discussed.

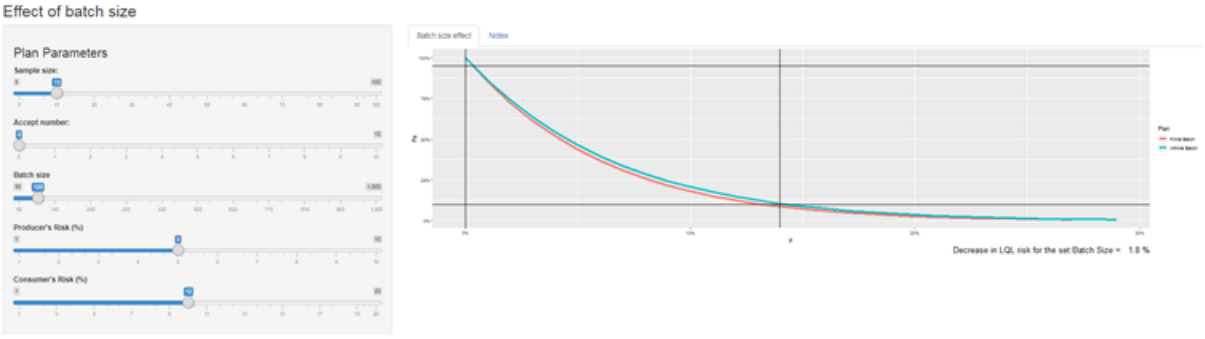
Resampling is used to reduce the producer's risk when random sampling of the lot is difficult whereas retesting is a way of overcoming inaccuracy of test results due to measurement uncertainty. If measurement errors are expected to dominate, sampling inspection plans can be adjusted for measurement errors. This adjustment can be done fairly to protect both the producers and consumers. This topic is covered in detail in a later section (Section 9).

5.1 Lot Size vs Sample Size

The OC curve is a fundamental tool for assessing the consumer's and producer's risks in acceptance sampling. The effect of lot size on the OC curve is minimal when only a small proportion of the lot is sampled for testing. This means that the risks will not change dramatically with lot size unless the sampling fraction is large. The absolute sample size is rather important, and it largely determines the protection afforded by a plan.

Schilling and Neubauer (2008) may be consulted for more discussion on why the lot size itself does not have an important role in determining protection to consumer and producer.

5.1.1 App to demonstrate the effect of lot size



This app can be accessed via the link: **App2**

5.2 Explanation of ISO, CXG 50 Sampling Plans

ISO Standards employ sampling schemes, switching between normal, tightened, and reduced inspection to effectively control quality, but these are generally not workable in international trade.

Normal inspection plans are used when the process is considered to be operating at, or slightly better than, the PRQ.

Tightened inspection plans use stricter acceptance criteria 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 plans permit smaller sample sizes than those used in normal inspection. When the level of the submitted quality is sufficiently good, reduced inspection offers sampling economy.

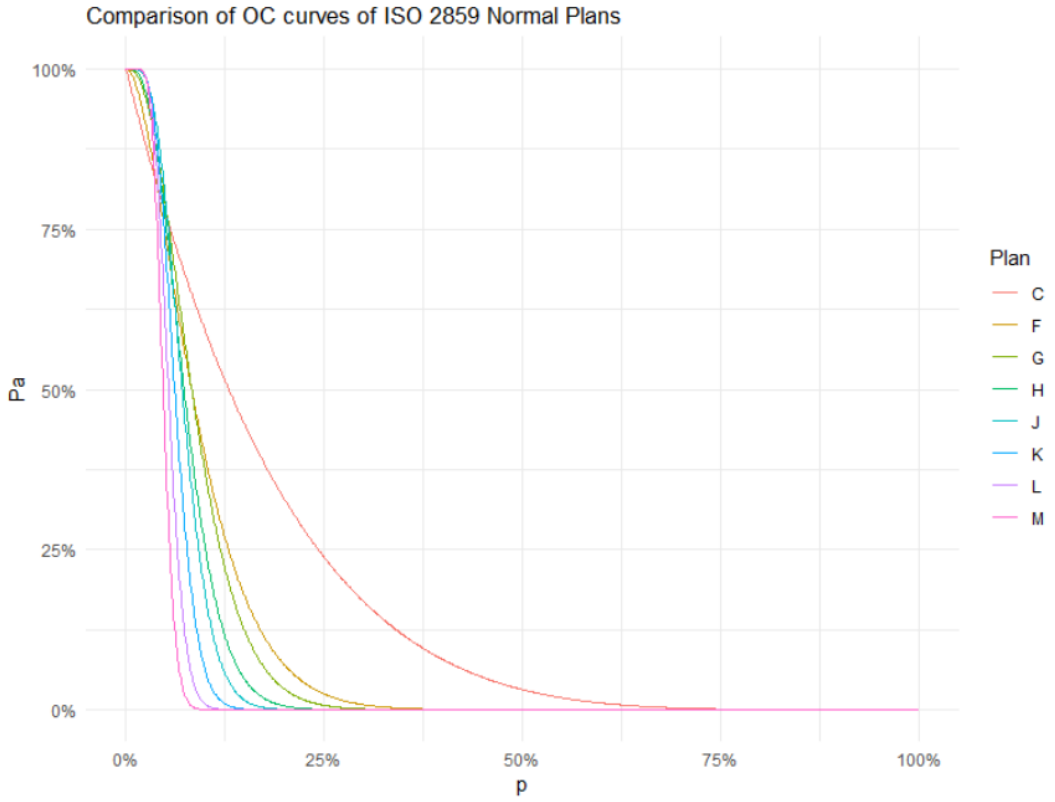
Switching rules govern the switching between normal, tightened, and reduced inspection based on recent inspection history.

Even though it is desirable that a product with a history of good quality will need less inspection compared to a product which has no history, or a history of poor quality, importers do not always have good access to the quality history data of the exporters and hence it is not possible to accurately determine whether the exporter's process average fraction nonconforming compares with the set PRQ.

The OC curves of normal, tightened, and reduced plans offer different levels of protection to the producer and consumer. The full effect of a sampling scheme is realised only when all the rules for switching to and from normal-tightened-reduced plans are fully implemented. In other words, the overall or steady state OC curve of a sampling scheme can only be realised for a very long series of lots of consistent quality. Hence sampling schemes are suitable only when producers and consumers enter a long-term supply arrangement for hundreds of lots. Sampling schemes indexed by PRQ do not fix the producer's risk at a fixed level such as 5%. Producer's risk will become smaller for only for large lot sizes. The table given below shows ISO 2859 normal single sampling plans for an AQL of 2.5 (Level II General Inspection):

Lot size range	Sample Code	(*n*, *c*)
16-25	C	(5,0)
91-150	F	(20,1)
151-280	G	(32,2)
281-500	H	(50,3)
501-1200	J	(80,5)
1201-3200	K	(125, 7)
3201-10000	L	(200, 10)
10001-35000	M	(315, 14)

The following graph shows the OC curves of the above selection of plans. The producer's and consumer's risks differ significantly for these plans and the selection is solely guided by the lot size.



