

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: [codex@fao.org](mailto:codex@fao.org) - [www.codexalimentarius.org](http://www.codexalimentarius.org)

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CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING**

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**Revised Information Document for the *General Guidelines on Sampling* (CXG 50-2004)**

*(submitted by Germany and New Zealand)*

The Annex to this document contains the revised information document for consideration by CCMAS44.

## Information Document for the *General Guidelines on Sampling (CXG 50-2004)*

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# 1 Introduction

The purpose of this document is to provide additional information on the sampling plans referred to in CXG 50, including background and examples for each of the main types of sampling plan. A link to the app1 for the design and evaluation of these sampling plans is included. Links for new apps will be included when they become available.

The document consists of two parts:

**Part 1** consists of Section 2 and Section 3 and contains general information relating to the design of sampling plans, including examples:

Section 2.1 deals with principles behind the “classical” approach to sampling plans based on specification of producer’s and consumer’s risks, to allow for any level nonconforming in a lot.

Section 2.2 contains information about the design process, including suggestions on the use of pre-defined sampling plans, such as ISO plans, as well as specifications of allowable risks, as a starting point.

Section 2.3 describes the different apps that were provided with the original package and provides a link to an on-line app for the design of attribute and variables sampling plans [with and without](#) measurement uncertainty.

Section 3 contains case studies showing the main types of sampling plans mentioned in CXG 50, including some where measurement uncertainty is non-negligible.

Sections 3.1 and 3.2 deal with various types of attributes and variables plans, including an explanation of the basis underlying the plans in the ISO2859 and ISO3951 standards.

Section 3.3 discusses sampling for bulk materials with a particular focus on the plans for mycotoxins described in the *General standard for contaminants and toxins in food and feed* (CXS 193-1995).

Section 3.4 covers other sampling plans. Examples include attribute sampling plans with an AQL of 6.5 taken from ISO, and ad hoc plans using small numbers of samples formed into composite samples for testing.

**Part 2** consists of Section 4 and Section 5 and contains more background on sampling plans including a statistical appendix:

Section 4 includes statistical derivation of attributes and variables plans when measurement uncertainty is negligible and references the sampling plans in Part 1.

Section 4.3 discusses measurement uncertainty and its role in acceptance sampling.

Section 4.6.5 covers the basis for sampling plans for Mycotoxins derived by Whitaker et al. that are special cases of plans for bulk materials and outlines the statistical complexity for the future development of sampling plans for bulk materials.

Section 4.7 contains information about other sampling plans, including 3-class attribute plans, used for microbiological assessments.

~~Section 5.5.2 discusses Bayesian plans based on a risk-based approach. More specifically, the plans are based on the concepts of specific consumer risk and conformance probability from JCGM 106. An overview of Bayesian risks is also provided. This approach was developed in ISO TC 69 SC 5 WG 10 and is described in a technical report as well as in a separate publication.~~

~~Section 5.5.3 discusses Bayesian plans based on a utility-based approach. Standard plans are provided for the practitioner. This approach was developed in ISO TC 69 SC 5 WG 10 and is described in a technical report as well as in a separate publication.~~ **Part 3 consists of Section 6 and provides information regarding Bayesian sampling plans.**

Section 6.2-5.5.2 discusses Bayesian plans based on a risk-based approach. More specifically, the plans are based on the concepts of specific consumer risk and conformance probability from JCGM 106. An overview of Bayesian risks is also provided. This approach was developed in ISO TC 69 SC 5 WG 10 and is described in a technical report as well as in a separate publication.

Section 6.3-5.5.3 discusses Bayesian plans based on a utility-based approach. Standard plans are provided for the practitioner. This approach was developed in ISO TC 69 SC 5 WG 10 and is described in a technical report as well as in a separate publication.

Note:

Some Excel formulas in the text (and in the Excel file provided) use the English style, with decimal points and comma separators.

# PART ONE

General information relating to the design of sampling plans

Examples and case studies

## 2 Design of sampling plans

### 2.1 Principles behind the design of sampling plans

#### 2.1.1 Producers and consumers

Depending on the nature of the transaction, a producer could include either:

- A manufacturer, supplier or seller of a food product or ingredients, or
- A regulatory agency providing assurance for exported product to an importing country agency.

and a consumer could include:

- A customer purchasing the food product or ingredient for the manufacture of other food products, or
- An importing country regulatory agency seeking to provide assurance to the individual consumers living in that country, or
- An exporting country regulatory agency providing official assurance to an importing country agency acting on behalf of the importing country, or
- An individual purchasing a food product, although individuals would not normally be able to carry out lot-based inspections of foods, or
- A manufacturer purchasing ingredients for the production of a food product.

#### 2.1.2 Producer's and consumer's risks

Acceptance sampling plans always carry intrinsic risks that a lot of poor quality will be incorrectly accepted or that a lot of good quality will be incorrectly rejected. These two risks are generally referred to as the consumer's risk and the producer's risk, respectively.

However, by following statistical principles sampling plans can be designed to control these risks to allowable levels. This is achieved by specifying a particular producer's risk quality level, the PRQ, and a particular consumer's risk quality level, the CRQ, along with a corresponding producer's risk (PR), the probability of rejecting a lot with quality level equal to the PRQ, and a consumer's risk (CR), the probability of accepting a lot with quality level is equal to the CRQ, respectively. Once these four parameters, the (PRQ, CRQ, PR and CR), are specified the sampling plan is uniquely determined and the probability of acceptance and therefore the producer's and consumer's risks at any quality level can be calculated.

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

The *Principles for the Use of Sampling and Testing in International Food Trade* (CXG 83-2013) recommends that ideally, producers and consumers should agree on a sampling plan prior to its use. However, direct collaboration/negotiation between producers and consumers on the sampling plan to be used or the way in which it will be used might not always be possible.

This is the traditional approach to the design of sampling plans. In this approach, risks are calculated on the basis of a known quality level, e.g. "if a lot contained  $X\%$  of nonconforming items, then the probability of acceptance would be  $P$ ."

However, it is also possible to introduce a Bayesian framework which allows other definitions of risk, involving the use of a prior distribution based e.g. on past inspections of a characteristic in a product. Bayesian methods can potentially allow the user to achieve a considerable reduction in sample size.

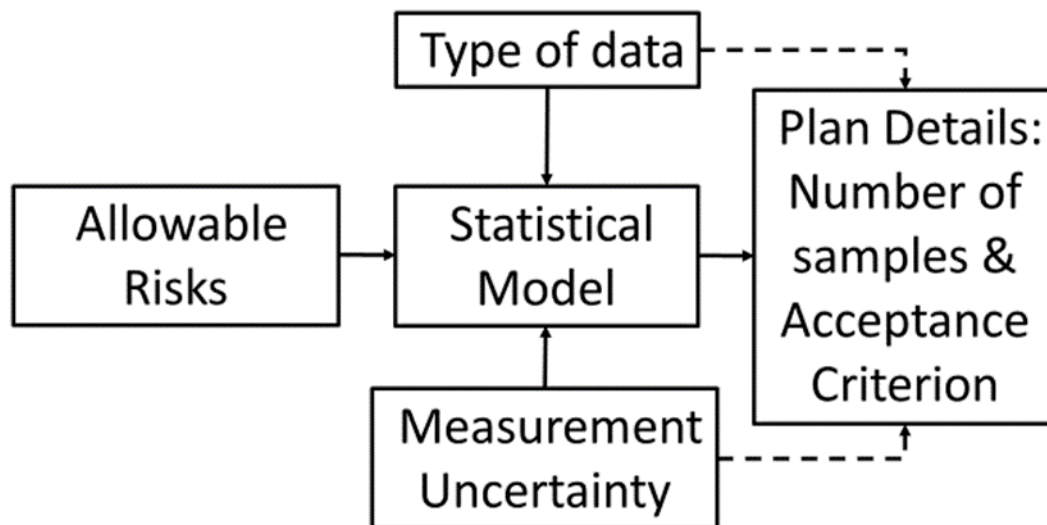
### 2.2 Design of sampling plans

#### 2.2.1 Overview of the design process



**Figure 1 Sampling Plan Design Process**

## Sampling Plan Design Process



This diagram shows a high-level view of the design process, showing the fundamental inputs to the design as reflected in the workflow in the *General Guidelines on Sampling* (CXG 50-2004).

Specification of the allowable risks is a key input, the producer's risk and the consumer's risk might both be specified or only one of those risks might be specified. In the ISO plans only the consumer's risk would be specified for the inspection of isolated lots of incoming goods whereas plans based on only the producer's risk might be used in the context of a long-term supply contact between a manufacturer and a customer.

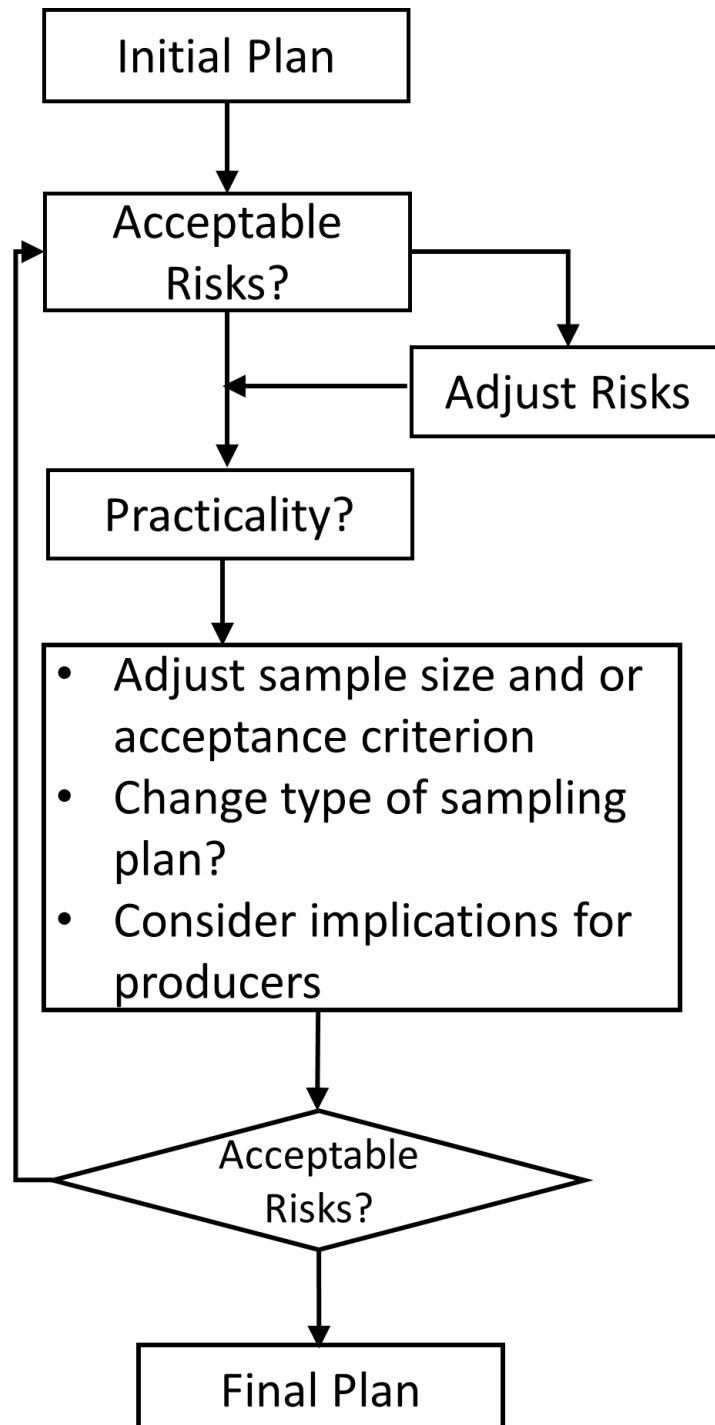
The type of data and non-negligible measurement uncertainty will determine the statistical model that is used to work out the details of the sampling plan. For example, if one has attributes data the statistical model is based on the binomial distribution, whereas if the one has variables data the model could be based on the normal distribution or in the case of a compositional proportion the beta distribution, or possibly some other distribution (not dealt with in CXG 50-2004).

The type of data and the presence of non-negligible measurement uncertainty also determine the form of the acceptance criterion; in the simplest case where measurement uncertainty is negligible an attributes plans is specified by the number of samples  $n$  and the acceptance number  $c$ , but a variables plan is specified by the number of samples  $n$  and the acceptability constant  $k$ . The form of the acceptance criterion could be more complex for variables plans where measurement uncertainty is non-negligible.

### 2.2.2 Process for the design of sampling plans

This diagram shows a process that might be used to design a sampling plan.

Figure 2 Process for Design of Sampling Plans



### Step 1 Select an Initial Plan as a starting point:

The design of sampling plans requires specification of the allowable consumer's and producer's risks following which sampling plans are designed using statistical methodology.

However, it is often difficult for designers of plans to decide on appropriate levels of allowable risks [that should possibly be decided jointly by both the producer and the consumer], so that the following process is suggested as a way of proceeding.

The starting point could be a plan from either ISO 2859-1 or ISO 3951-1, depending on whether one has attributes or variables data. In CXG 50-2004 Appendix 1 plans with selected PRQ and CRQ levels were used as starting points.

The following plans based on these ISO standards could be used as starting points for the design of plans. In these plans the producer's risk (PR) is 5% and the consumer's risk (CR) is 10%.

Table: Attributes plans from ISO 2859-1 for PRQ = 6.5%

PRQ	c	n	CRQ
6.5%	0	2	68.4%
6.5%	0	3	53.6%
6.5%	1	5	58.4%
6.5%	1	8	40.6%
6.5%	2	13	36.0%
6.5%	3	20	30.4%
6.5%	5	32	27.1%
6.5%	7	50	22.4%

Table: Attributes plans from ISO 2859-1 for PRQ = 1.5%

PRQ	c	n	CRQ
1.5%	0	8	25.0%
1.5%	0	13	16.2%
1.5%	1	20	18.1%
1.5%	1	32	11.6%
1.5%	2	50	10.3%

Table: Variables plans from ISO 3951-1 for PRQ = 2.5% ( $\sigma$ -method)

PRQ	k	n	CRQ
2.5%	1.115	3	35.4%
2.5%	1.240	6	23.7%
2.5%	1.419	8	16.7%
2.5%	1.366	8	18.1%
2.5%	1.370	12	15.9%
2.5%	1.439	16	13.2%
2.5%	1.456	21	12.0%
2.5%	1.533	29	9.76%
2.5%	1.606	42	7.95%

### Step 2 Examine the OC curve:

A plan taken directly from a standard might not necessarily be suitable for a particular application, it might be too stringent or not stringent enough. Users need to consider whether the acceptance probability, the proportion of lots that will be accepted in the longer term by the plan, is acceptable at various levels nonconforming that might occur, for example:

- Is the probability of acceptance of lots containing 10% (or 5% or 20%) of nonconforming product acceptable?

### Step 3 Adjust the Risks to the desired levels.

Step 4 Consider the practicality of the proposed sampling plan:

A key consideration is the number of samples that will need to be taken and tested for each lot that is inspected, and the expected number of lots that will be inspected in any year.

In general sample numbers can be economized by:

- Increasing the CRQ or decreasing the PRQ, or both
- Increasing the producer's and/or the consumer's risks PR and CR (both might be increased)
- Use of indifference quality plans for commodity characteristics (refer CXG 50-2004 3.2.2)
- Requiring a lower stringency at the individual lot level in favour of assurance in the longer term.

Specific ways to economize sample numbers include:

- Not assessing compliance of the lot on an individual basis but treating the product in the lot as a bulk material and inspecting the lot as a whole rather than focusing on compliance of the individual items
- Use of variables plans instead of attributes plans where applicable.
- Use of known lot standard deviations, if they are known.
- Use of plans based on the beta distribution for compositional characteristics.
- Use of offsets (including offsets to allow for non-negligible laboratory bias) (refer CXG 50-2004 3.2.3)
- Bayesian plans may be another way sample numbers might be reduced.

Step 5 Examine the OC curve to check that the risks are acceptable.

Step 6 Adopt the sampling plan or return to step 3 and repeat the process.

Measurement uncertainty should also be allowed for if it is non-negligible.

The resulting plan should be reviewed to ensure it will meet users' expectations and, where appropriate to ensure that it is fair to producers – choice of a suitable sampling plan should focus on the control of risks and the total cost, especially the costs of incorrect acceptance and incorrect rejection of lots, rather than just the cost of sampling and testing.

However, if multiple characteristics are inspected when assessing compliance to a standard, there is a risk that the producer's risk of inappropriate rejection will increase with the number of characteristics inspected. This risk can be mitigated by reducing the producer's risk on each of the individual sampling plans, so that the overall producer's risk is not excessive. This measure should be applied only among 'similar' characteristics, such as compositional characteristics.