5.2.1 Equivalent sampling plans

It is possible to design attribute or variables sampling plans equivalent to ISO, CXG 50 sampling schemes. The steady state or composite OC curve of the sampling scheme must be consulted to obtain the PRQ and CRQ values for the set producer's and consumer's risk. The routine single attribute or variables plans can then be obtained. For an example of this approach to obtaining equivalent plans by matching the OC curve at two-points of the OC curve, consult Chapter 11 in Schilling and Neubauer (2008).

5.3 Provision for Reinspection or Resampling

Sampling inspection plans usually assume that a random sample is taken from the lot. When random sampling of pre-packaged commodities from large containers is difficult, physical sampling may be done poorly. Hence it is natural for the producers or consumers to occasionally suspect or dispute the sampling done.

When the original sampling or inspection results are suspect, the provision for lot Reinspection or resampling can be incorporated. Reinspection or resampling is done when a lot was rejected on the first inspection, but it is resubmitted for acceptance inspection so that a second new sample can be taken to make a decision on the lot.

The resampling scheme, discussed in Govindaraju and Ganesalingam (1997), is implemented as follows:

The operating procedure is as follows:

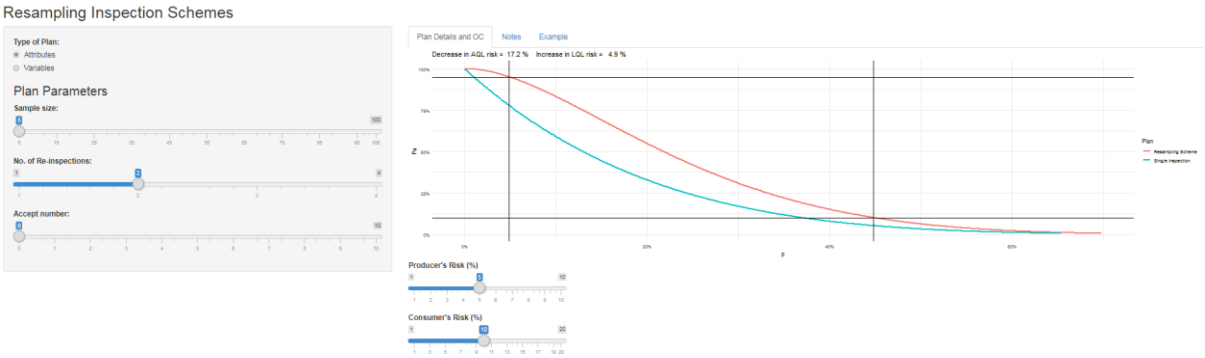
1. Do an original inspection (for example: a single sampling plan with sample size, ***n*** and acceptance number, ***c***.)
2. Given that this original inspection was not accepted, apply the same plan ***m-1*** *more* times and reject the lot if it is not accepted on ***(m-1)****st* re-submission.

Resampling schemes are particularly useful with zero acceptance number sampling plans. It is well known that the zero-acceptance number plans generally involve higher risks to the producer. Hence resampling schemes allow the producer to opt for reinspection of the lot when there is good process history to believe that the quality of the lot is indeed good but rejected due to poor sampling.

Variables sampling plans with large ***k*** values such as ***k=2*** can also be harsh on the producers. These plans also involve a small sample size. Resampling can also help here to reduce the producer's risks.

5.3.1 App to implement resampling plans

The following app deals with resampling for both attribute and variables plans. The user can adjust the number of resampling or reinspections allowed. It should be noted that the app controls the overall risk and hence the plan design still controls the consumer's risk at the set level.



This app can be accessed via the link: **App6**

5.3.2 Further Details of Resampling tool

At the true fraction nonconforming ***p***, the OC function of the resampling scheme that allows ***m-1*** *re*inspections including the initial inspection becomes:

$$P_A(p) = 1 - \left(1 - P_a(p)\right)^m$$

where $P_a(p)$ is the OC function of the original (single) inspection plan. Both attribute and variables plans can be implemented under the resampling scheme.

The main advantage of the resampling scheme is the greater reduction of the producer's risk, particularly for zero acceptance number single sampling plans or variables plan with large acceptability constant ***k***.

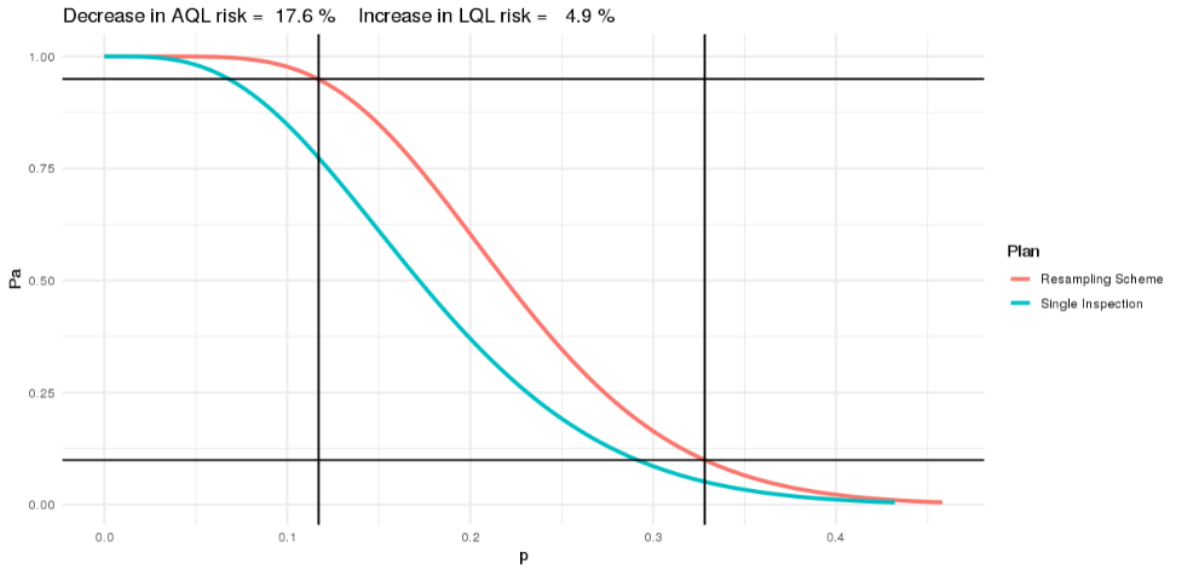
This app allows users to design resampling schemes by trial and error examination of the OC curve to control the overall Producer's risk and Consumer's risk at the desired levels.

5.3.3 Example

Quick frozen fillets are slices of fish of irregular size and shape which are removed from the carcass of the same species of fish suitable for human consumption. A sample unit is the primary container or for individually quick-frozen products is at least a 1 kg portion of the sample unit. Sampling and testing for Odour and Flavour characteristic can be difficult. Occasionally the result may be disputed by the

producer because sensory and physical of fillets are harder to assess and re-examination may be required in the event of a dispute.

Assume that sampling inspection of lots is done using a single sampling attributes plan *n=21*, *c=3* corresponding to PRQ=6.5 (in percent). In the event of reinspection, how much additional risk to the consumer occurs and how much producer's risk can be reduced because of resampling can be examined using this tool (see the figure below).

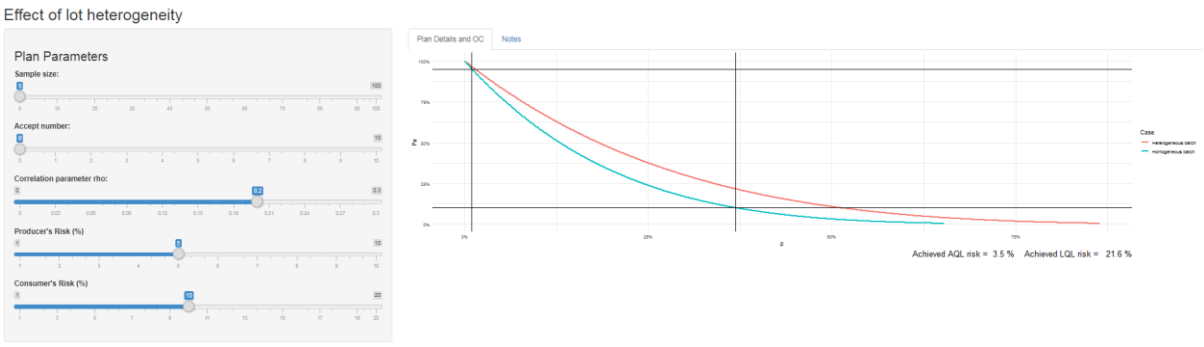


5.4 Inhomogeneous Lots

Lots that are similar in nature are described as homogeneous. Inhomogeneous lots are therefore not similar.

Acceptance inspection and compliance testing often necessitate levels of protection for both the consumer and the producer that require large sample sizes relative to lot size. A given sample size can, however, be made to 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.

The effect of lot heterogeneity on producer's and consumer's risks is demonstrated using the following app.



This app can be accessed via the link: **App5**

This app demonstrates the effect of lot heterogeneity on producer's and consumer's risks. If a lot is homogeneous, the fraction nonconforming is a constant say *p*. When a random sample of size *n* is taken from a lot, the number of nonconforming units *d* follows the binomial distribution which the OC curve is drawn for the homogeneous case.

In heterogeneous lots, the degree of heterogeneity can be described by an additional parameter, ρ (rho), describing the correlation. When ρ = 0, the lot is homogeneous, and the regular binomial case is obtained.

This app shows that the risks can be higher in general, and the consumer's protection may be compromised when the inspection lot fails to be homogeneous, so that some caution is needed when using a sampling plan whose design assumes homogeneity, on lots that are potentially inhomogeneous.

6 Compliance of the Average Level

Instead of controlling the proportion nonconforming *p*, variables plans can also be used to control the mean (i.e. the average) level.

Single Specification Limit Plans: It is assumed that the quality characteristic *X* is normally distributed, although the assumption of normality is not so critical for plans for the average level. The single specification limit plans also assume that either a lower specification limit, *L* or an upper specification limit, *U* is specified.

When the lot standard deviation σ is known based on historical process data, the inspection plan is operated as follows:

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

In the case of an upper specification limit *U*, the acceptability constant *A* is set as $U - k\sigma$, and the acceptance criterion is reversed as $\bar{x} < A$.

The parameters of the plan are *n* and *k* (or *A*).

When the lot standard deviation σ is unknown, it is replaced with the sample standard deviation *S*. The Operating Characteristic (OC) performance for known and unknown σ plans will differ. The plan based on *S* will call for a greater sample size or else the OC curve of the unknown σ plan will be less discriminatory. See Schilling and Neubauer (2008) for more information.

The following app demonstrates how the OC curves are drawn for sampling plans for controlling the average level. Note that the probability of acceptance is plotted against the true mean *instead of the fraction nonconforming* p*.

6.1.1 Example

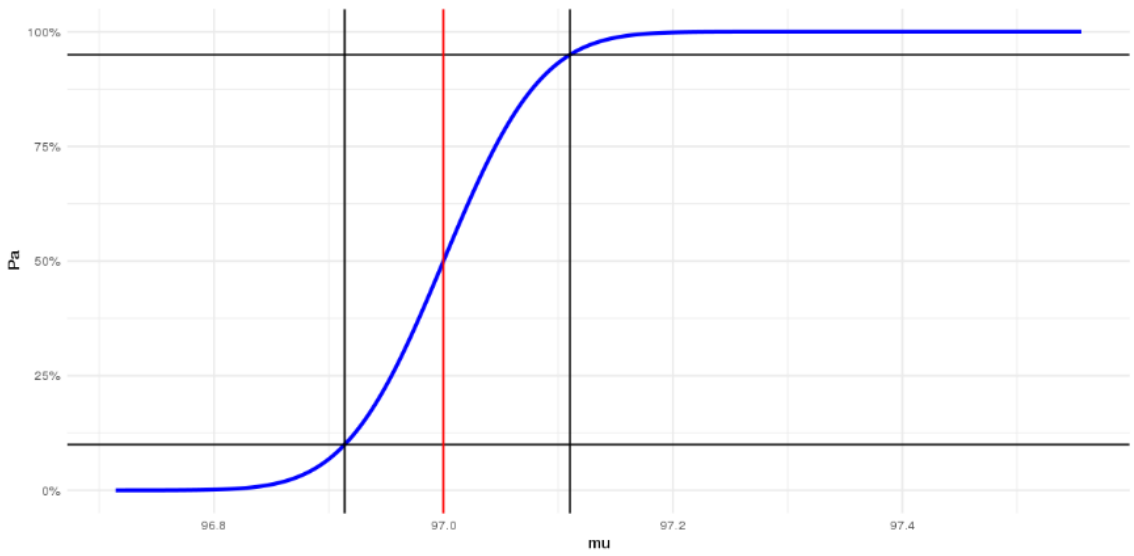
The *Standard for Food Grade Salt* (CXS 150-1985) prescribes that the average content of NaCl shall not be less than 97% on a dry matter basis, exclusive of additives.

One of the lot acceptance criterion is that the average NaCl in a sample of size *n* should be at the minimum level specified, 97%, or more.

Assume that a sample of size 80 is taken for a lot of size 8,000. The sample mean NaCl must be 97% or more for acceptance of the lot. The OC performance of this acceptance criterion is evaluated setting *k=0* in the app.