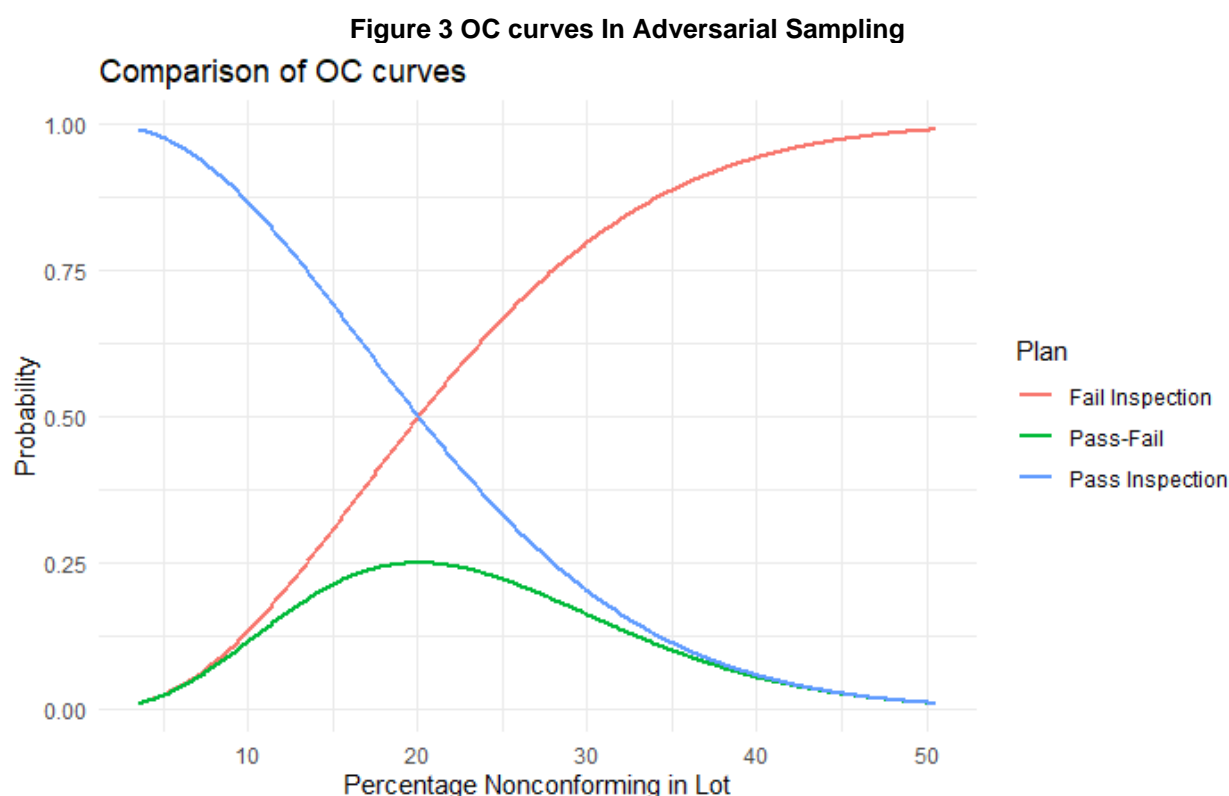
In the interests of fairness, designers of plans should also take account of the measures that the producer may have to take to ensure compliance, remembering that in Codex, CXG 50-2004 will be applied mainly to compositional characteristics and commodity defects (refer CXG 50-2004 3.2.2 Fairness).

### 2.2.3 Use of the same sampling plan by the producer and the consumer

It is not always appropriate for a producer to use the same sampling plan as that used by a consumer, particularly if the consumer is also going to inspect the lot.

The following plot shows the probability of acceptance of a lot for a given plan [in blue] for the inspection and the probability of rejection using the same plan [in red]. The green line shows the probability that a lot will be accepted in the producer's inspection but then be rejected in the consumer's inspection. The maximum probability of a lot being accepted on an initial inspection and then being rejected on a subsequent inspection using the same plan is 25% that occurs when the probability of acceptance by the plan is 50%.

This shows that producers are potentially disadvantaged in adversarial sampling situations, where both the producer and the consumer both test the product; that should be considered in the design of plans to ensure fairness.



The OC curves on the plot have been calculated as follows.

- The probability of acceptance (the blue line) is the usual calculation, described in section 3.1 for attributes plans and section 3.2 for variables plans for cases when the measurement uncertainty is negligible. If measurement uncertainty is non-negligible it is necessary to use the app.
- The probability of rejection (red line) is easily calculated since if a lot is either accepted or rejected:  

$$\text{Probability of rejection} = 1 - \text{Probability of acceptance}$$
- The probability of acceptance of a lot and subsequent rejection upon reinspection (the green line) is the product of the two probabilities:

$$\text{Probability (Pass – Fail)} = \text{Probability of acceptance} \times \text{Probability of rejection}$$

Obvious mitigations include:

- the producer using a plan that reduces the risk of rejection if the lot is inspected by a consumer,
- for the producer to operate at a quality level that ensures a lower rate of rejection if the lot is inspected by the consumer,
- consumers might rely on the producer's inspections rather than inspect the lots themselves.

## 2.2.4 CCMAS endorsement of sampling plans

Commodity Committees might propose sampling plans for provisions, or they might propose outcomes for sampling plans in terms of the maximum allowable producer's and consumer's risks for the inspection of a provision. This means that there is often more than one option for the sampling plan that could be used. The latter approach, specifying the outcome, is needed when measurement uncertainty is non-negligible as the plan will depend on the lot standard deviation, that will vary among producers.

The OIML International Recommendation R087<sup>1</sup> for the average quantity system in prepackaged is an example where maximum allowable producer's and consumer's risks are specified:

### Producer's Risk

The probability of rejecting a lot whose true mean weight is equal to or exceeds the label quantity e.g. weight should be at most 0.5%.

<sup>1</sup>OIML Recommendation (OIML R 87): Quantity of product in prepackages, International Organisation for Legal Metrology, Paris (2016)

### Consumer's Risk

The probability of accepting a lot whose true mean weight is less than the label quantity e.g. weight by more than a specified amount (not provided here) should be at most 10%.

These risk specifications are used in two ways to design plans for the inspection of quantities by weights, in a variables-plan to check compliance of the average weight and in an attributes plan to check that there is not an excessive proportion of deficient packages, weighing less than the label weight by more than a certain amount, in the lot.

## 2.3 Apps for the design and evaluation of sampling plans

This section contains a brief description of each of the three apps provided with the CXG 50-2004 package, along with links from where they can be run. References to the relevant sections in CXG 50-2004 are provided and further information can be found in this document.

The apps all follow the same general format and have been designed to:

- *Plan Evaluation* of a specified sampling plan to calculate the probability of acceptance in terms of the percentage nonconforming<sup>2</sup> in a lot and to show the Operating Characteristic (OC) curve, and to calculate the producer's and consumer's quality levels PRQ and CRQ corresponding to specified producer's and consumer's risks (with default values of 5% and 10% respectively)
- *Plan Design*, the design of a sampling plan, working out the number of samples and the acceptance criterion, the acceptance number 'c' or the acceptability constant 'k', from specifications of the producer's and consumer's risk quality levels and their associated probabilities of rejection and acceptance, respectively.

### 2.3.1 Description of apps

**App1** relates to the design and evaluation of attributes sampling plans and variables plans for normally distributed characteristics, including situations where measurement uncertainty is also normally distributed. The app can be used to examine and compare the producer's and consumer's risks and the OC curves for different sampling plan options.

In attributes plans, the app can evaluate a sampling plan specified by a sample size 'n' and an acceptance number 'c' or design a plan based on the specified values of the PRQ, CRQ, producer's risk, and consumer's risk. The OC curves and the producer's and consumer's risks are shown for both plans.

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 app also takes account of measurement uncertainty with the values of the components of measurement uncertainty and the lot standard deviation where these values have been specified.

This app has been deployed on the shinyapps.io server:

<https://codex-testing.shinyapps.io/codex-testing-SamplingPlan/>

Links for following apps will be included when they become available.

App2 relates to Fractional Nonconformance Plans and allows users to evaluate a specified plan, specified by the number of samples and the maximum allowable value of the individual sample FNC values for acceptance of the lot, or to design a sampling plan from specifications of consumer's and producer's risks. See section 3.2.4 for further details.

App3 relates to plans for the assessment of lots for compositional characteristics. These plans are based on the beta distribution so that it is possible to apply the plan based on a single test of a composite sample formed from a specified number of increments. The app can evaluate a specified plan or design a plan based on specified risks. Refer to section 3.3.23 for details.

<sup>2</sup>The proportion of nonconforming items expressed as a percentage. Also called the proportion nonconforming in the ISO 2859 and 3951 standards.

### 3 Case studies (examples for specific scenarios)

These examples follow the step-by-step design process described in CXG 50-2004 Appendix 1 and illustrate the use of the apps.

#### 3.1 Examples on the Use of Attributes plans

##### 3.1.1 Example: Attributes plan with $c > 0$

In general, if both the consumer's and producer's risks are specified in the design of the plan, as might be appropriate for non-food safety characteristics such as commodity defects, it is unlikely that the acceptance numbers, the  $c$  values, will be zero. It should be noted that rather large sample sizes (and large acceptance numbers) might be needed for plans where the operating ratio (CRQ/PRQ) is small.

##### Example: Browning in Milk powder

- A customer found higher than usual levels of browning (discoloration) in a lot of WMP. The customer advised that they could accept the powder provided no more than 20% of the powder was nonconforming, as it would still be usable.
- The manufacturer wanted to control the risk of rejecting product that might still be usable, so that the product should be accepted [most of the time] if there was 10% nonconforming in the lot.

Key steps in the step-by-step design process

1. Attributes or variables data?

Excessive browning is an example of attributes data, samples are classified as either PASS or FAIL when compared against a reference powder.

2. Inspection error negligible or non-negligible?

It is assumed that inspection error is negligible in this example.

3. Set consumer's risk quality level (CRQ):

The customer has advised that the powder is still usable even if the level nonconforming was 20%, so that, for the purposes of the inspection, the consumer's risk quality level could be set at 20%.

4. Set producer's risk quality level (PRQ):

The PRQ can be set anywhere below the CRQ, noting that the smaller the operating ratio  $\frac{CRQ}{PRQ}$ , the larger the number of samples required to be taken.

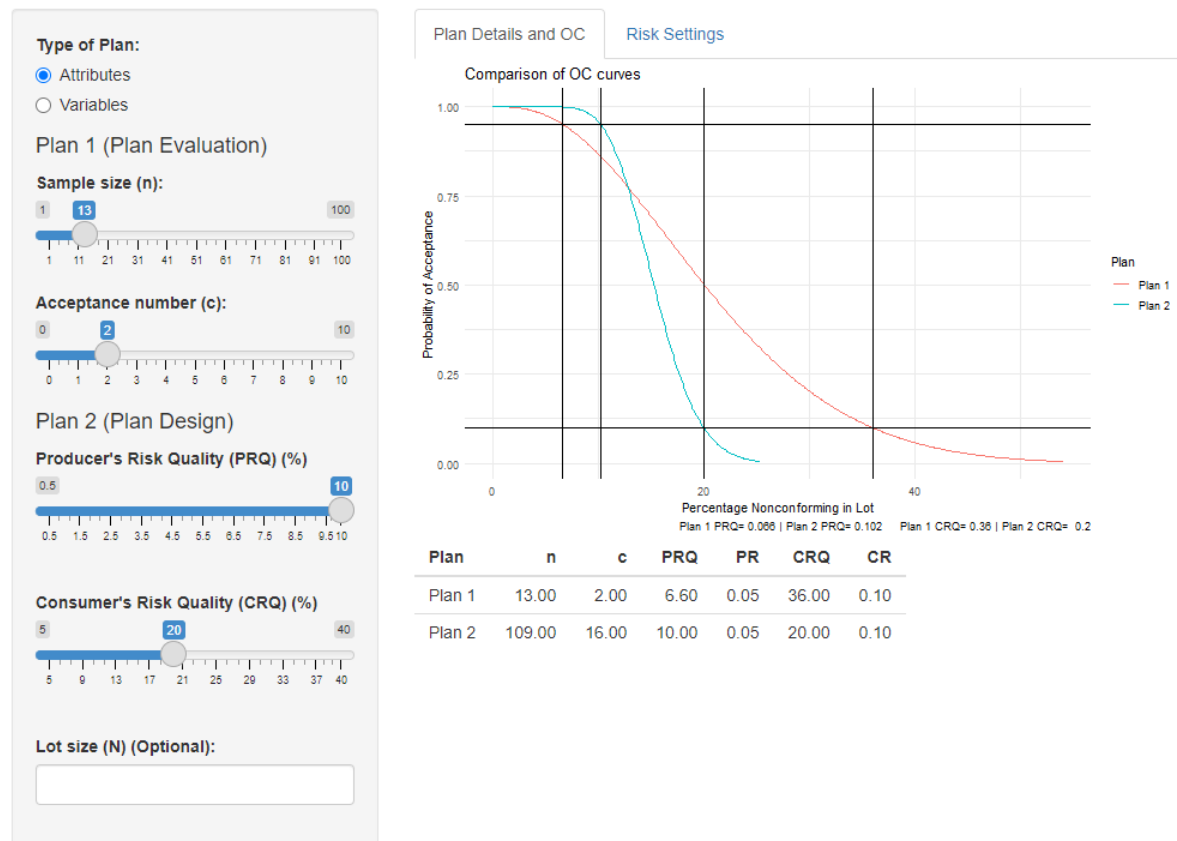
Various values of the PRQ can be tried to assess the required sample size. Some possible options are:

PRQ	CRQ	n	c
5%	20%	38	4
10%	20%	109	16
15%	20%	500	88

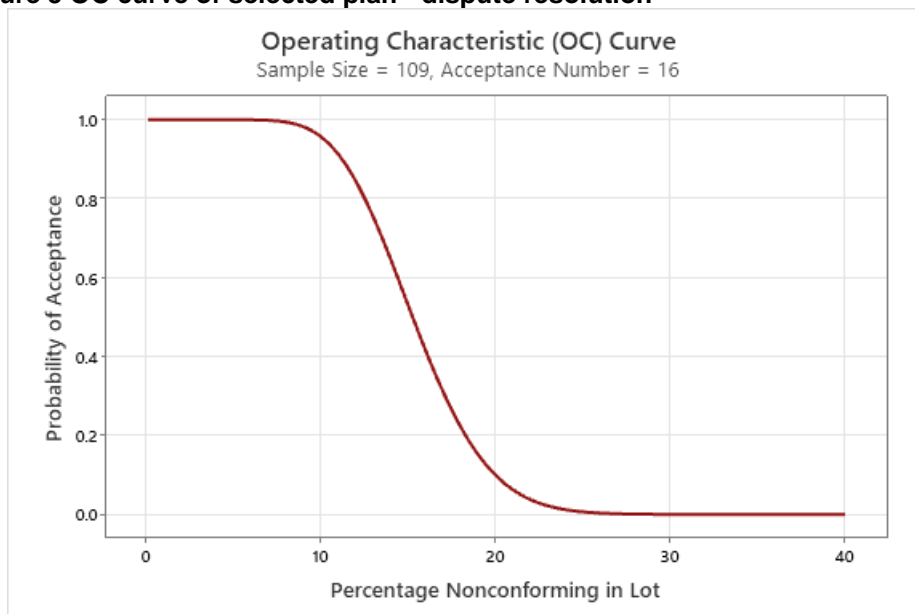
For the purposes of this example, a producer's risk quality level of 10% was used; a PRQ of 5% is too stringent considering that the powder is still usable if up to 20% of the lot was nonconforming, and 500 samples is too many to take and evaluate.

**Figure 4 Design of plan for dispute resolution**

## Design and Evaluation of Sampling Inspection Plans



The required sampling plan, required to control the consumer's and producer's risk to the specified levels is ( $n = 109$ ,  $c=16$ ) i.e.  $n=109$  samples are taken, and the lot is accepted provided no more than 16 of those samples is nonconforming.

**Figure 5 OC curve of selected plan - dispute resolution**

The Operating Characteristic shows a 95% chance of accepting the lot when the level nonconforming is 10% (i.e. the PRQ), a 50% chance approximately of accepting the lot when the level nonconforming is 15% and a 10% chance of accepting the lot when the level nonconforming is 20% (the CRQ).

### 3.1.2 Example: Attributes plan with $c=0$

Refer to CXG 50-2004 4.2.5 Zero-acceptance number plans.