Even though normal distribution is often a poor fit for compositional proportions, the acceptance criterion is just based on the mean NaCl level and hence the OC curve of the variables plan based on normal distribution can be employed to assess the risks.

The following is a screenshot of the OC curve produced by the tool for *n=80*, *L=80*, *k=0* for the true SD σ=0.6.



6.2 Average Quantity System

The International Recommendation OIML R 87 Edition 2016 (E) *Quantity of product in prepackages* is based on the following three main principles:

1. If Q_{nom} is the nominal prepackage quantity, q_i is the actual quantity of the ith prepackage, then the error for the ith prepackage $e_i = Q_{nom} - q_i$. In a random sample of size *n* drawn from the lot whose prepackage quantity is normally distributed with mean *and standard deviation* σ*, it is ensured that the lot is rejected when* $e_{avg} < c$ *where* c is a constant found satisfying:

$$Pr(e_{avg} < c|\mu = Q_{nom}) = 0.005$$

In other words, the *c* constant is a parameter for the **test of average requirement** which mainly protects the interest of the producer. The producer's risk of rejecting the lot, whose true mean is at the nominal value, is controlled.
For consumer's protection, the probability of rejection is at least 0.9 for unacceptable lots with $\mu < Q_{nom} - 0.74\sigma$. The consumer's risk for unacceptable lots will be no greater than 10%.
The sample size *n* must satisfy the inequality

$$\frac{n(N-1)}{N-n} \geq \frac{t_{0.9,n-1} - t_{0.005,n-1}}{0.74}$$

in order to meet the producer's and consumer's risks pertaining to the test for average requirement.

2. **T1 error control**. Firstly, a parameter *T* is defined in such a way that T is a parameter that ensures that the percentage of prepackages with $q_i < Q_{nom} - T$ is no greater than 2.5 %.

The T1 error is when the individual package error is less than -*T* but equal to or greater than -*2T*.

For the sample of *n* prepackages, d_{T1}, the number of prepackages failing T1 criterion is limited to c_{T1} or less.

In other words, the attribute plan $(n,\ c_{T1})$ is applied to control the proportion of prepackages not conforming to the T1 error criterion.

3. **T2 error** control. Individual prepackages with errors less than -2T are called T2 error prepackages, which are extremely short compared to the nominal Q_{nom}. The lot is rejected in the event of a T2 error. In other words, a zero acceptance number attributes plan is employed to control the proportion of prepackages not conforming to the T2 error criterion.

The International Recommendation OIML R 87 Edition 2016 (E) aims to control both the average quantity as well as the proportion of packages which may be too *short* (having weight or content less than the nominal level).

Sampling plans for small finite size lots are given which are based on the hypergeometric distribution. Large lots are modelled using the normal distribution but adjusted for the small sample size using the Student's *t* distribution.

OIML R 87 Edition 2016 does not evaluate the performance of the sampling inspection scheme using OC curves. The statistical basis for the proposal assumes normality and heavily relies on the Student's t distribution for finding various constants. The limits for T1 and T2 errors serve as a protection limit but their efficacy is not fully evaluated. As a result, this quantity assurance scheme may not achieve the same producer's and consumer's risks for various lot sizes. (It is necessary to resort to simulation studies in order to evaluate the producer's and consumer's risks).

7 Bulk materials

7.1 Introduction

Bulk materials are continuous, and are made of particles of different density and sizes etc. An example is milk powder. It is impossible to view bulk materials present in a lot as a set of distinct objects because there is no way of selecting the items one by one in a way that is not biased when using simple random sampling. This is where a different methodology is introduced, which brings with it sampling bias and non-representativeness.

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. These factors include things such as how the device is employed, and the conditions that the device is used under.

In bulk sampling, the lots of bulk material are 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. Other means of real or synthetic division can also occur.

The following general objectives of bulk sampling were described by Bicking(1978):

1. Characterise the material in place as to location, amount, and value
2. Characterise the material as to grade, any need for further processing, and its destination
3. Control during processing
4. Acceptance on a lot-to-lot basis
5. Determination of weight for purposes of payment
6. Determination of properties that must be known so that the end use will be appropriate
7. Experimentation and analysis to determine further sampling procedures and uses of the material.

Schilling and Neubauer (2008) may be consulted for further references on bulk sampling inspection plans.

Bulk materials being continuous, parts of a samples can be mixed together to form a composite. This composite then gets tested only once, rather than having to do many tests on the individual parts. This is a physical way of being able to average the samples that are composites.

7.2 Sampling Inspection Plans for Compositional Proportions

Compositional characteristics are often quality measures for bulk materials. For example, the percentage protein is a primary quality measure for milk products, and a minimum protein limit such as 34% is set for milk powders. Compositional fractions in a lot of manufactured product can be modelled using the beta distribution. Variables sampling plans based on the normal distribution can only be approximate for compositional proportion and plans based on the normal distribution can involve higher consumer's risks than desired.

Composite sampling is also commonly used for bulk products. Variables sampling inspection plans based on the beta distribution can be designed to control the fraction of nonconforming product.

Let the total bulk material amount sampled be G (such as 100g, 200 ml). G can be expressed as a multiple of the standard or primary unit mass g. Let $m=G/g$ (which need not be an integer). The quantity m is similar to the sample size n fixed for discrete or non-bulk items. Let the random variable $\hat{\mu}$ be the

mean compositional fraction for amount *G*. Note that $\hat{\mu}$ can be a single measurement based on a well-mixed composite and need not be the arithmetic mean of *m* measurements of individual test samples.

The distribution of $\hat{\mu}$ can be fitted using the beta distribution instead of approximating with the normal.

A variables plan based on the beta distribution is implemented as follows:

1. Obtain *m* primary samples or increments of bulk material and form a composite of amount *G*
2. Test the sample(s) and estimate the compositional fraction $\hat{\mu}$ as the average level.
3. Estimate the standard deviation $\hat{\sigma} = \sqrt{\hat{\mu}(1-\hat{\mu})/\theta}$ where *θ* is the known precision parameters found from past data.
4. Accept the lot if $\hat{\mu} - k\hat{\sigma} > L$ where *L* is the lower specification limit. For upper specification limit *U*, the acceptance criterion becomes $\hat{\mu} + k\hat{\sigma} < U$.

If past history is unavailable, a conservative (or a smaller) value of θ can be used.

7.2.1 Example

Milk powder production process generally involves only a very small amount of variability. A conservative value of θ=10000 can be employed to implement the sampling plan based on the beta distribution.