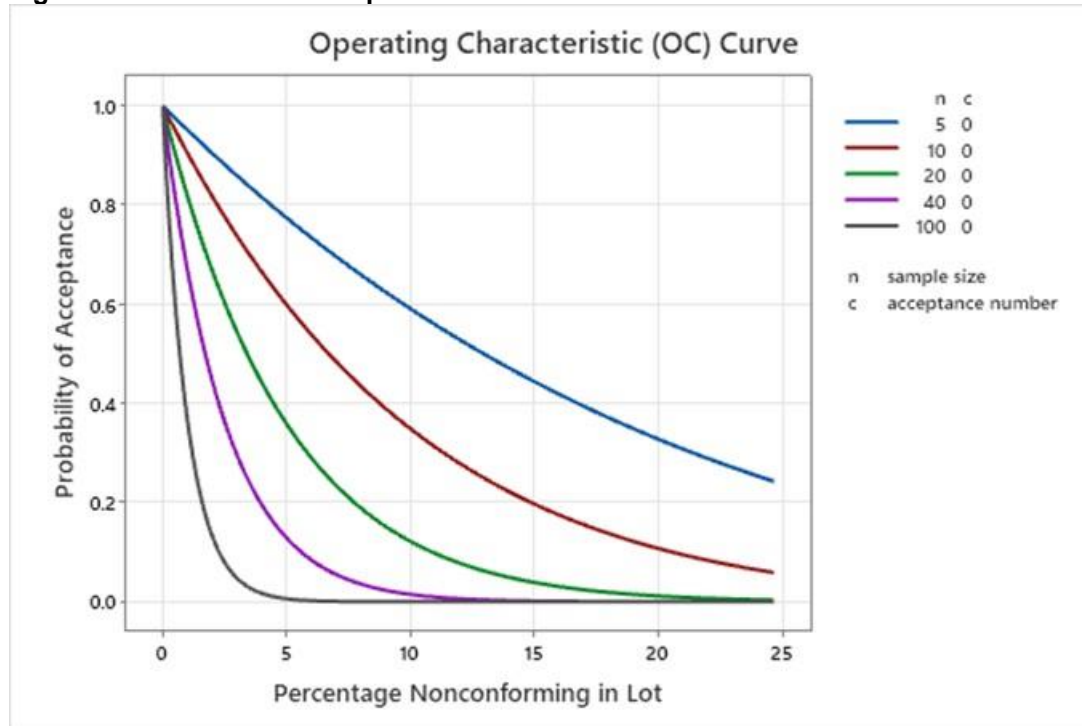


Zero-acceptance number (ZAN) plans are a special case of two-class plans in which the acceptance numbers are set to  $c = 0$ . These plans are used in more critical situations such as for pathogens or foreign matter where only CR is considered directly and acceptance of lots demands that nonconforming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

ZAN plans are commonly used, apparently based on the philosophy of zero defects and the perception that if  $c > 0$  then lots containing nonconforming product are being accepted.

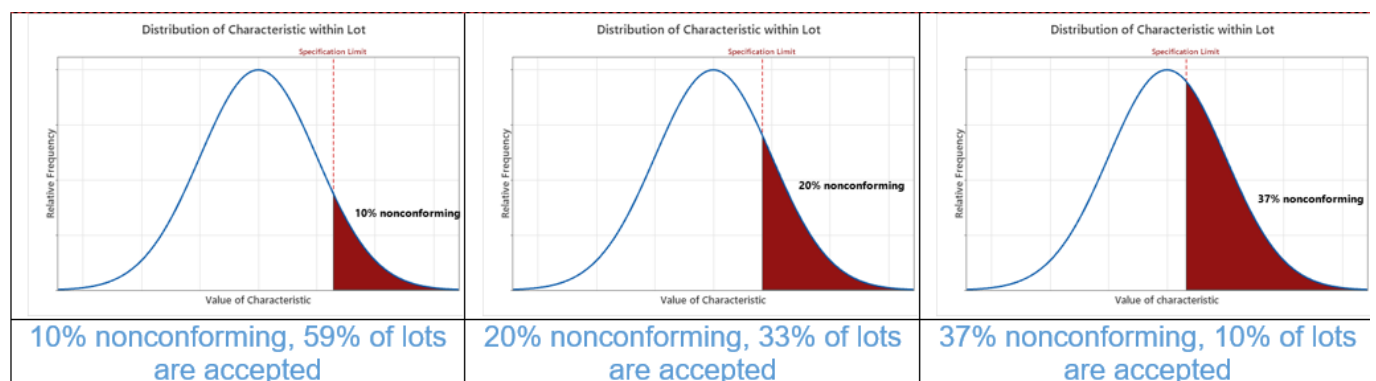
The following shows the Operating Characteristics for several ZAN plans:

**Figure 6 OC curves for ZAN plans**



However, ZAN plans cannot guarantee that lots that have passed inspection do not contain nonconforming items; no matter which plan is used there will always be a risk of accepting a lot containing some level of nonconforming product. The following shows the chance of accepting a lot for various levels nonconforming, using the  $(n=5, c=0)$  sampling plan.

**Figure 7 Risks with  $n=5, c=0$  plans**



The number of samples  $n$  can be calculated directly using the formula:

$$CR = (1 - CRQ)^n \text{ or } n = \log(CR) / \log(1 - CRQ)$$

Typical outcomes that are often expressed in terms of the quality in the lot are as follows:

- If we select 60 items, taken at random from a 'lot', and find none of those items nonconforming, then we can claim with 95% confidence that no more than 5% of ALL the items in the lot are nonconforming.

- If we select 150 items, taken at random from a 'lot', and find none of those items nonconforming, then we can claim with 95% confidence that no more than 2% of ALL the items in the lot are nonconforming.
- If we select 300 items, taken at random from a 'lot', and find none of those items nonconforming, then we can claim with 95% confidence that no more than 1% of ALL the items in the lot are nonconforming.

If one or more nonconforming items has been found, it is still possible to make a statement about the quality level within the lot.

The Excel file pexact.xlsx included in the package can be used to calculate the 95% confidence intervals for the level nonconforming in a lot, or the total number of defects in a lot, for any number of nonconforming items or defects found in the sample, noting that an individual item may have more than a single defect:

- The sheet Binomial calculates 95% confidence intervals for the level of individual items conforming in the lot overall.
- The sheet Poisson calculates 95% confidence intervals for the number of defects in the lot overall. These limits can be converted to rates by dividing by the number of items examined.

Excel formulas for the calculation of the lower and upper 95% confidence limits for the two cases are given in Section 4.1.1.



### Examples:

#### Binomial Case

If  $n=60$  items were examined and  $c=2$  of those 60 items were found nonconforming, then the estimated percentage of nonconforming items in the lot is  $2/60 = 3.33\%$  and, with 95% confidence, the level nonconforming in the lot lies between 0.41% and 11.53%.

#### Poisson Case

If 60 items were examined and 5 defects were found, with possibly more than one defect found on a single item, then with 95% confidence the number of defects in the lot lies between 1.62 and 11.67. Equivalently, these numbers could be expressed as defect rates of  $1.62 \times 100/60 = 2.7$  to  $11.67 \times 100/60 = 19.45$  defects per 100 items.

### Example: Inspection for Foreign Matter

It is suspected that a lot is contaminated with foreign matter but that the contamination is not believed to be a food safety concern. However, it is known that the intended customer will not accept product in which any foreign matter has been found, so that a zero-acceptance number (ZAN) plan should be used.

Since the contamination is not a food-safety issue, it was decided to design a plan based on a consumer's risk (CR) of 5%, at a consumer's risk quality level (CRQ) of 3%.

The number of samples  $n$  can be calculated directly using the formula given above:

$$CR = (1 - CRQ)^n \text{ or } n = \log(CR) / \log(1 - CRQ)$$

Using the second formula we have:

$$n = \frac{\log(CR)}{\log(1 - CRQ)} = \frac{\log(0.05)}{\log(0.97)} = \frac{-2.9957}{-0.0305} = 98$$

Therefore, the lot is accepted provided none of the 98 samples inspected contains any foreign matter contamination. In practice one might use  $n=100$  for simplicity.

#### 3.1.2.1 ( $n=1, c=0$ ) sampling plans

These sampling plans, often used by classifying variables data as attributes, are commonly used for inspection of contaminants and more widely, with or without allowance for MU.

For contaminants these plans rely on an assumption of homogeneity and possibly also on the usually large offsets between the decision limits used in those plans and food safety levels, so that allowance for MU may

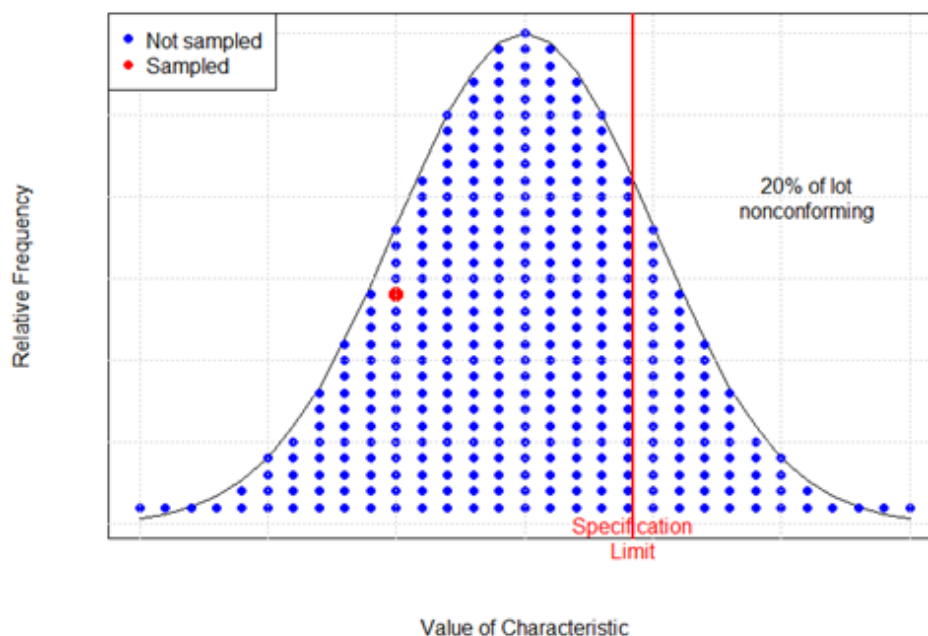
not be necessary. However, there is a considerable risk of incorrectly accepting a noncompliant lot if that lot was not homogeneous.

For other characteristics ( $n=1$ ,  $c=0$ ) plans are often used but might not provide the desired level of assurance to consumers. This might be due to:

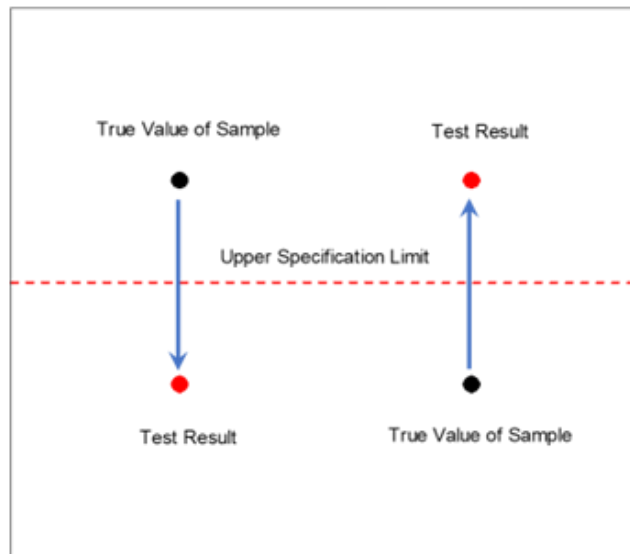
- Attempting to minimize the cost of testing
- Ignoring of the principles of sampling
- Performing a spot check on compliance of the lot, that is potentially unfair to producers, without any intention of protecting consumer's risk; this practice often leads to complaints, there being a wide perception that if nonconforming items/samples are found on inspection then the entire lot is nonconforming

The fundamental problem with ( $n=1$ ,  $c=0$ ) plans is that decisions on acceptance or rejection are not necessarily related to the quality of the lots (Refer CXG 50-2004 Section 2.2). The following diagrams show the potential risks when using ( $n=1$ ,  $c=0$ ) sampling plans. The first plot shows the risk of making an incorrect decision due to sampling error, when 20% of the lot is nonconforming there is an 80% chance of not finding a nonconforming sample if only one sample is taken, assuming measurement uncertainty is negligible.

**Figure 8 Risk due to sampling uncertainty for  $n=1$  plans**



The second plot shows the risk of making an incorrect decision due to analytical measurement uncertainty.

**Figure 9 Risk due to measurement uncertainty in n=1 plans**

The (n=1, c=0) plans have been extended to include allowance for MU [See CXG 54-2004 Figure 1 where MU uncertainty intervals are included to show the decision process.].

These plans, however, cannot simply be extended to lot inspection by including sampling components in the MU while allowing the PR and CR to be controlled to specified levels. Also, given that a single result is an estimate of the mean of a lot, use of this adjustment amounts to assessing compliance of the mean level of the lot by comparing it against a maximum or minimum limit for the entire distribution. This comparison remains inappropriate regardless of whether sampling uncertainty is allowed for or not.

Sometimes guard-bands are applied, but their use may be unfair to producers.

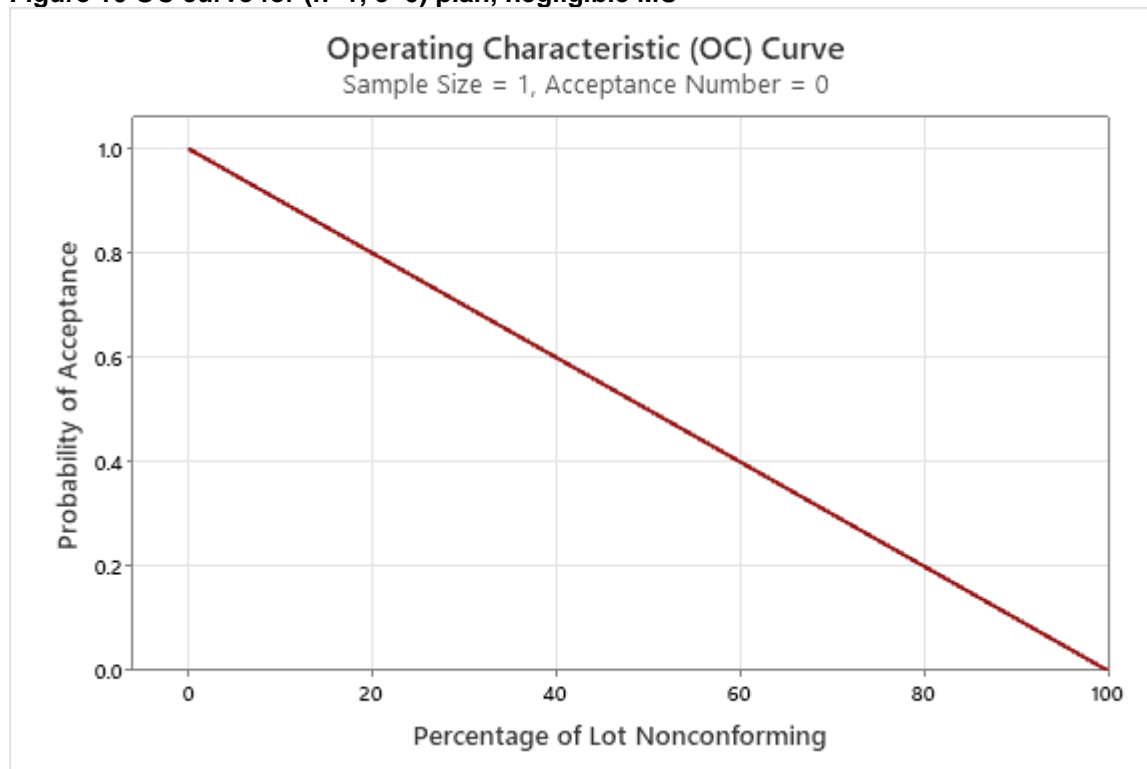
If the characteristic is a compositional proportion, then provided measurement uncertainty is negligible, it is possible to design a sampling plan that can control both producer's and consumer's risks, but which requires only a single test of a composite sample to be performed.

Refer to the example in section 3.3.2.

Section 5.5 discusses Bayesian sampling plans that allow plans controlling producer's and consumer's risks to be designed while requiring only small sample sizes.

### **Operating Characteristic Curve (n=1, c=0) sampling plan**

The ideal Operating Characteristic Curve, i.e. where analytical measurement uncertainty is negligible, for this plan is shown below – basically this says that if a percentage  $P$  of the product in a lot is nonconforming then the probability of acceptance,  $p_{acc} = 1 - P$ .

**Figure 10 OC curve for (n=1, c=0) plan, negligible MU**

This and the points above show that there is a high risk of making an incorrect assessment of a lot using these plans, and indeed any plan based on a small number of samples. This suggests that confirmatory sampling and testing using on a more discriminatory sampling plan should be undertaken prior to raising a dispute.

### 3.1.3 Example: Attributes plans based on AQL of 6.5%

The CXS 3-1981 Standard for Canned Salmon has three provisions based on sampling that must be met for acceptance of a lot.

Section 8 defines defective sampling units (cans) in terms of foreign matter, odour and flavour, texture, discolouration exceeding 5% of the net contents and objectionable matter.

A lot is accepted provided:

1. the total number of defectives as classified according to Section 8 does not exceed the acceptance number (c) of an appropriate sampling plan with an AQL of 6.5%;
2. the total number of sample units not meeting the form of presentation as defined in Section 2.3 does not exceed the acceptance number (c) of an appropriate sampling plan with an AQL of 6.5%;
3. the average net weight and the average drained weight where appropriate of all sample units examined is not less than the declared weight or drained weight as appropriate, and provided there is no unreasonable shortage in any individual container.

In this standard, Section 7.1 contains the following information:

#### SAMPLING

- (i) Sampling of lots for examination of the final product as prescribed in Section 3.3 shall be in accordance with an appropriate sampling plan with an AQL of 6.5%.
- (ii) Sampling of lots for examination of net weight shall be carried out in accordance with an appropriate sampling plan meeting the criteria established by the CAC.

The following options for sampling plans are from ISO 2859-1999, CXG 50-2004 Appendix II ISO INSPECTION PLANS INDEXED BY PRODUCER'S RISK from ISO 2859-1 Plans indexed by AQL.

Using the table, for a lot of size  $N=500$  cans, a sample size of  $n=50$  cans would be required at the normal inspection level, with the lot rejected if more than 7 of those cans were nonconforming, that is if they contained foreign matter, objectionable matter, atypical odour or flavour, abnormal texture, or discolouration exceeding 5% of the net contents.

Presumably, in this plan, each of the 50 cans is examined for each of the listed defects with a can classified as nonconforming if the criterion is breached for any one of them.

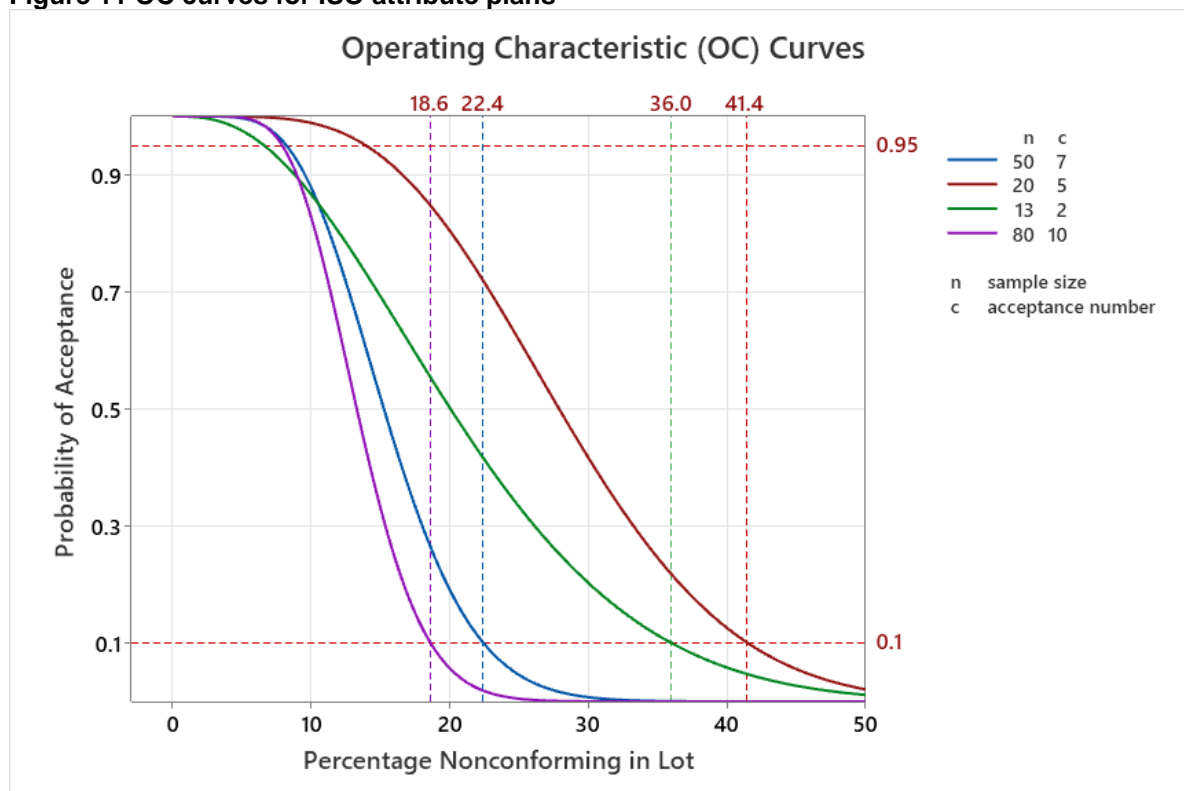
The consumer's risk quality level (CRQ) for this plan ( $n=50$ ,  $c=7$ ) is 22.4% meaning that there is a 10% chance of accepting a lot in which 22.4% of the cans are nonconforming. A decision should be made whether this is an acceptable level of risk before this plan is used.

This number of samples could be considered excessive, especially in terms of the overall lot size, although, as noted in CXG 50, the sampling fraction does not play a role in the design of sampling plans except possibly for quite small lots.

If it was decided to use the reduced inspection plan, ( $n=20$ ,  $c=5$ ) the consumer's risk quality level would increase to  $CRQ = 41.4\%$ . If the sample size versus lot size relationship was disregarded and if the plan ( $n=13$ ,  $c=2$ ) was applied, then the CRQ would increase to 36%. On the other hand, if the plan ( $n = 80$ ,  $c=10$ ) was used, then the consumer's risk quantity level CRQ would decrease to 18.6%.

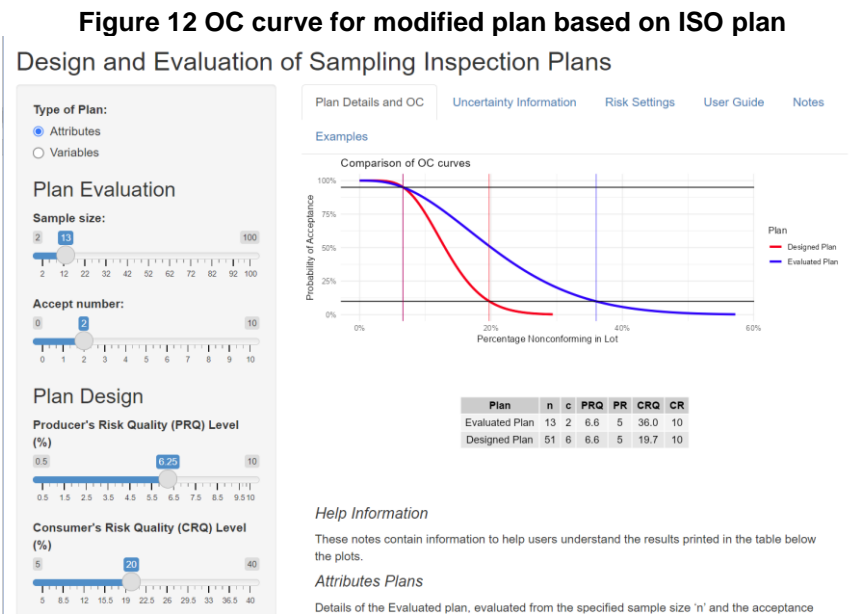
Operating characteristic curves for the four options are:

**Figure 11 OC curves for ISO attribute plans**



### Extension

Suppose we wanted to modify this plan to provide a greater level of assurance to customers against accepting lots containing high levels of nonconforming product and that we were happy to keep the PRQ level at 6.5% but set the CRQ at 20%. This is easily accomplished using the app that shows the required plan is ( $n=50$ ,  $c=6$ ). The output from the app is shown below. Note that unlike the ISO tables, the plan does not depend on the lot size.



## 3.2 Examples for Variables plans

### 3.2.1 Example: Variables plan with negligible MU

#### Fat in Whole milk powder

The examples for variables plans are based on the provision for fat in whole milk powder from Codex Standard CXS 207-1999. The provision states that the milkfat content should exceed 26%.

From Codex Standard CXS 234 the analytical test method for fat in whole milk powder is the Röse-Gottlieb method (ISO 23318/IDF 249). The method contains the following precision data:

The repeatability limit is 0.2% (0.2 percentage points)  
The reproducibility limit is 0.3% (0.3 percentage points)

Using these values, the repeatability standard deviation is calculated as:

$$\sigma_r = 0.2 / (1.96 \cdot \sqrt{2}) = 0.2 / 2.77 = 0.072 \text{ (percentage points)}$$

With a similar calculation for the reproducibility standard deviation:

$$\sigma_R = 0.3 / (1.96 \cdot \sqrt{2}) = 0.3 / 2.77 = 0.108 \text{ (percentage points)}$$

Using these values, the 'between-laboratory' standard deviation is calculated as:

$$\sigma_L = \sqrt{\sigma_R^2 - \sigma_r^2} = \sqrt{0.108^2 - 0.072^2} = 0.081 \text{ (percentage points)}$$

Refer to the Guidelines on Analytical Terminology CAC/GL 72-2009 for more information about the repeatability and reproducibility.

Key steps in the step-by-step design process

The design process involves finding the number of samples  $n$ , and the acceptability constant  $k$ , in order that the risks of incorrect decisions can be controlled the levels specified by the producer's risk (PR) and consumer's risk (CR) at their corresponding quality levels PRQ and CRQ respectively.

In this context the plan evaluation feature of the app might not be relevant but still might be useful for comparison of the designed plan with other options.

#### 1. Attributes or variables?

Fat is a measured characteristic so this is an example of variables data.

2. Does the provision relate to the average value or to the entire distribution, i.e. to a maximum or minimum allowable level for the characteristic in the lot?

The provision specifies a minimum limit so relates to the entire distribution – ‘most’ of the product in the lot should comply.

3. Does the distribution of the characteristic follow a normal or some other distribution?

For the purposes of this example, we assume that lot consists of 1000 cans of milkpowder and that the milkfat content of the cans in the lot is normally distributed. This is a reasonable assumption if the cans are produced using powder from a manufacturing process in a state of statistical control.

4. Is measurement uncertainty negligible or non-negligible?

If the standard deviation representing the variation of the characteristic in the lot was  $\sigma = 0.3$ , then the error-variance ratio is  $(0.072/0.3)^2 = 0.058$ , that, being less than 10%, means it would not be necessary to allow for measurement uncertainty in the design of this plan.

5. Specify the stringency required for the sampling plan.

Consumer's Risk Quality (CRQ):

What of percentage nonconforming cans would you be prepared to allow in lots that you would want to reject most of the time?

Consumer's Risk (CR):

How often would you want to accept such lots? (Usually 10%)

Producer's Risk Quality (PRQ)

What percentage of nonconforming cans would you be prepared to allow in lots that you would want to accept most of the time?

Consumer's Risk (CR):

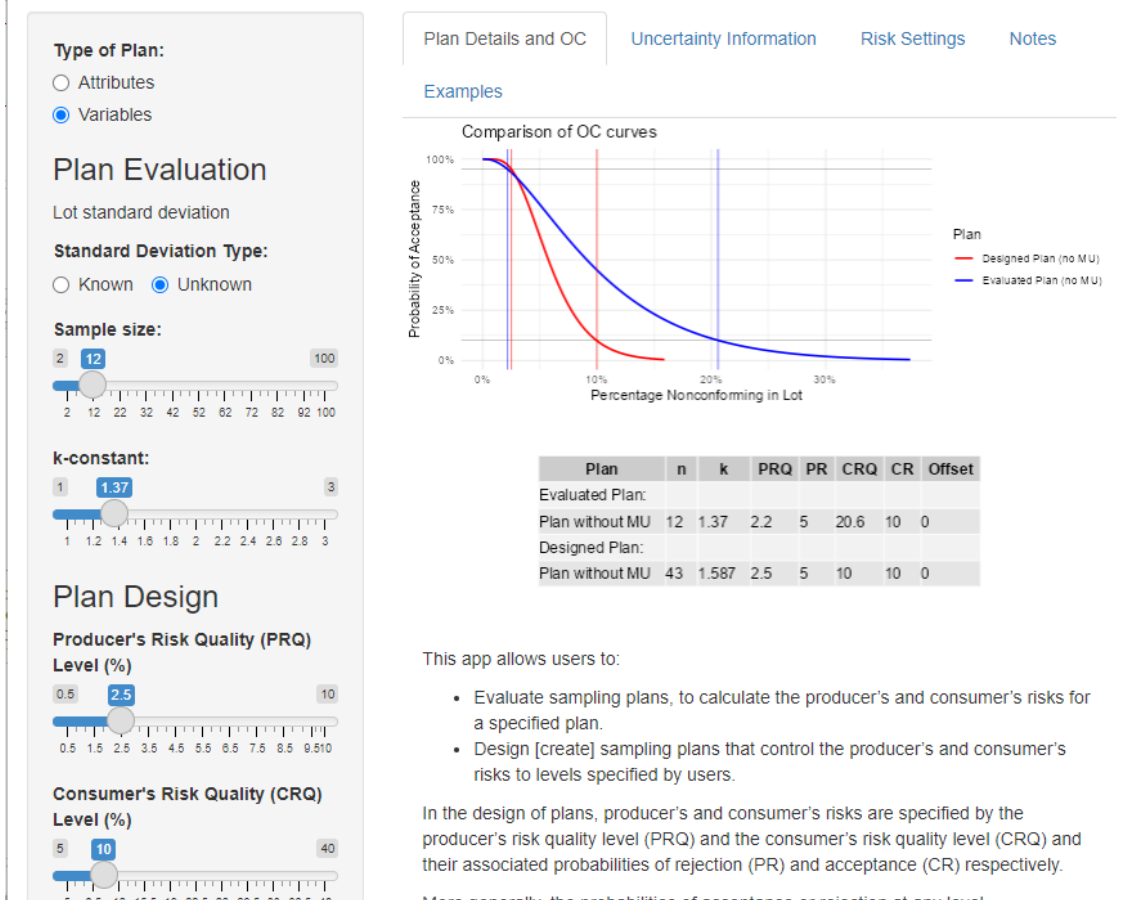
How often would you want to reject such lots? (Usually 5%)

In this example the CRQ was chosen as 10% and the PRQ as 2.5%, with the CR and PR unchanged. This means that the plan will have:

- A 10% chance of accepting a lot in which 10% of the product is nonconforming.
- A 5% chance of rejecting a lot in which 2.5% of the product is nonconforming.



**Figure 13 OC curve for variables plan - negligible measurement uncertainty**  
**Design and Evaluation of Sampling Inspection Plans**



The plan required to control risks to the specified levels is ( $n=43$ ,  $k=1.59$ ), i.e. 43 samples need to be taken from the lot and tested. The lot is accepted provided the average and the standard deviation of the results meet the acceptance criterion:

$$\bar{x} - k \times s \geq 26$$

where:

- $\bar{x}$  is the average of the 43 individual results and 's' their standard deviation,
- $k$  is the acceptability constant,  $k=1.59$  in this example.
- It is assumed that the measurements are expressed as percentages e.g. moisture of 5% on a weight/weight basis.

Note that the ISO plan for  $PRQ = 2.5\%$  for a lot size  $N=1000$  (Sample Code J, Inspection Level II) is ( $n=12$ ,  $k=1.370$ ) if the lot standard deviation is known and ( $n=46$ ,  $k=1.482$ ) if the lot standard deviation is unknown. Both plans have an actual PRQ of about 3.4% and a CRQ of about 11.3%.

### Negligible measurement uncertainty

The validity of the assumption of negligible measurement uncertainty can be checked using the app, as follows.

Step 1.

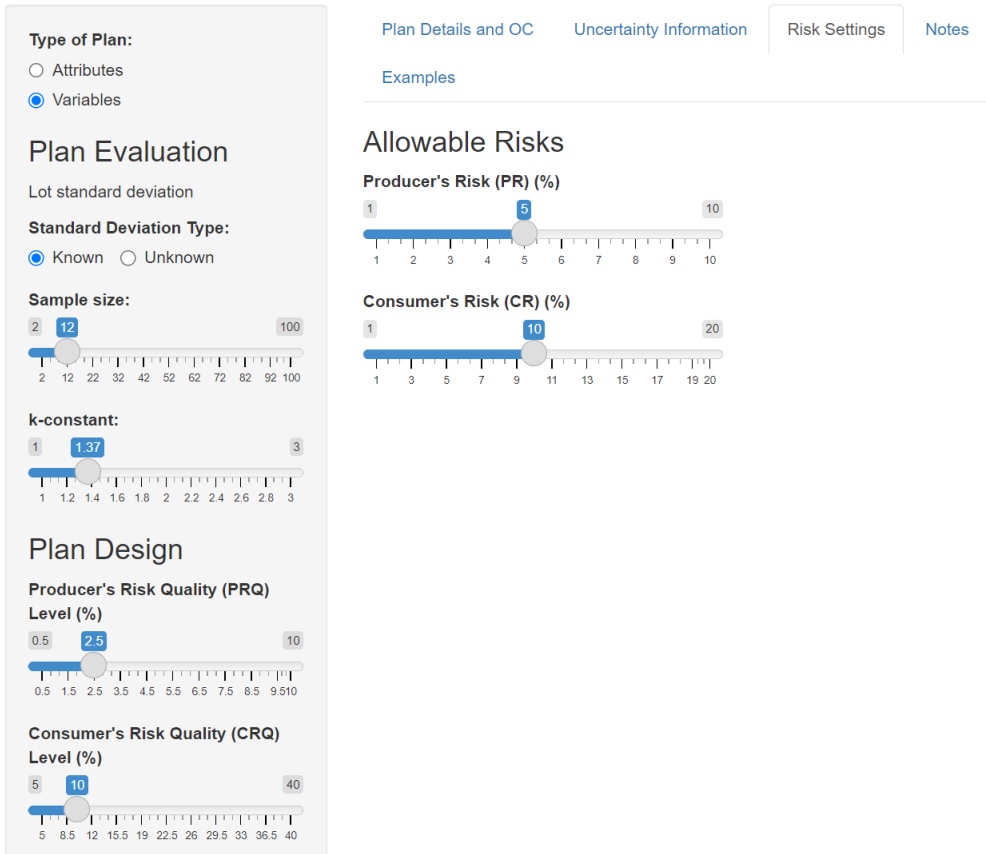
Open the app and select 'Variables' as the type of plan.