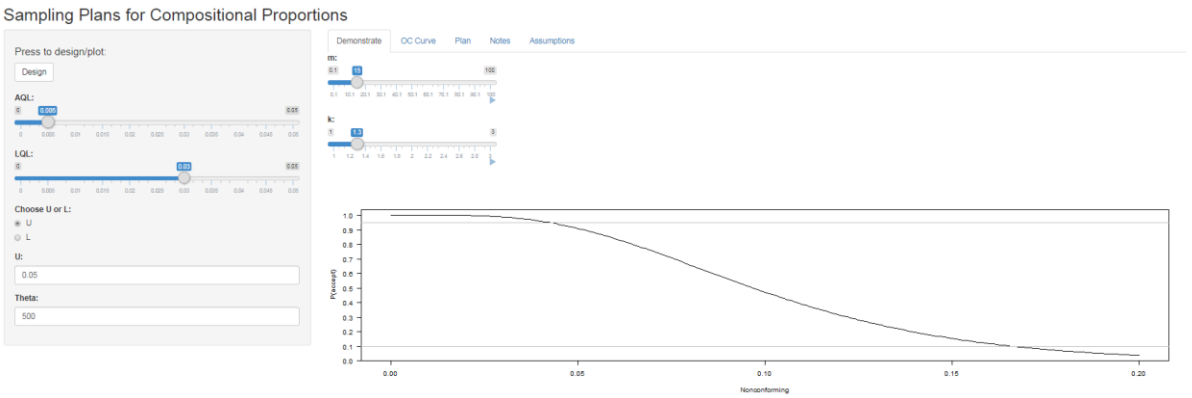
1. Using *m=24* subsamples, a final composite is formed.
2. The estimated protein composition of 33.2% is obtained after lab test.
3. The SD is estimated as $=\hat{\sigma} = \sqrt{\hat{\mu}(1-\hat{\mu})/\theta} = \sqrt{0.332(1-0.332)/10000}$=0.00471. For L=32.4% and *k=1.3*, $\hat{\mu} - k\hat{\sigma} = 0.332 - 1.3 * 0.0015 = 32.6\%$ which is greater than the lower limit L=32.4%. The lot is therefore accepted.

The plan parameters *G* (or *m*) and *k* can be determined for any given two points of the OC curve, such as the Producer's Risk Quality (PRQ) the Consumer's Risk Quality (CRQ). Let α and β be the producer's and consumer's risks respectively corresponding to p_1 and p_2. This two-point design imposes the conditions $P_a(PRQ) = 1 - \alpha$ and $P_a(CRQ) = \beta$. The amount *G* or *m* controls the variability in the estimates $\hat{\mu}$ and $\hat{\sigma}$ while *k* mainly influences the achieved producer's and consumer's risks.

For implementation of the beta plan, a tool is provided. The user will need to input the usual PRQ, CRQ, producer's and consumer's risk as well as the precision parameter θ to design the beta plan, i.e. to determine the number of primary increments ***m*** to be taken and the ***k*** constant. This tool will compute the values of ***m*** and ***k*** and also show the OC curve of a given plan with ***m*** and ***k*** so that the risks can be evaluated graphically.

7.2.2 7.2.2 App for the design of beta sampling plan

The main limitation of the beta plan tool is that it does not incorporate the measurement error in the determination of the compositional fraction using the composite sample.



This app can be accessed via the link: **App10**

7.3 Sampling Plans for Compositional Means

If the lot is homogeneous, sampling plans to control the average level discussed in Section 7 can be used to control the average compositional levels.

It is however necessary to ensure that the normal distributional assumption is satisfactorily met using historical data.

When the lot is heterogeneous, two stage sampling inspection plans are recommended in the literature. For details, see Schilling and Neubauer(2008).

The ISO Standard ISO 11648-1:2003 deals with many of the non-manufactured bulk materials, including particulate matter etc. For food export inspection, these procedures are of limited use. This is because lack of homogeneity in food quality characteristics can be detrimental for consumer protection.

8 Measurement and Inspection Errors

8.1 Measurement Errors for Numerical Data

The term **measurement errors** relates to numerical measurements on the quality characteristic of interest. The following definitions relating to measurement errors are based on ISO-5725.1.

Trueness is the closeness of agreement between the mean of a large number of test results and the accepted reference value. Trueness is normally expressed in terms of bias.

Bias is the difference between the expectation of the test result and the accepted reference value.

Precision is the closeness of agreement between test results. Precision is necessary because tests that are performed in what appear to be identical circumstances, often do not give identical results. This is because of random errors that are present in all measurements, which cannot all be controlled.

Repeatability is the minimum variation in results. By the term **repeatability conditions**, it is meant that results are obtained using the same method, in the same lab, by the same person, and with the same equipment within a short time frame.

Repeatability standard deviation is the standard deviation of the results from the test that are gained under the conditions listed previously. The term **repeatability limit** refers to the expected value equal or less to the difference of two test results with 95% confidence (probability), given that the repeatability conditions were met.

Reproducibility is the maximum variability in results. The **reproducibility conditions** are where test results are obtained using the same method, but with different labs, different people, and different equipment.

The **reproducibility standard deviation** is a measure of dispersion of the distribution of results obtained under the reproducibility conditions. Likewise, the **reproducibility limit** is also the same as the repeatability limit, except it is based on results that are obtained by the reproducibility conditions.

In reproducibility, the conditions do contribute to the random variability of the test results, however, in repeatability the conditions do not contribute to the systematic variability of test results. Hence, repeatability and reproducibility are the two extremes of precision.

Accuracy combines both trueness and precision and is known as the total displacement of a result from a reference value due to random and systematic effects.

An **outlier** is a value which is inconsistent with other members from a set.

Error is the difference between the measured value and the true value of what is being measured. Errors can be either random or systematic. Random errors are uncorrelated, but they affect the results of the repeated measurements. Some examples are: whether they are repeatable, whether they are reproducible, and whether they are stable. Systematic errors are different, in that they affect all measurements taken in the same way and can be identified when the random errors are small. Some examples are: accuracy, bias, and drift.

In order for measurements to be made in the same way, there needs to be a standardised measurement method (to eliminate as many differences as possible). This requires a procedure that contains full details on how the measurements will be carried out.

Accuracy measures can be determined by a series of test results reported by different labs. An accuracy experiment can be considered a practical test of the adequacy of a standard measurement method. The results found in an accuracy experiment will show how effective the standardisation of the method was.

The metrological objective is to produce reliable test results which can later help to make good decisions. On the other hand, acceptance sampling inspection aims to make good decisions on the lot given that there are measurement error related issues.

Sampling inspection plans can be designed and adjusted when measurement and classification errors of random kind are present. This adjustment can be done for both attribute and variables type sampling plans. The term **inspection error** is used to mean the random errors of classifying a conforming items as nonconforming and vice versa. For example, certain sensory tests are subjective in nature, and even a trained analyst is expected to cause inspection errors. In the next section, a procedure for adjusting the single sampling attribute plans for inspection errors is briefly described.

8.2 Measurement Error Adjustment

Hahn (1982) presented simple methods of removing the measurement errors from the observed numerical data. Even though the examples given by Hahn related to net weight assurance for containers, they can be extended to a general situation. The mathematical theory on the effect of repeatability error and bias on the OC curve of a variables plan is discussed in Owen and Chou (1983).