Step

In the Plan Design section of the Plan Details and OC tab, set the Producer's Risk Quality level (PRQ) to 2.5% and the Consumer's Risk Quality level (CRQ) to 10%. There is no need to change the producer's and consumer's risks from their default settings, 5% and 10% respectively, at least for this example.

2.

Figure 14 Negligible MU example - setting allowable risks




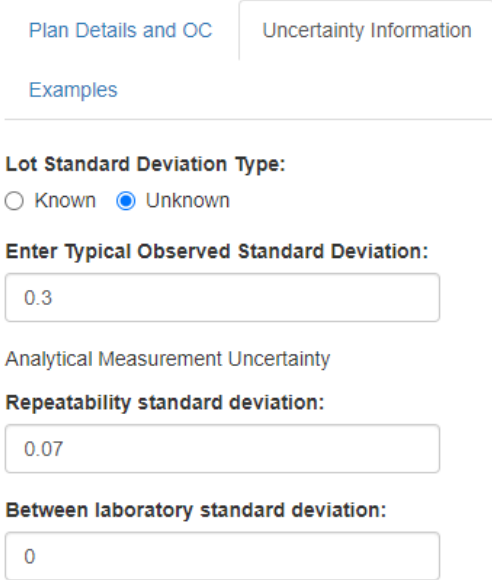
Step 3  
Go to the Uncertainty Information tab.  
Select the “Lot Standard Deviation Type” to “Unknown”.  
In the same window set the typical value of the observed standard deviation to 0.30 using the spin button  or by entering the value directly and the repeatability standard deviation to  $\sigma_r = 0.07$  similarly.  
Note that the app has been designed so that if the lot standard deviation is known that value is used but if it is unknown, a typical value of the observed total standard deviation inclusive of repeatability error is entered.

Figure 15 Variables Plan example - setting uncertainty information

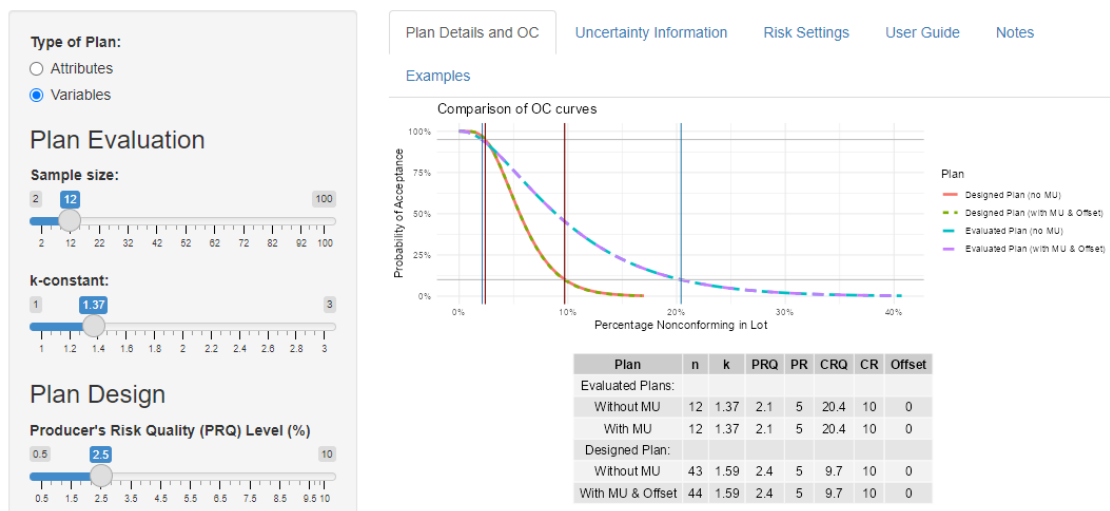


Step 4

Return to the Plan Details and OC tab to view details of the plan and the OC curve. The app shows the OC curves and details of the plans including the risks,

**Figure 16 Variables plan example - output**

### Design and Evaluation of Sampling Inspection Plans



The last row of the table shows that the designed plan with the specified risks, allowing for the measurement uncertainty specified is ( $n=44$ ,  $k=1.59$ ), the same as the plan where there is no measurement uncertainty shown in the line above. This differs slightly from the evaluated plan with the same  $n$  and  $k$  due to rounding of the  $k$  value within the app.

Notice also that although less than 10%, the error variance ratio of 0.058 means that one would expect the sample number to increase from 43 to  $43 \times (1 + 0.058) = 45.5$  that, when rounded up gives  $n=46$ . However, for the unknown lot standard deviation case Hahn's adjustment (CXG 50 section 5.2.7) has been applied, meaning that although allowance must be made for the unknown standard deviation, it is not necessary to adjust the lot standard deviation for the measurement uncertainty. In any case, there is little difference between the plans in their sample numbers or risks and the 'error-free' plan can be used.

The lot is accepted provided the average and the standard deviation of the results meet the acceptance criterion:

$$\bar{x} - 1.59 \times s \geq 26$$

where:

- $\bar{x}$  is the average of the 43 individual results and 's' their standard deviation.
- It is assumed that the measurements are expressed as percentages e.g. a fat level of 26.5% on a weight/weight basis.

Although it is unnecessary in this example, the calculations assume that Hahn's adjustment has been applied to the observed total standard deviation, calculated from the inspection data. The adjusted standard deviation can be calculated using the formula:

$$s_{adj}^2 = s_{obs}^2 - \sigma_r^2$$

provided the right-hand side is greater than zero, otherwise the value of the adjusted standard deviation is taken as zero.

### 3.2.2 Example: Variables plan with non-negligible MU with no laboratory bias

It is assumed that the specified producer's and consumer's risks are set at the same levels and the between laboratory component of the analytical measurement uncertainty is negligible. However, in this example the lot standard deviation is assumed known.

If the lot standard deviation was  $\sigma = 0.2$ , the error-variance ratio is  $(0.072/0.2)^2 = 0.13$  and, being greater than 10%, suggests that to allow for measurement uncertainty the number of samples should be increased to  $19 \times (1 + 0.13) = 21.5 = 22$  after rounding.

The app is used in the same way as in the example above, except that the lot standard deviation type is set to known (and, of course, a different value of the lot standard deviation is entered).

**Figure 17 Variables plan example - non-negligible MU**

Plan Details and OC    Uncertainty Information

Examples

**Lot Standard Deviation Type:**  
☒ Known   ☐ Unknown

**Enter Known Lot Standard Deviation:**

Analytical Measurement Uncertainty

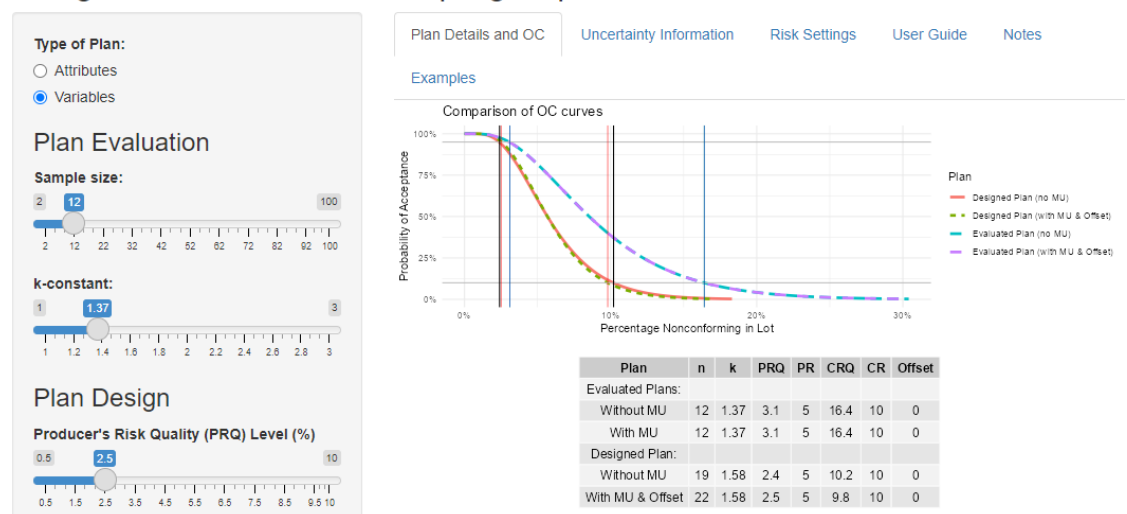
**Repeatability standard deviation:**

**Between laboratory standard deviation:**

The last row of the table below the OC curves confirm the calculation above, that there is a modest increase in sample size to n=22.

**Figure 18 Variables Plan design - non-negligible MU**

### Design and Evaluation of Sampling Inspection Plans



Alternatively, in the known standard deviation case, or if the error variance ratio  $\gamma$  is known, say from a measurement error study if the lot standard deviation is unknown, the acceptability constant  $k$  can be reduced to compensate for the increase in variability without the need to increase the sample size:

$$k^* = k / \sqrt{1 + \gamma}$$

where:

$k$  is the acceptability constant for the original plan,

$k^*$  is the acceptability constant for the modified plan.

Suppose the variables sampling plan ( $n=23$ ,  $k=1.19$ ) is being used to assess compliance of a particular characteristic having an upper limit of  $U = 10$  and we have obtained test results as follows:

9.92, 9.85, 10, 9.62, 9.94, 10.02, 9.87, 9.8, 9.87, 9.95, 10.05, 10.03, 9.57, 9.83, 9.93, 9.93, 9.89, 9.79, 9.97, 9.96, 9.92, 9.83, 10.05

It is known from a previous measurement study that the error-variance ratio, the ratio of the repeatability variance to the lot standard deviation variance, is 0.25. Recall from CXG 50-2004 that the variance is the square of the standard deviation.

If the assessment of compliance proceeds in the usual way, the mean value of the results is  $m=9.90$ , the standard deviation  $s = 0.12$ , so that the acceptance criterion has a value of  $9.90 + 1.19 \cdot 0.12 = 10.04$ , and the lot should not be accepted.

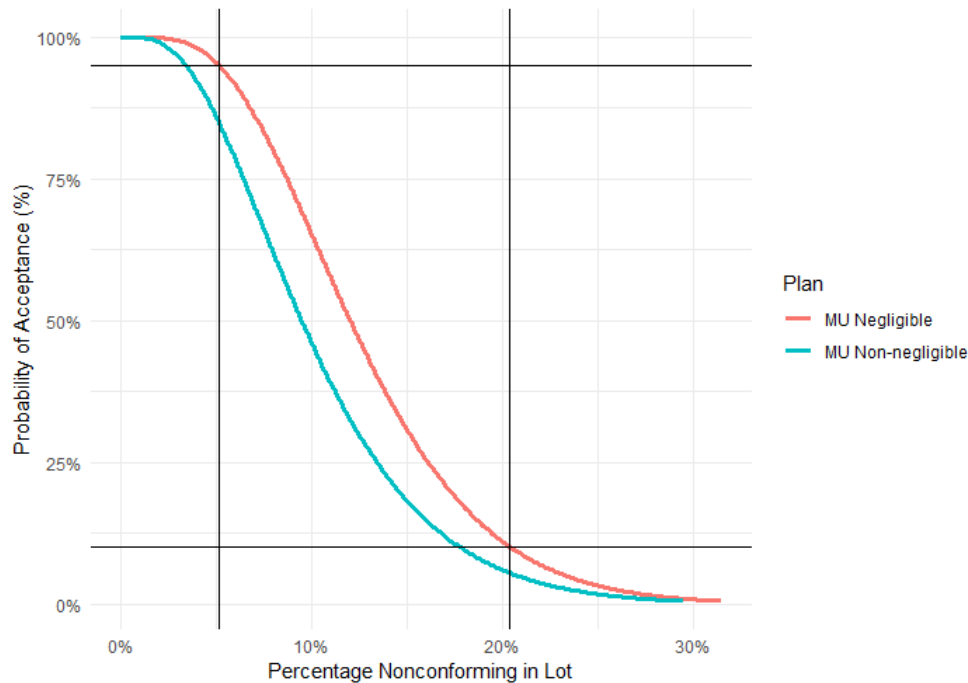
However, it is possible that measurement uncertainty has caused the lot to fail inspection. Hahn's adjustment can be applied to adjust the observed standard deviation for measurement uncertainty using the repeatability standard deviation is known from method validation. Supposing the repeatability standard deviation is  $\sigma_e = 0.10$ , the adjusted observed standard deviation  $s_{adj}$  is calculated by:

$$s_{adj}^2 = s_{obs}^2 - s_e^2 = 0.12^2 - 0.10^2 = 0.0044$$

so that the adjusted standard deviation  $s_{adj} = 0.066$  and the updated value of the acceptance criterion is  $9.90 + 1.19 \cdot 0.066 = 9.98$  and the lot can be accepted.

The OC curves below show that the probability of acceptance at any given percentage nonconforming in a lot will be less when repeatability-type measurement uncertainty is present.

**Figure 19 OC curves with and without MU (no bias)**



Plan	n	k	PRQ	PR	CRQ	CR
Error-free Plan	23	1.19	5.1	5	20.4	10
Error-prone Plan	23	1.19	3.4	5	17.8	10

Another way of overcoming non-negligible, repeatability measurement uncertainty is to increase the sample size; ISO3951-1: 2013 gives the formula:

$$n^* = n(1 + \gamma)$$

where:

$n$  is the sample size for the original plan in which measurement uncertainty is negligible,

$n^*$  is the sample size for the modified plan, and

$\gamma$  is the error-variance ratio.

Alternatively, if the error variance ratio  $\gamma$  was known, the acceptability constant  $k$  can be reduced to compensate for the increased variability without the need to increase the sample size:

$$k^* = k / \sqrt{1 + \gamma}$$

where:

$k$  is the acceptability constant for the original plan,

$k^*$  is the acceptability constant for the modified plan.

### 3.2.3 Example: Variables plan with non-negligible MU with laboratory bias

In this example it is assumed that the lot standard deviation of  $\sigma = 0.2$  is known and that the between laboratory component of measurement uncertainty has a standard deviation of  $\sigma_L = 0.08$  as in the original example (Section 3.2.1).

**Figure 20 Entering uncertainty information - Non-negligible MU (inc. bias)**

Plan Details and OC    Uncertainty Information

Examples

**Lot Standard Deviation Type:**  
☒ Known   ☐ Unknown

**Enter Known Lot Standard Deviation:**

Analytical Measurement Uncertainty

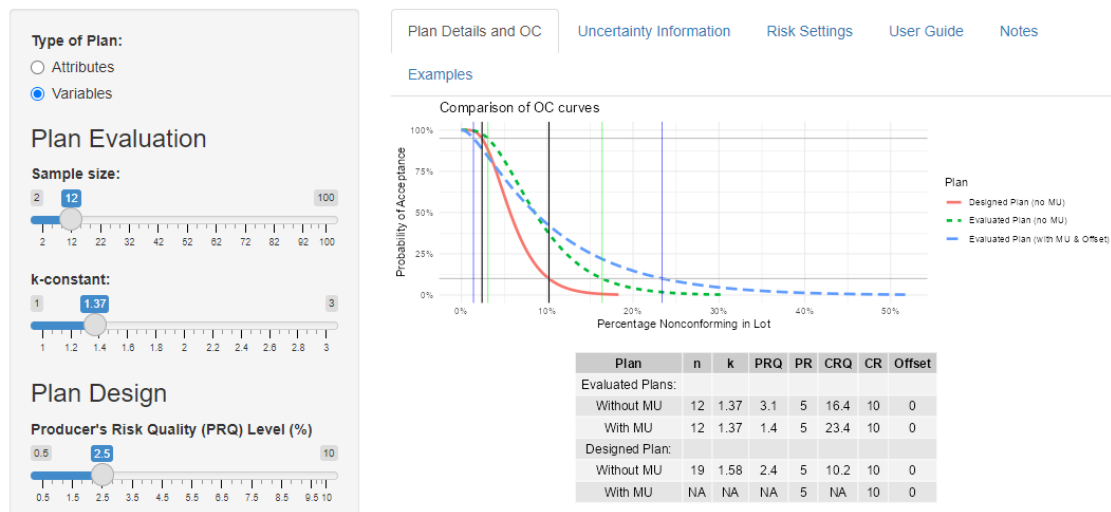
**Repeatability standard deviation:**

**Between laboratory standard deviation:**

The NA (not available) values in last row of the table shows that a plan allowing control of the producer's and consumer's risks to the levels specified cannot be found.