Let Y_i, i = 1, 2,…,n be *n* apparent or observed measurements. Let $\bar{x}$ and S_y be the sample mean and standard deviations respectively.

Let X_i, i = 1, 2,…,n be the true but unknown levels corresponding to these measurements. Under the simple additive error model $Y = X + Z$ where Z are the measurement errors, the variances are decomposed as

$$\sigma_Y^2 = \sigma_X^2 + \sigma_Z^2$$

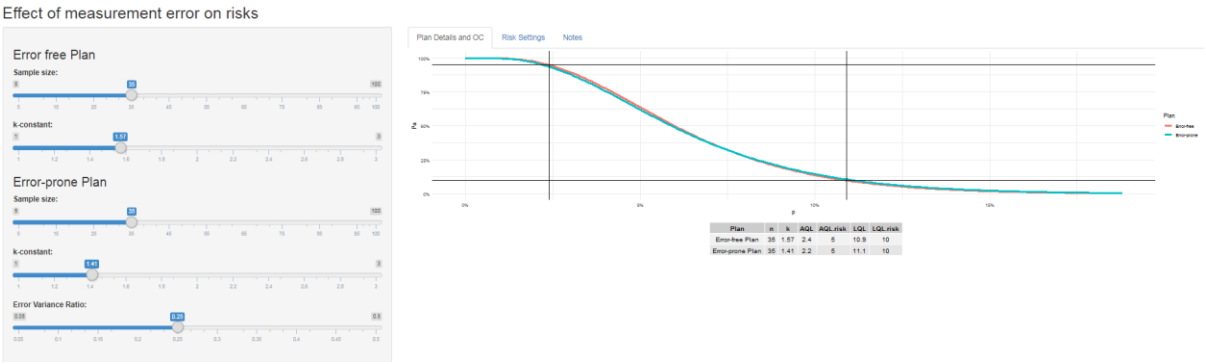
The ratio σ_Z^2/σ_Y^2 is called-the `error variance ratio`. Good knowledge of this ratio based on past measurement system studies is required to be able to allow for measurement error in variables plans.

The OC curve of the *k*-method variables plan can be adjusted for given error variance ratio. The acceptability constant will be smaller when adjusted for the repeatability SD in general.

In order to adjust for the bias, the actual measurements can be converted to bias adjusted measurements and then the variables plan can be applied.

8.2.1 Tool for adjusting variables plans

This tool requires the user to specify the error variance ratio, so that the OC curves of the variables plan with and without measurement errors can be compared and adjusted for the measurement errors.



The default settings shows how the *k* constant becomes smaller in the presence of measurement errors. This app can be accessed via the link: **App15**

8.3 Inspection Errors (Attribute Plans)

Schilling and Neubauer (2008) details some of the reasons for inspection inaccuracy as follows:

1. Wilful errors which include: criminal acts, and falsification to make it more convenient for the inspector.
2. Intermediate errors due to: bias, rounding off etc. Failure to call a defect when it is close to the specification limit falls into this category also.
3. Involuntary errors due to: blunders, fatigue, or other human imperfections

Inspection errors are caused when testing a unit of inspection for its conformance. The sources of inspection errors include human error, instrument error, or any other measurement related errors. Type I errors are when a true conforming unit is placed as apparently nonconforming. The type II errors are when a true nonconforming unit is placed as apparently conforming.

The impact of these two types of inspection errors on the OC curve has been studied by many. When inspection errors are present, they generally increase the producer's risk when compared to the consumer's risk. The impact of inspection error is particularly greater for zero acceptance number plans.

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

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

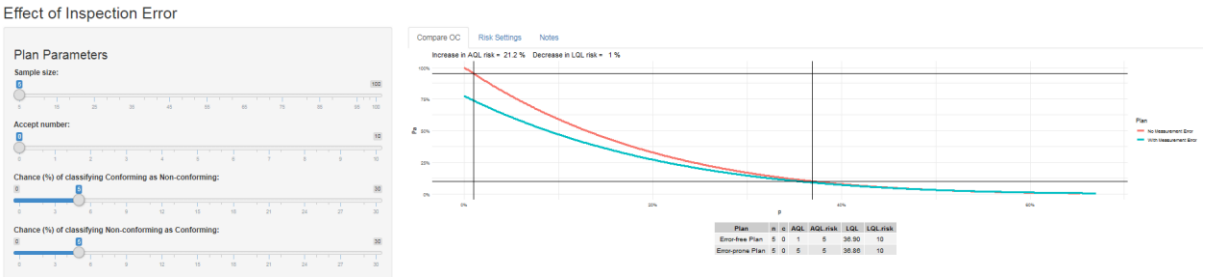
e_1 is the probability of classifying a conforming item as nonconforming and

e_2 is the probability of classifying a nonconforming item as conforming.

It is established in the literature that e_1 is more important than e_2, the OC curve of the single sampling plan is influenced more by e_1 than e_2.

8.3.1 Tool for attribute plan inspection error adjustment

This tool allows a comparison of the OC curves of single sampling attribute plans with and without inspection errors. For example, conformity testing procedures (see Section 1.23) are based on 95% confidence intervals so that, e_1, the Type I error probability of misclassifying a conforming item as nonconforming, is fixed as 0.05 by design. As a result, the attribute classification using a conformity test procedure will hugely increase the producer's risk when the measurements are closer to the specification.



This app can be accessed via the link: **App7**

Unlike variables plans, adjustment for the inspection errors cannot be done for attribute inspection plans. The remedy lies in repeated testing so that the overall Type I misclassification errors becomes small. This is discussed in the next section.

8.4 Repeated Testing

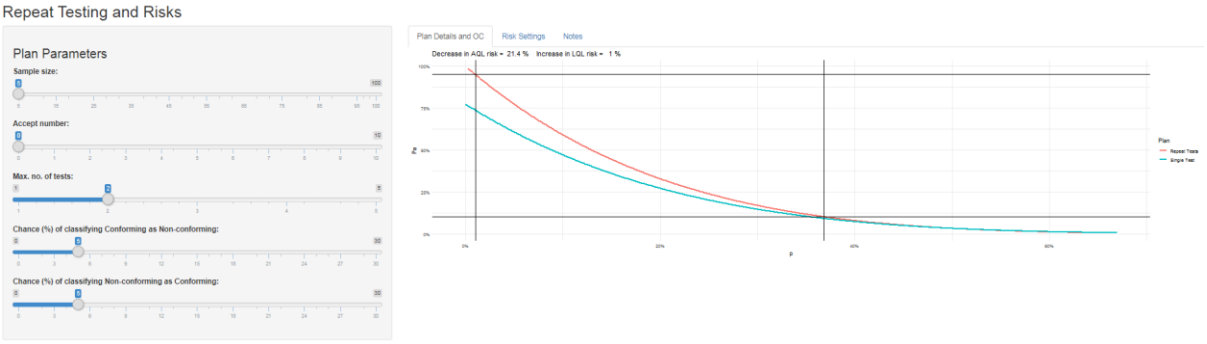
One of the approaches to mitigate the impact of inspection and measurement errors is retesting. If an item is found to be nonconforming, it can be tested again. This is because production of nonconforming units is expected to be in a smaller proportion and only occasionally will retesting be used. Even though conforming units can be re-tested, this strategy is often not beneficial due to economic and other reasons. It is more important to try control the Type I inspection error (of classifying conforming items as nonconforming) because the lot quality is generally good rather than bad. Therefore, it makes more sense to re-test the items that are apparently nonconforming as compared to the items that are apparently conforming. Re-testing of an item can be done up to a maximum of ***m*** times. This means that each sampled item will have a maximum of ***m*** chances for conformance. There needs to be the

assumption that testing will not degrade the quality of the item. If a sample is of non-discrete type physical material such as powder, then it is assumed that ***m*** homogeneous sub-samples can be made for every unit of the sample.

If classification errors are large, retesting of nonconforming items is necessary to reduce the adverse impact of inspection errors on the producer's risk. The presence of inspection error affects the consumer's risk, but it can be compensated for by adjusting the sample size slightly. However, the use of repeat tests is particularly essential to avoid rejection when the quality is in the parts per million range.

8.4.1 App to evaluate repeated testing

A single sampling attribute plan can be evaluated using the tool shown below. The OC curves of the single sampling plan with and without inspection errors are shown. The plan parameters can be adjusted so that the risks are maintained at the desired PRQ and CRQ.



This app can be accessed via the link: **App4**

8.5 Fractional Nonconformance Inspection

The term fractional nonconformance or **FNC** refers to the probability of an error-prone observation breaching the specification limits.

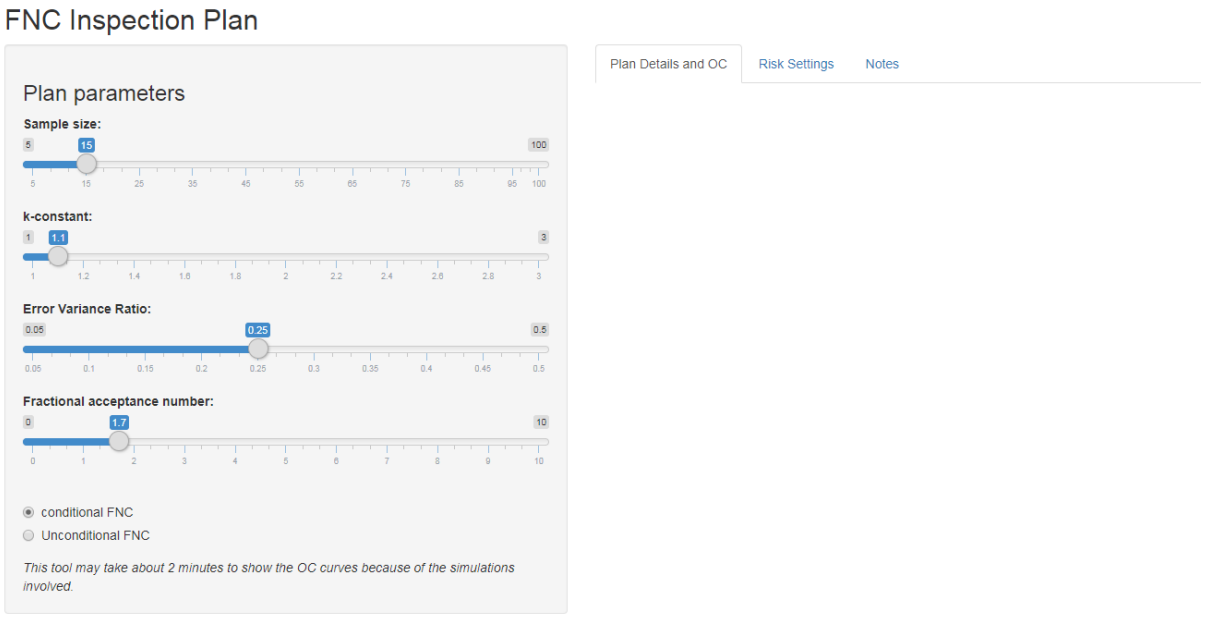
An observed measurement *Y* is classified with certainty as conforming or not for given specification limits only when there are no measurement errors. Analytical testing of fat content etc. involves considerable measurement uncertainty, often up to half of the observed variation. The distribution of the measurement errors (*Z*) can be fairly well ascertained using past calibration studies. Measurement error uncertainty results only in an estimated probability of conformance of a unit. The probability of nonconformance of an individual unit based on the error-prone measurement is defined as the *fractional* nonconforming unit. The following figure illustrates the concept of fractional nonconformance. Given the measurement error distribution, the probability of breaching the upper specification limit, $\hat{p}_{iu}$ is the FNC value.

Even though the observed measurement is below the USL, there is still a small chance that the true value of the sample is nonconforming because of the measurement errors.

As an example, consider five numerical measurements of a weight characteristic (100.5, 100.7, 100.2, 100.6, 100.4). If the measurement error distribution is known to be normally distributed with mean zero and standard deviation 0.25, i.e. N(0, 0.25), the probabilities of these five measurements falling below the lower specification limit of *L=100* are (0.023, 0.003, 0.212, 0.008, 0.055). The sum of all the FNC values, $\sum \hat{p}_{iu}$ is given by 0.3. This sum can be compared with a fractional acceptance number such as 0.5. This approach is similar to comparing the number of nonconforming units *d* with the acceptance number *c* in the attribute plan. The plan can also be implemented using the mean FNC which can be compared with the maximum allowable fraction nonconforming.

A conditional version of the FNC can also be defined. The probability distribution of the measurement error *Z* conditional on the given observed measurement value *y* is used to obtain the conditional FNC, $\hat{p}_{ic}$ values. The additional knowledge that an apparent measurement has been made and its distance from the sample mean contains additional information on its nonconformance.

A shiny tool to evaluate the OC curves of the FNC based plans and measurement error adjusted variables plans is shown below:



This app can be accessed via the link: **App16**

The conditional FNC based adjustment for measurement error is more powerful because it provides better discrimination between good and poor-quality lots.

The main advantage of the FNC inspection plan is that the plan can be used even when the underlying quality characteristic is not normally distributed. On the other hand, a variables plan requires the underlying distributional assumptions to be met. If normality does not hold, the OC curve of the variables plan based the normal assumption is not fully trustworthy.

In Section 1.25, a further tool to compute and chart the FNC values for user data is available.

8.6 Conformity Testing

Conformity testing, also known as evaluation of conformity or compliance testing, is used to assure that an 'entity' meets a specific requirement and/or regulatory standard. In this context entity refers to the sample actually tested.