**Figure 21 Output - Non-negligible MU example**

### Design and Evaluation of Sampling Inspection Plans

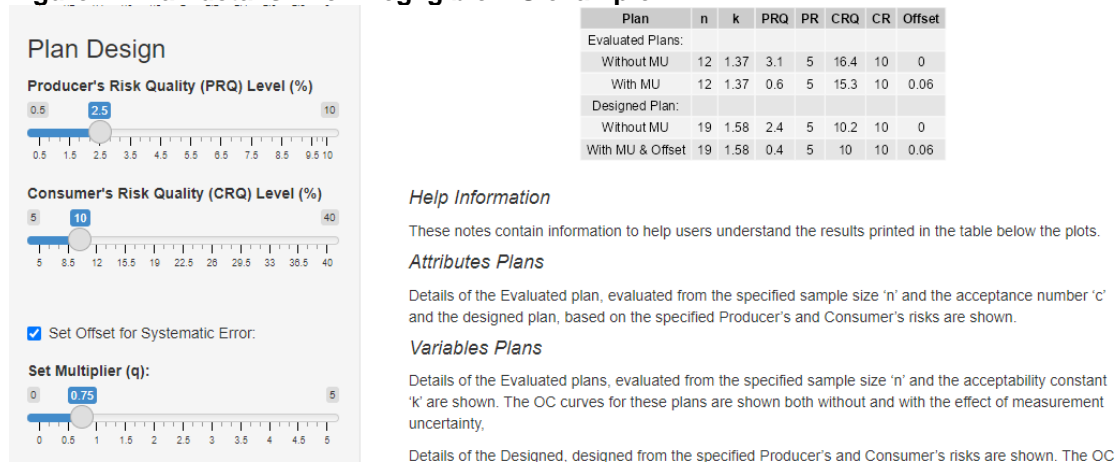


To find a plan it is necessary to introduce an offset.

Open the sub-window "Set Offset for Systematic Error" and move the slider to set a value of "q" until a plan is found. For example, as shown in the image below, if the multiplier is set to  $q = 0.75$ , then the offset in the acceptance criterion is then  $q \cdot \sigma_L = 0.75 \cdot 0.08 = 0.06$  so that with  $n=19$  and  $k = 1.58$  so the acceptance criterion would then become:

$$\bar{x} + k \cdot \sigma + 0.06 \leq USL$$

Note that while the consumer's risk quality level (CRQ) remains unchanged, the producer's risk quality is significantly reduced.

**Figure 22 Plan details - non-negligible MU example**

### 3.2.4 Example: Fractional Nonconformance plans

Suppose we have measurements from testing 15 samples from a lot to assess whether the lot conforms with the lower specification limit of  $L = 50$ . The measurement process is known to be normally distributed, with no laboratory bias and a standard deviation of  $\sigma = 0.045$ .

The following results were obtained:

50.01, 50.04, 50.07, 50.1, 50.15, 50.2, 50.29, 50.42, 50.45, 50.48, 50.55, 50.6, 50.8, 51.2, 51.3

The fractional nonconformance values for each sample can be calculated using Excel, using the formula:

$$fnc = NORMDIST(50, x, 0.045, TRUE)$$

where 'x' represents a single test result. This gives the following FNC values:

0.4121, 0.187, 0.0599, 0.0131, 0.0004, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0

The sum of these values is 0.6725, so if the acceptance limit  $A_c$  was 0.75 the lot would be accepted.

This example shows the principle behind the calculation, that can easily be extended to allow for measurement uncertainty distributions other than the normal distribution.

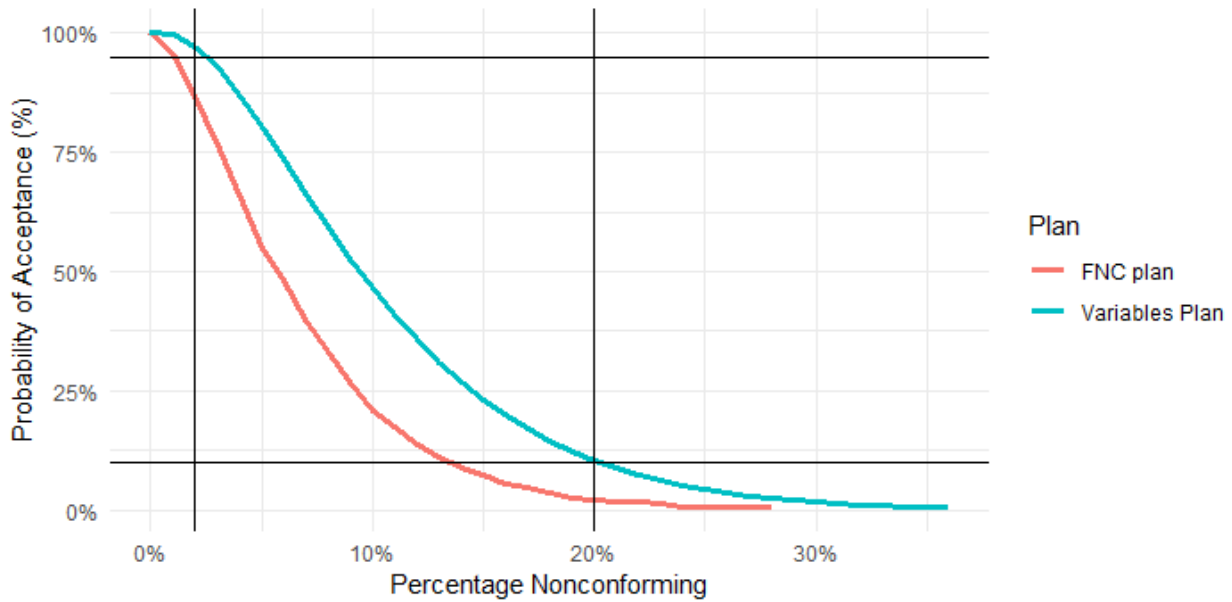
The following shows the OC curves for a variables plan and for a FNC plan, both with the same error-variance ratio.

Fractional nonconformance plans are an example of attribute-variables (attri-variables) plans where measurements are reclassified into another 'measure' of conformance for each sample, with the decision on acceptance of the lot made using the sum of these new measures.

The ICMSF sampling plans used in microbiological assessments for counted characteristics are another example of attri-variables plans as are attributes plans used with measurements that are classified as pass or fail with respect to a limit.

See also Section 4.4.

The FNC app uses a modified procedure from that described above; differences of each observation from the sample mean are also taken into account. This provides a more stringent procedure requiring fewer samples than the unmodified method. Both methods are described in Govindaraju, K. and Jones, G. [31] (2015). Fractional acceptance numbers for lot quality assurance. In Knoth, S. and Schmid, W., editors, *Frontiers in Statistical Quality Control*, volume 11, pages 271–286. Springer.

**Figure 23 Fractional Nonconformance Plans**

Plan	n	k_Ac	AQL	AQL.risk	LQL	LQL.risk
Variables Plan	15	1.20	2	5	20	10
FNC plan	15	0.75	1	5	14	10

### 3.3 Lots consisting of bulk materials

#### 3.3.1 Example: Aflatoxin sampling plans due to Whitaker (2006) et al.

Refer to 5.6.5 Aflatoxin sampling plans

##### Shelled Almonds for further processing

Suppose the average concentration of aflatoxins in the lot was  $C = 8 \mu\text{g/kg}$  and  $n_s = 20000$ , 20 kg @ 1000 shelled nuts per kg, were taken as a sample, and this sample was ground and well-mixed composite formed. If a subsample of 50g was taken and a single aliquot ( $n_a=1$ ) tested, the standard deviation  $S$  representing the uncertainty of the average level would be:

$$S^2 = \frac{7730 \times 5.759}{20 \times 1000} 8^{1.561} + \frac{100 \times 0.170}{50} 8^{1.646} + \frac{0.048}{1} 8^2 = 70.67$$

Giving  $S = 8.41$ . The first component representing the sample-by-sample variation is much larger than the other two.

The maximum limit for shelled nuts for further processing is  $20 \mu\text{g/kg}$ , based on an initial sample of 20kg shelled almonds and one laboratory determination.

At an average level of contamination of  $C=8 \mu\text{g/kg}$ , the variance  $S^2 = 70.67$  and from the formula above, the value of  $k$  is worked out using:

$$70.67 = 8 + 8 \times 8/k$$

from which

$$k = \frac{64}{70.67 - 8} = 1.0212 \text{ and } \frac{k}{C + k} = \frac{1.0212}{8 + 1.0212} = 0.1132$$

The probability of acceptance be calculated using Excel:

BETA.DIST( $k/(C+k)$ , $k$ ,maximum\_Limit,TRUE) that is equivalent to the Negative Binomial distribution<sup>3</sup>.

<sup>3</sup> Although the negative binomial distribution function is available in Excel, it is not in a form suitable for these calculations.



$$BETA.DIST\left(\frac{k}{c+k}, k, \text{maximum limit}, TRUE\right) = BETA.DIST(0.1132, 1.0212, 20, TRUE) = 0.906$$

or 90.6%

Note that the probability of acceptance at the maximum limit  $C = 20\mu\text{g/kg}$  is 0.622, that shows again that the principle of offsets has been employed in the setting of limits to provide consumer protection.

The calculations of the probabilities of acceptance in the Mycotoxin S&T Guide appear approximate, the actual calculations are unknown but the differences from results calculated in other known ways are small enough so as not to matter.

Probabilities of Acceptance for Shelled Corn ( $n_s=3000$ ,  $n_{ss}=50$ ,  $n_a = 1$ )

Concentration ( $\mu\text{g/g}$ )	Variance	Mycotoxin S&T Guide (%)	Negative Binomial (R) (%)	Beta Distribution (R) (%)	Beta Distribution (Excel) (%)
0	0	100	100	100	100
5	72.76	94.07	94.29	94.29	94.29
10	148.01	84.9	85.3	85.3	85.3
20	302.74	61.53	62.23	62.23	62.23
30	461.41	38.87	39.8	39.8	39.80

### 3.3.2 Example: Plans based on the beta distribution

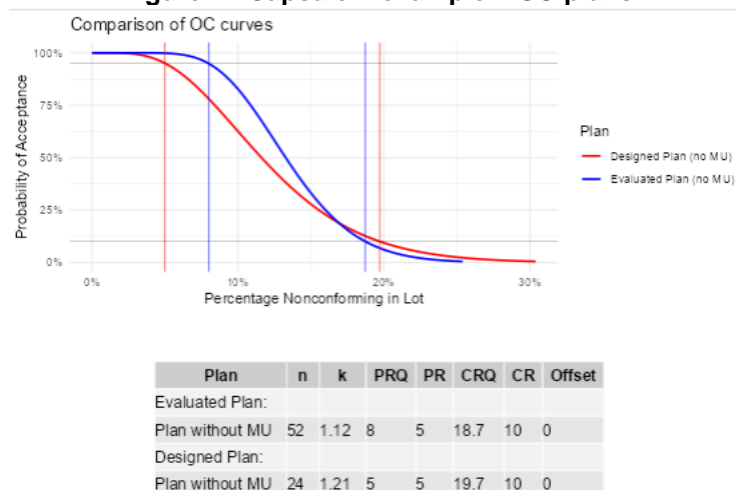
#### Plan for Capsaicin – based on Codex Standard 294-2023

Codex Standard CXS294 - 2023 for Gochujang contains a provision for capsaicin, that the levels should not be less than 10 mg/kg on a weight:weight (w/w) basis with lot acceptance decided using an attributes sampling plan with AQL = 6.5%, where a container is classed as nonconforming if the result from testing a sample taken from that container is less than the limit.

The number of samples will depend on the size of the lot but could be considerable, e.g.  $n=80$  samples for a lot consisting of 1000 containers [packages]. However, capsaicin is tested using the HPLC method, so it is not feasible to perform more than relatively few tests on each lot.

As commented elsewhere, the use of attributes plans classifying measurements as attributes is inefficient and, for a lot size of 1000 containers the corresponding variables plan from ISO3951-1 (standard deviation unknown, negligible measurement uncertainty) with AQL = 6.5% is  $n=52$ ,  $k=1.120$ , that has an AQL (PRQ) of 8%, with PR = 5%, and LQL (CRQ) of 18.7%, with CR = 10%.

Figure 24 Capsaicin example - ISO plans

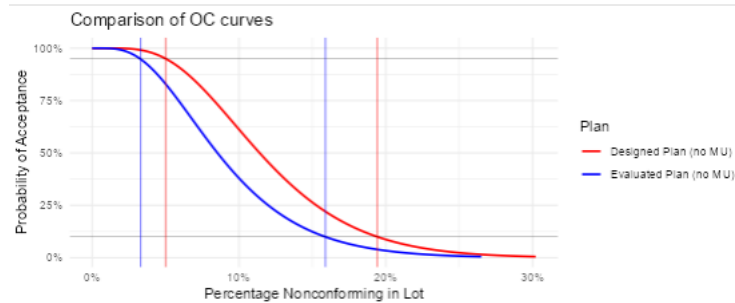


An alternative approach is to consider compliance of capsaicin levels in the overall lot rather than at the individual container level and, being a measured characteristic, it means that variables plans could be used.

Using the same consumer's and producer's risks as those for protein and moisture above (a producer's risk of 5% of rejecting lots containing 5% nonconforming product and a consumer's risk of 10% of accepting lots

containing 20% nonconforming product) the resulting variables plan is ( $n=14$ ,  $k=1.205$ ) assuming the lot standard deviation is known. This plan can be modified to allow for non-negligible measurement uncertainty.

**Figure 25 Capsaicin example - Variables plan**



Plan	n	k	PRQ	PR	CRQ	CR	Offset
Evaluated Plan:							
Plan without MU	12	1.37	3.3	5	15.9	10	0
Designed Plan:							
Plan without MU	14	1.205	5	5	19.4	10	0

Further, capsaicin is a compositional characteristic, so that, if measurement uncertainty is negligible plans based on the beta distribution (refer to CXG 50-2004 Section 4.3.1) would be applicable. Use of these plans would mean that:

- (1) a composite sample is formed from a requisite number of subsamples, that number being determined in the design of the plan based on specifications of allowable risks.

Acceptance of the lot would be determined by an acceptance criterion of the form:

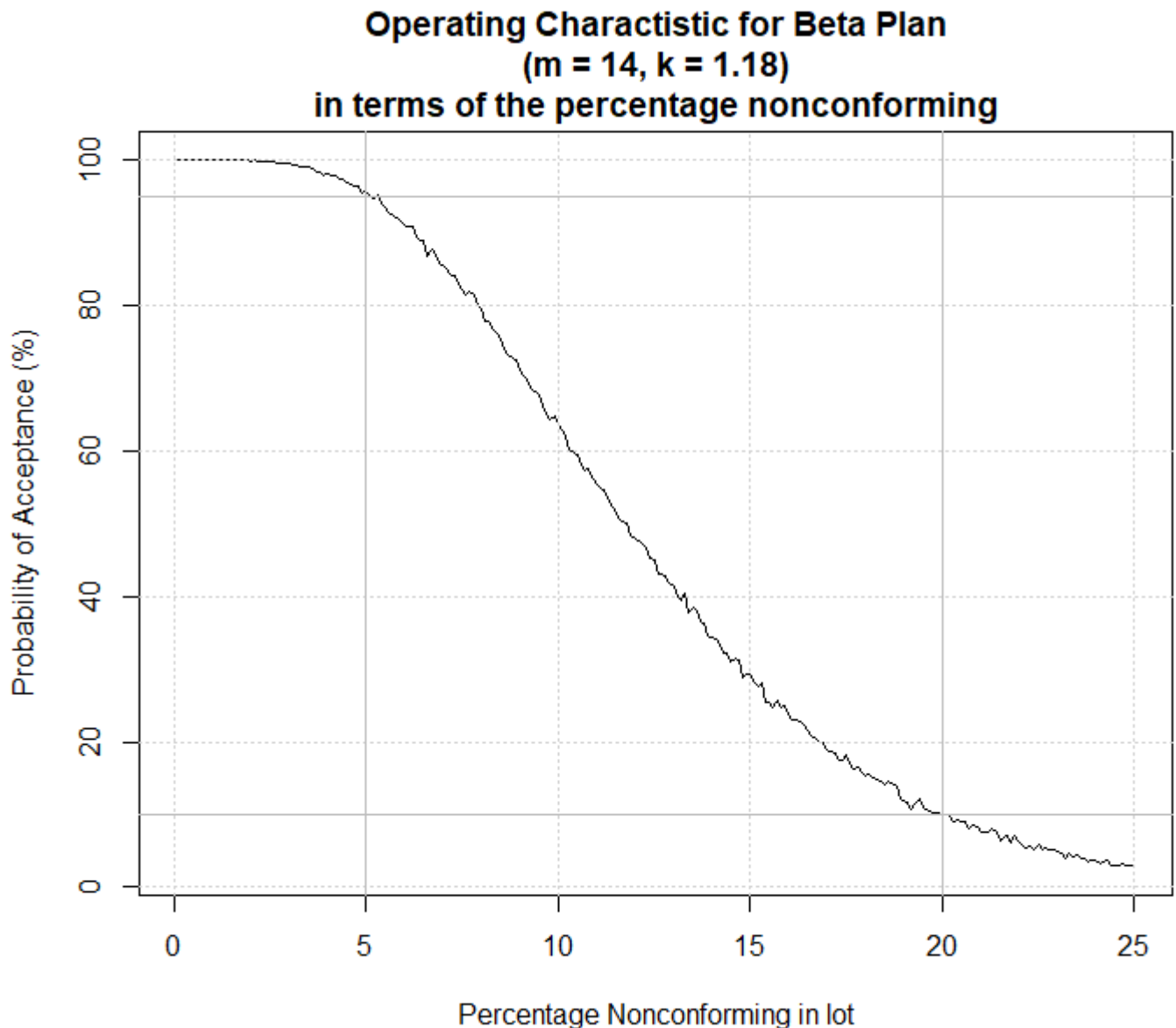
$P - k \times s \geq L$  where  $P$  is the test result or average test result and  $s = \sqrt{P(1-P)/\theta}$ ,  $L$  is the minimum limit (10ppm) and  $k$  is the acceptability constant for the plan.