The objective of conformity assessment differs from that of acceptance sampling - acceptance sampling uses a limited number of samples to determine whether to accept or reject a lot of some product whereas, in contrast, in conformity testing the inference is limited to the 'entity' i.e. the sample tested. In other words, conformity testing is a procedure for making a decision about the particular sample whereas the proportion nonconforming in a lot is the main quality measure of interest in acceptance sampling.

Examples of conformity testing include the test of the concentration of some trace elements in the blood of employees for their health evaluation, the analysis of an athlete's urine to detect abuse of xenobiotic anabolic steroids, testosterone and doping etc.

The specification for the quantifiable characteristic, such as the maximum allowable concentration of a drug or trace element in blood for normal people, is called as a limiting value (LV) in the conformity testing protocols. The LV could be understood as either a minimum value (Lower limit or LSL) or a maximum value (Upper limit or USL), or both. The interval containing all permissible values of the characteristic is called the region of permissible values. A conformity testing protocol provides assurance of conformity by checking whether the measurement of interest falls within the region of permissible values or not. Conformity can be declared if and only if the whole uncertainty interval is located within the region of permissible values.

Measurement and sampling uncertainties, including metrological traceability, become crucial for the declaration of conformity, especially when the measured value is close to the set limiting value.

Measurement uncertainty is usually reported as an uncertainty interval, given in the form of a confidence interval. The common practice for conformity testing is to compare the MU interval around the measurement result with the region of permissible values.

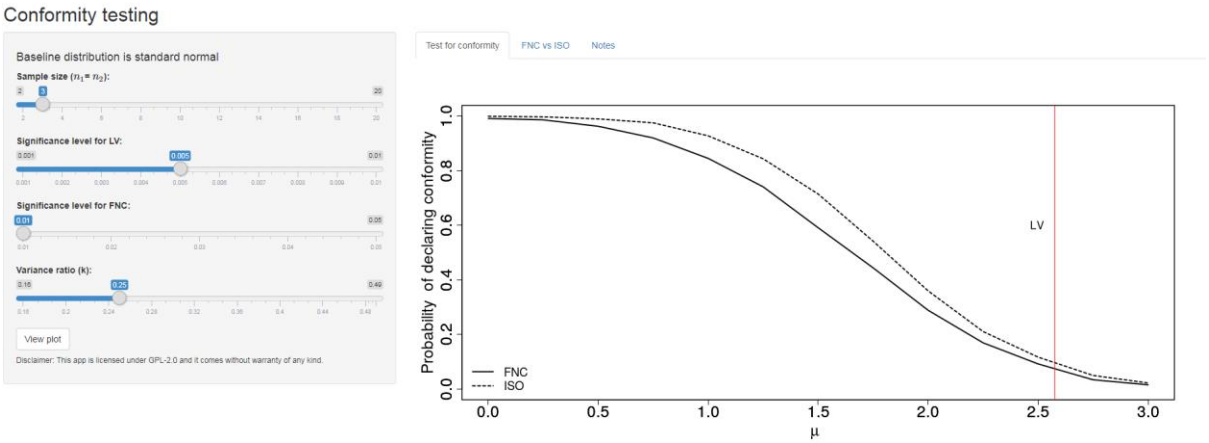
ISO 10576-1 International Standard recommends performing the conformity test as a two-stage procedure, which was initially proposed by Holst, Thyregod, and Wilrich (2001). The rules for asserting conformity or nonconformity are:

- Assurance of conformity: The uncertainty interval is inside the region of permissible values.
- Assurance of nonconformity: The uncertainty interval is included in the region of non-permissible values.
- Inconclusive result: The uncertainty interval includes LV.

The main disadvantage of the conformity testing procedure is that in many cases, inconclusive results will be obtained even though a sample is conforming but due to measurement errors, the uncertainty interval includes the limiting value.

The ISO 10576-1 Standard does not encourage reduction of measurement errors by design and hence poorer measurement systems will produce a higher proportion of inconclusive results. Hence producers are forced to guardband in order to reduce the inconclusive result for a measurement. In other words, the conformity testing procedures, not being acceptance sampling procedures, do not aim to make a decision on the lot but only concerned with the risk that the measured sample is conforming or not.

A FNC based two-stage conformity testing procedure is found to reduce the probability of incorrect declaration of conformity or inconclusive result for nonconforming entities (Type II error) when the number of test samples is greater than one and this superiority becomes more significant when the sample size increases. A new tool that looks at the probability of declaring conformity for both the FNC and ISO methods of assessing conformance in the presence of measurement errors is presented below.



This app can be accessed via the link: **App9**

A sample size, the significance level for the limiting value (LV), the significance level for FNC and the variance ratio each need to be selected. Plots are then displayed which show the probability of conformity and nonconformity for ISO two-stage and FNC testing procedures to compare. It is assumed that both these conformity testing procedures have equal samples that are tested.

9 Special Purpose Sampling Inspection Tools

The following is a quick summary of certain special purpose sampling inspection plans and the tools for implementing them. These tools may not have universal applications.

9.1 Microbiological Sampling Plans

Sampling inspection for food safety forms a special class of acceptance sampling plans. The International Commission on Microbiological Specifications for Foods (ICMSF, the Commission) has formulated a number of sampling inspection plans for food safety.

Their online tools are available at the ICMSF sampling plan tools website.

The ICMSF plans evaluate the producer's and consumer's risks using OC curves. It is essential to consult these tools to assess the discriminatory performance of the chosen plan.

10 Summary

Ad hoc or convenience sampling involves a sample being taken from a part of a population that is nearby and convenient. It is non-probability sampling and is sometimes used in pilot testing. There is no basis for it, other than the samples being readily available for testing. Even though convenience sampling can be cost effective in terms of testing, it is not possible to quantify the producer's and consumer's risks for such plans. The potential sampling error and lack of representation of the lot render them very unreliable due to the bias this ad hoc sampling inspection carries.

Sampling inspection plans for routine inspections are often single sampling plans. Both attribute and variables sampling plans intended for routine inspection assume that physical sampling is done correctly, and no errors are present in testing or measuring the variables of interest.

The evaluation of the risks to the producer and consumer for such routine sampling plans can be done using their Operating Characteristic (OC) curves. Both the producer and consumer must be fully aware of the risk or chances that good quality lots are rejected as well as poor quality lots being wrongly accepted as good. It is necessary to control these risks with the appropriate choice of the sample size and set an acceptance criterion accordingly.

It is also important to recognise that the routine plans may fail in the presence of excessive measurement or inspection errors. Routine sampling plans can be adjusted for measurement uncertainty and then the risks can be evaluated. The OC curve again serves as the appropriate tool for making this risk assessment.

With the advancement of software technology, it is easy to evaluate the underlying risks quantitatively using online web tools. A number of such tools and examples are presented in this document.

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Appendix V

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