Historical data would first need to be analysed to estimate the precision parameter  $\theta$  but a hypothetical value of the precision parameter of  $\theta = 44 \times 10^6$  has been used in the following example.

Using those same consumer's and producer's risks the resulting plan is ( $m=14$ ,  $k=1.18$ ) i.e. a composite sample would be formed from 14 subsamples taken randomly from the lot, with the composite tested just once – the test result would then be the estimate of “P”.

The Operating Characteristic for this plan is shown below.

Figure 26 Capsaicin example - Beta distribution plan



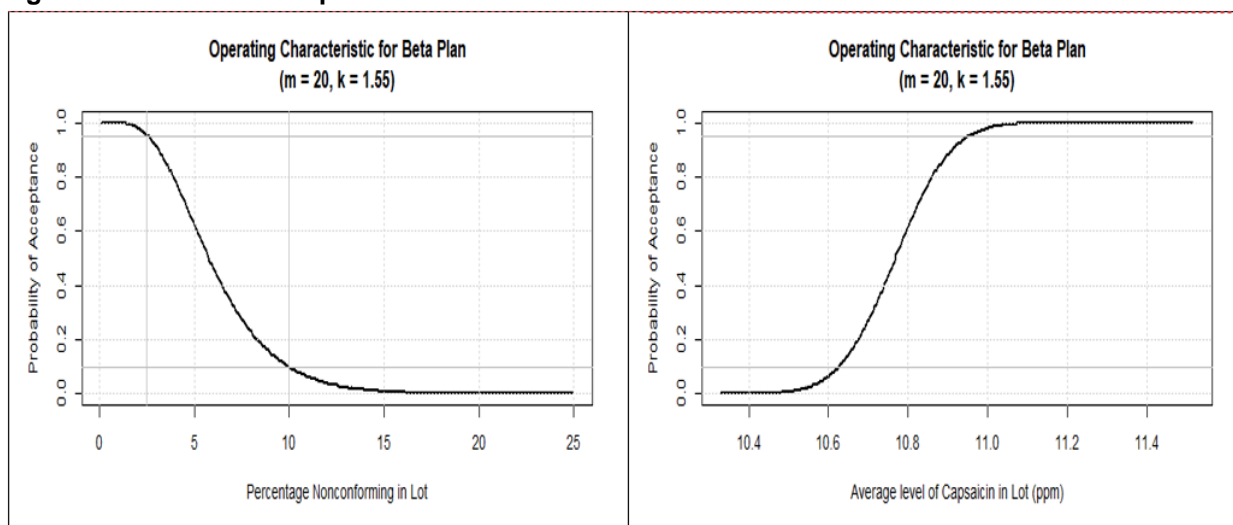
If however, we decided that capsaicin was a more critical characteristic for the product then we may wish to reduce the consumer's risk – instead of decreasing the chance of acceptance at the CRQ we can reduce the CRQ itself, to 10%, and also reducing the PRQ to 2.5%.

<b>Consumer's Risk Quality level (CRQ)</b>	
What percentage nonconforming would you allow in lots that you would want to <u>reject</u> most of the time?	10%
How often would you want to <u>accept</u> such lots (default = 10%)?	10%
<b>Producer's Risk Quality level (PRQ)</b>	
What percentage nonconforming would need to be present in lots that you would want to <u>accept</u> most of the time?	2.5%
How often would you want to <u>reject</u> such lots (default = 5%)?	5%

The corresponding sampling plan is ( $m=20$ ,  $k=1.55$ ) i.e. a composite sample would be formed from 20 subsamples randomly taken from the lot and the acceptance criterion would use a multiplier of the standard deviation of  $k=1.55$ .

The Operating Characteristics for this plan are shown below, in terms of both the percentage nonconforming and the average level of capsaicin in the lot.

**Figure 27 OC curves for plan based on the beta distribution**



### 3.4 Other sampling plans

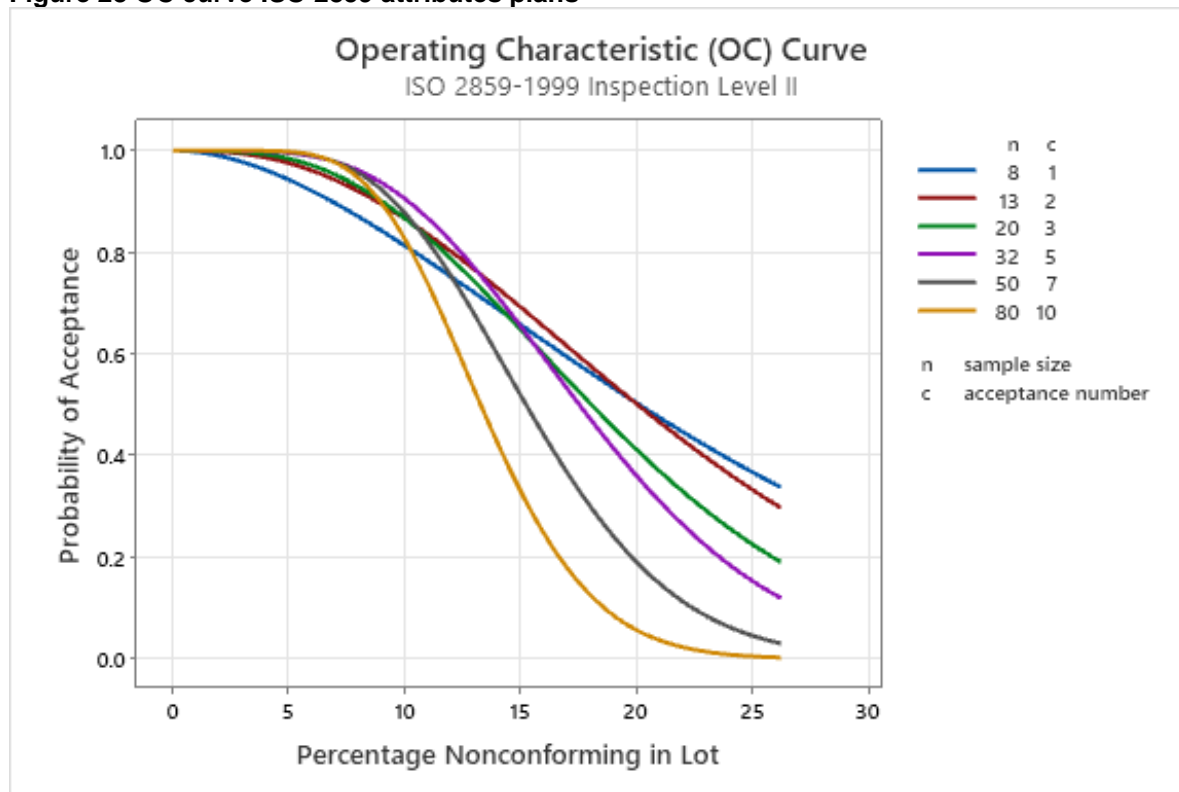
#### 3.4.1 Example: ISO sampling plans – 6.5% AQL

Refer to 3.2.2 Design of sampling plans, Table: Attributes plans from ISO 2859-1 for PRQ = 6.5 percent

A number of Codex standards contain sampling plans from the ISO standard ISO 2859<sup>4</sup> with an AQL of 6.5%, apparently because these plans were promulgated in the now defunct CODEX STAN 233, CODEX SAMPLING PLANS FOR PREPACKAGED FOODS (AQL 6.5) CODEX STAN 233-1969. While these plans might be suitable in some applications, users should first check that they will meet expectations around the control of producer's and consumer's risks before use. In particular, these plans might suffer from following problems:

- There could be poor control of the consumer's risk, that will vary according to the lot size.
- The plans should not be used by classifying variables data as attributes, except as a last resort, and not used in cases where measurement uncertainty is non-negligible.
- The ISO plans are intended to be used with switching rules; if not there will be no safeguards against deteriorating quality, nor any reward by way of reduced inspection for good quality.

<sup>4</sup> International standard ISO 2859-1: Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection.

**Figure 28 OC curve ISO 2859 attributes plans**

From CXG 50 Appendix II ISO INSPECTION PLANS INDEXED BY PRODUCER'S RISK:

Lot size (number of packages, each containing 1 or more units)	AQL	Inspection level					
		reduced		normal		tightened	
		<i>n</i>	<i>c</i>	<i>n</i>	<i>c</i>	<i>n</i>	<i>c</i>
2–8	0.65%	8	0	8	0	8	0
	2.50%	2	0	5	0	8	0
	6.50%	2	0	2	0	3	0
9–15	0.65%	8	0	15	0	15	0
	2.50%	2	0	5	0	8	0
	6.50%	2	0	2	0	3	0
16–25	0.65%	8	0	20	0	25	0
	2.50%	2	0	5	0	8	0
	6.50%	5	1	8	1	13	1
26–50	0.65%	8	0	20	0	32	0
	2.50%	2	0	5	0	8	0
	6.50%	5	1	8	1	13	1
51–90	0.65%	8	0	20	0	32	0
	2.50%	13	1	20	1	32	1
	6.50%	5	1	13	2	13	1
91–150	0.65%	8	0	20	0	32	0
	2.50%	13	1	20	1	32	1
	6.50%	8	2	20	3	20	2

Lot size	AQL	Inspection level					
		reduced		normal		tightened	
151–280	0.65%	8	0	20	0	32	0
	2.50%	13	1	32	2	32	1
	6.50%	13	3	32	5	32	3
281–500	0.65%	50	1	80	1	125	1
	2.50%	20	2	50	3	50	2
	6.50%	20	5	50	7	50	5
501–1 200	0.65%	50	1	80	1	125	1
	2.50%	32	3	80	5	80	3
	6.50%	32	6	80	10	80	8
1 201–3 200	0.65%	50	1	125	2	125	1
	2.50%	50	5	125	7	125	5
	6.50%	50	8	125	14	125	12
3 201–10 000	0.65%	80	2	200	3	200	2
	2.50%	80	6	200	10	200	8
	6.50%	80	10	200	21	200	18
10 001–35 000	0.65%	125	3	315	5	315	3
	2.50%	125	8	315	14	315	12
	6.50%	80	10	200	21	200	18
35 001–150 000	0.65%	200	5	500	7	500	5
	2.50%	200	10	500	21	500	18
	6.50%	80	10	200	21	200	18
150 001–500 000	0.65%	315	6	800	10	800	8
	2.50%	200	10	500	21	500	18
	6.50%	80	10	200	21	200	18
500 001 and over	0.65%	500	8	1250	14	1250	12
	2.50%	200	10	500	21	500	18
	6.50%	80	10	200	21	200	18

#### Producer's and Consumer's Risk Quality Levels (PR = 5%, CR = 10%)

n	c	PRQ%	CRQ%
8	1	4.64	40.62
13	2	6.60	35.98
20	3	7.14	30.42
32	5	8.50	27.07
50	7	8.22	22.42
80	10	7.91	18.60

#### Conclusion

Whilst possibly facilitating trade, plans with low sample numbers do not provide high levels of consumer protection, that will vary according to the lot size.

#### Net weight

It appears Codex has not provided any guidance on sampling plans for net weight. However, the need for provisions relating to weight has possibly been superseded by the introduction of weight legislation using

the Average Quantity System, based on the OIML International Recommendation R087 published by BIPM.

### 3.4.2 *Ad hoc* plans

Suppose, for example, that 4-6 samples are taken, formed into a composite sample and a single laboratory sample taken from the thoroughly mixed composite for analysis.

This is not the standard statistical approach to the design of sampling plans as the plan is not designed from specifications of allowable risks; therefore, we must evaluate it to check that it will control risks satisfactorily.

Four options have been evaluated:

- (1) use of the single result in an ( $n=1$ ,  $c=0$ ) sampling plan for the assessment of compliance to an average level (see 3.4.2.1 Compliance of the average level scenario evaluation),
- (2) use in an ( $n=1$ ,  $c=0$ ) attributes plan (see 3.4.2.2 Compliance of the average level scenario evaluation),
- (3) use in a variables plan (see 3.4.2.3 Variable Plan scenario evaluation) and
- (4) use in a plan based on the beta distribution if the characteristic is a compositional proportion and measurement uncertainty is negligible (see 3.4.2.4. Beta distribution plan scenario evaluation).

Notation:

$U$  the upper specification limit,

$\sigma$  (*sigma*) the assumed known value of the lot standard deviation (rather than an estimate of  $\sigma$ ).

Alternatively, the error-variance ratio must be well known; in this case it refers to the ratio of the reproducibility variance to the lot variance.

$$\text{Error - variance ratio} = \frac{u^2}{\sigma^2}$$

$u$  the assumed known standard deviation representing the standard measurement uncertainty.

The uncertainty of the average level  $\bar{x}$  of the composite sample formed by taking  $n$  samples will be  $\sigma/\sqrt{n}$  and the uncertainty variance of the measured value will be  $\sqrt{u^2 + \frac{\sigma^2}{n}}$

The following examples reinforce the guidance in ISO2859 that ad hoc sampling methods are not recommended since they lead to uncalculated risks and often to unjustifiably high risks; further, there is no logical basis for either the acceptance or rejection of the product.

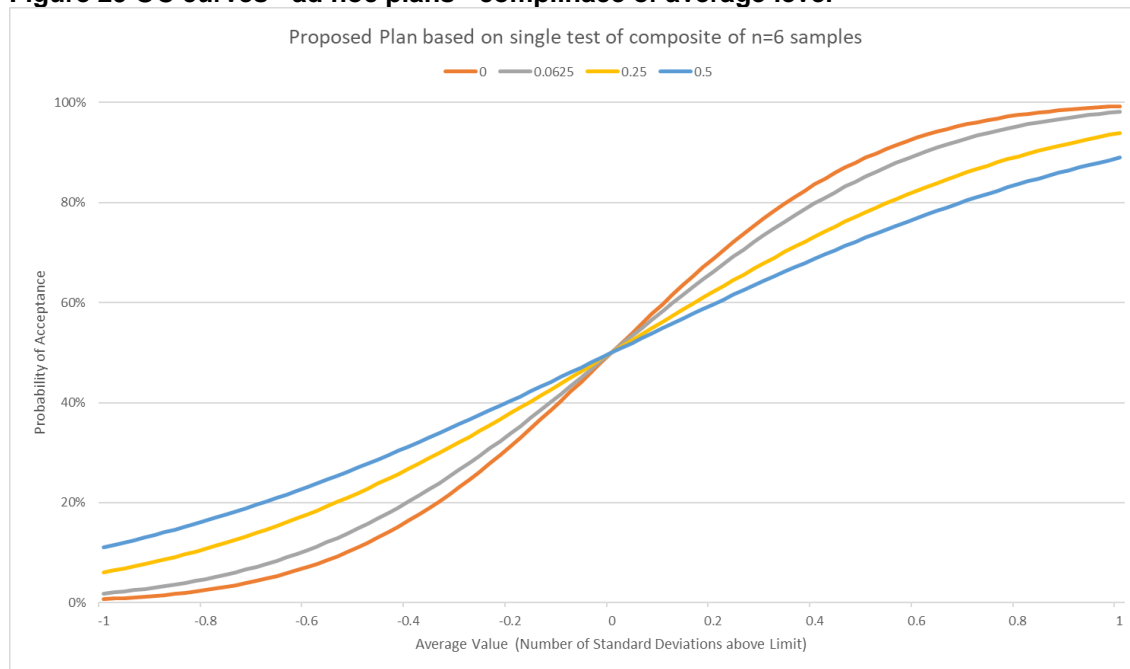
#### 3.4.2.1 Compliance of the average level scenario evaluation

The probability of acceptance, of accepting a lot against a lower limit  $L$  in terms of the true average level  $\mu$  in the lot is given by:

$$p_{acc} = \text{NORMSDIST}(k * \sigma / \text{SQRT}(\sigma^2/n + u^2))$$

Using Excel formula notation, where:

$k * \sigma$  is the offset from the limit.

**Figure 29 OC curves - ad hoc plans - compliance of average level**

The different lines show the OC curves for different values of the error-variance ratio.

### Conclusion

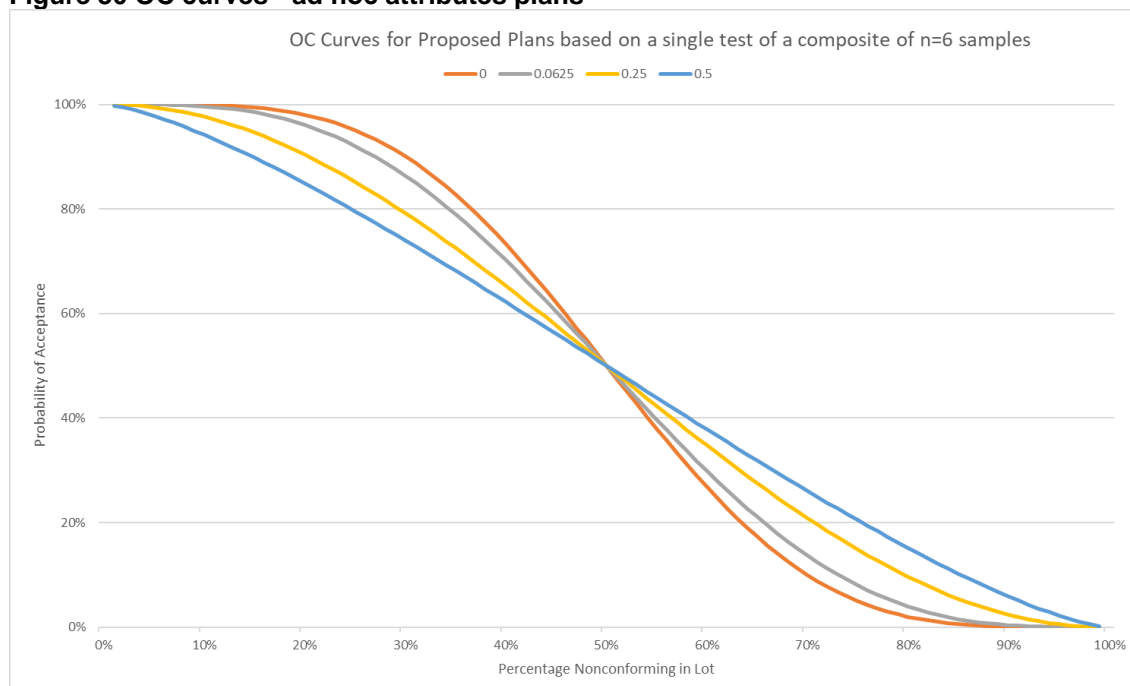
This shows that the proposed plan is ineffective for assessing compliance of an average level – for example there is still a high chance of acceptance when the true average level is a reasonable number of standard deviations below the limit; for example, around 20% chance of acceptance when the average level is 0.5 standard deviations below.

#### 3.4.2.2 Attributes Plans

The probability that a single result will meet the upper limit is given by:

$$p_{acc} = NORMSDIST(NORMSINV(1 - NC) * \sigma / \sqrt{\sigma^2/n + u^2})$$

where NC is the percentage nonconforming in a lot.

**Figure 30 OC curves - ad hoc attributes plans**



## Conclusion

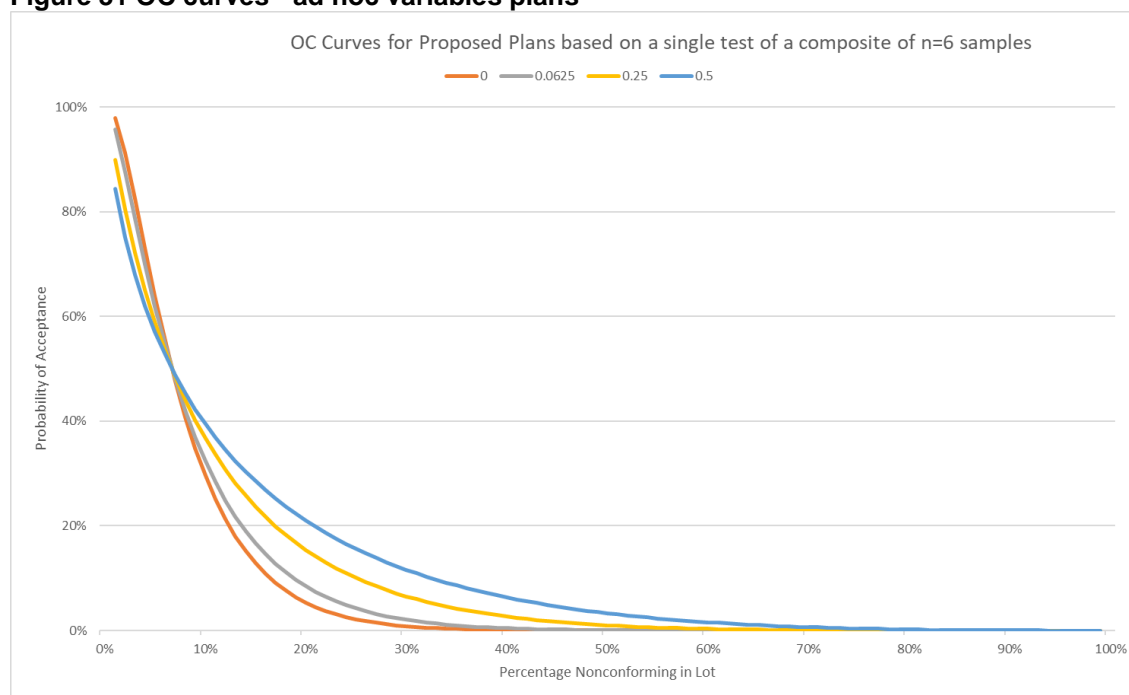
This plan also appears ineffective for assessments against upper or lower limits; this is not surprising since a composite sample represents the average level in a lot. Note that a single sample is also a representation of the average level of a lot.

Refer to section 4.1.2 for a discussion about (n=1, c=0) sampling plans.

### 3.4.2.3 Variables Plans

$$p. acc = NORMSDIST((NORMSINV(1 - NC) - k) * sigma / SQRT(sigma^2/n + u^2))$$

**Figure 31 OC curves - ad hoc variables plans**



## Conclusion

By using variables plans one can better control the risks of noncompliance by varying the value of k, the acceptability constant; the image shows the OC curves for k=1.5.

However, use by consumers of large k values for simplification or to reduce costs of testing does not seem to be a fair practice, considering that CXG50 is intended to apply mostly to commodity characteristics such as composition of 'commodity defects' and should serve to facilitate trade.

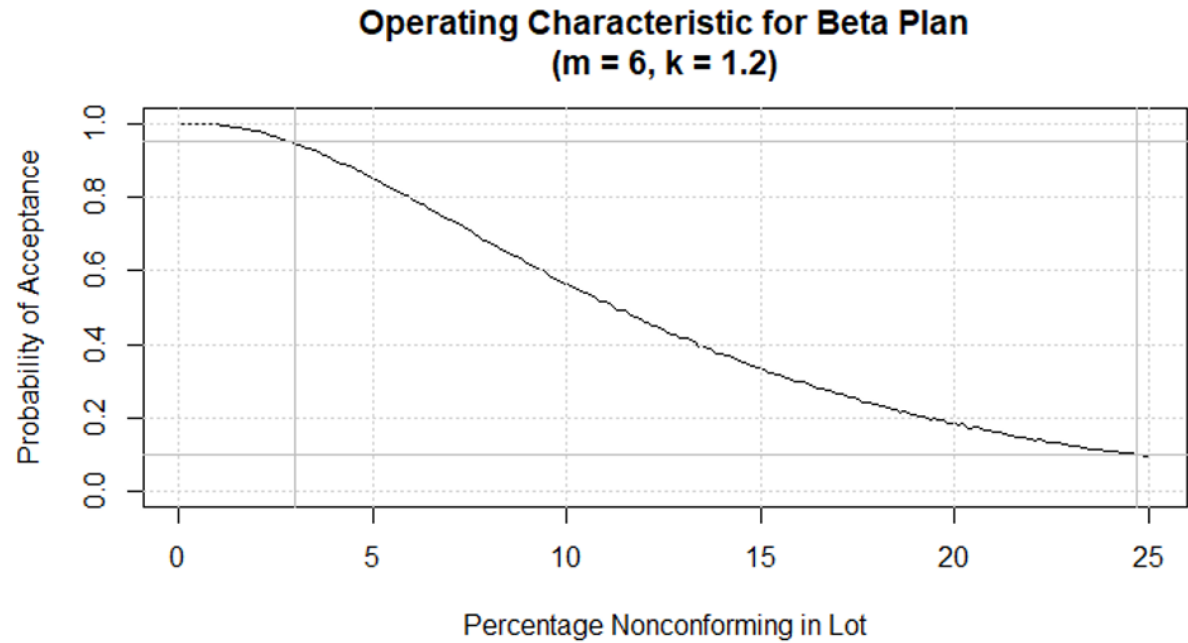
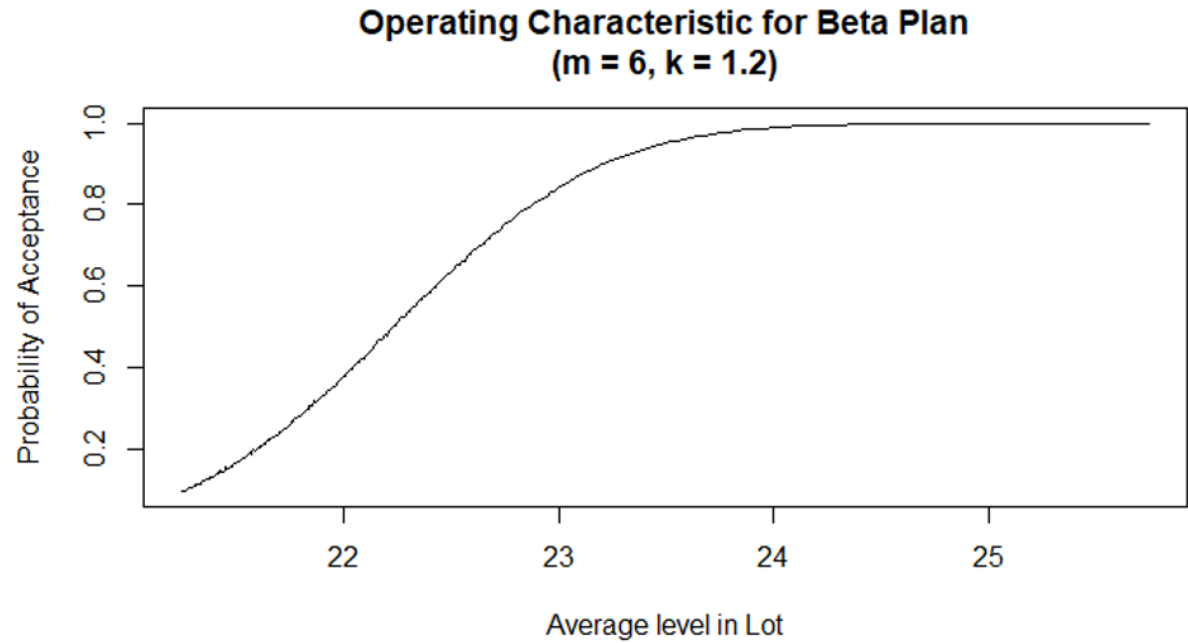
### 3.4.2.4 Beta distribution plans

Use of a composite sample does not allow the use of attributes plans, and conventional variables plans won't be very useful unless one is assessing compliance against an average level (and maybe not even then).

The only possible classical solution seems to be the plans based on the beta distribution that requires the characteristic to be a compositional proportion and that measurement uncertainty is negligible.

These examples are based on a value of the theta parameter of  $\theta = 500$  and a minimum limit of  $L=20$ , (some previous work found that theta values for fat, protein and moisture in milk powders were between 700-3000).

Figure 32 OC curves for ad hoc beta plan



# PART TWO

Background on sampling plans

Statistical appendix

## 4 Background to Acceptance Sampling Plans

### 4.1 Attributes plans

Two class attributes plans are based on the binomial distribution; for the plan (n, c) the probability of acceptance is given by:

$$\text{Prob acceptance} = \sum_{k=0}^c \binom{n}{k} p^k (1-p)^{n-k}$$

where p is the percentage nonconforming in the lot. This formula can be used to calculate the probability of acceptance for any level nonconforming p, to construct the operating characteristic.

This expression can be conveniently evaluated using the Excel function BINOM.DIST().

Example, the probability of accepting a lot in which p= 10% of the items are nonconforming, using the sampling plan (n=10, c=1) is given by.

$$\text{BINOM.DIST}(1,10,0.1,\text{TRUE}) = 0.736$$

or by the formula:

$$p_{acc} = \binom{10}{0} 0.9^{10} + \binom{10}{1} 0.9^9 \times 0.1 = 0.9^{10} + 10 \times 0.9^9 \times 0.1 = 0.736$$

However, if the level nonconforming varies between lots, this OC curve will not properly reflect the longer-term probability of acceptance with this plan; one solution due to Calvin [14] is to describe the variation in the level conforming by a beta distribution, in which case the long-term probability of acceptance will be given by a Polya distribution.

In general, if both the consumer's and producer's risks are specified in the design of the plan, as might be appropriate for non-food safety characteristics such as commodity defects, it is unlikely that the acceptance numbers, the c values, will be zero. It should be noted that rather large sample sizes (and large acceptance numbers) might be needed for plans where the operating ratio (CRQ/PRQ) is small.

Section 2.4.2 contains an Excel file that allows the calculation of 95% confidence intervals for the percentage nonconforming or the number of defects in a lot when nonconforming items have been found in the sample.

The lower 95% confidence limit (LCL) for the proportion of nonconforming items in the lot can be calculated using the Excel formula:

$$\text{LCL} = \text{BETAINV}(0.025, x, n-x+1),$$

and the upper 95% confidence limit by:

$$\text{UCL} = \text{BETAINV}(0.975, x+1, n-x)$$

where x is the number of nonconforming items observed in the sample and n is the total sample size.

Similarly, the lower 95% confidence limit (LCL) for the number of defects in the lot can be calculated using:

$$\text{LCL} = 2 * \text{GAMMA.INV}(0.025, x, 0.5),$$

and the upper 95% confidence interval by:

$$\text{UCL} = 2 * \text{GAMMA.INV}(0.975, x+1, 0.5)$$

### 4.2 Variables plans

In the case of variables plans, once PR, CR, PRQ and CRQ have been specified, then the sample size n and the acceptance constant k can be calculated as follows:

$$k = \frac{Z_{1-PR} \cdot Z_{1-CRQ} - Z_{1-PRQ} \cdot Z_{CR}}{Z_{1-PR} - Z_{CR}}$$

where, for  $0 < p < 1$ ,  $z_p$  denotes the one-sided quantile of a standard normal distribution, i.e.

$$\mathcal{P}(X \leq z_p) = p$$

for

$$X \sim \mathcal{N}(0,1).$$

In Excel, these quantiles can be calculated by means of the `NORM.S.INV(p)` function.

For the case that the lot standard deviation is known ( $\sigma$  method), the sample size can be determined as follows:

$$n = \left( \frac{Z_{CR} - Z_{1-PR}}{Z_{1-CRQ} - Z_{1-PRQ}} \right)^2$$

For the case that the lot standard deviation is not known ( $s$  method), the above expression for  $n$  must be multiplied by the factor  $1 + \frac{k^2}{2}$ .

The derivation of this concept is quite instructive and provided in Section 5.1.2.

#### 4.2.1 Basis for calculations in App1

Firstly, when measurement uncertainty is negligible, the probabilities of acceptance for the variables sampling plans can be calculated using the formulas above, shown in terms of Excel functions as follows:

Known standard deviation 'sigma'

$$Prob. acc = NORMSDIST((NORMSINV(1 - theta) - k) * SQRT(n), TRUE)$$

Unknown standard deviation (sigma unknown, estimated from the inspection data):

$$Prob. acc = NORMDIST((NORMSINV(1 - theta) - k) * SQRT(n) / SQRT(1 + k * k / 2))$$

where:

$n$  is the number of samples,

$k$  is the acceptability constant,

$\theta$  ( $\theta$ ) is the level nonconforming in the lot at which the probability of acceptance is to be calculated,

`NORMSDIST()` is the cumulative standard normal distribution function, and

`NORMSINV()` is the inverse of the standard normal distribution function.

There is no exact solution when the between laboratory standard deviation is non-negligible, so one must rely on an approximation. Wetherill [29] uses the following method based on a normal approximation for the negligible measurement uncertainty case.

$$p_{acc} = pr(\bar{x} + k \cdot s \leq U) = pr(\bar{x} + k \cdot s - \mu - k \cdot \sigma \leq U - \mu - k \cdot \sigma)$$

where  $k$  is the acceptability constant,  $U$  the upper specification limit and  $\sigma$  the lot standard deviation.

Making the substitution for  $U - \mu = \sigma \cdot NORMSINV(1 - \theta)$ , and standardising to a standard normal random variable  $Z \sim \mathcal{N}(0,1)$  using the well-known normal approximations for the expected value and standard deviation (uncertainty) of a standard deviation:

$$E(s) = \sigma \text{ and } var(s) = \frac{\sigma^2}{2(n-1)} \approx \frac{\sigma^2}{2n}$$

we get:

$$p_{acc} = pr\left(Z \leq \frac{NORMSINV(1 - \theta) - k}{\sqrt{\frac{\sigma^2}{n} + \frac{k^2}{2n}}}\right) = NORMSDIST\left(\frac{NORMSINV(1 - \theta) - k}{\sqrt{\frac{\sigma^2}{n} + \frac{k^2}{2n}}}\right)$$

This expression can be extended to allow for measurement uncertainty and any offsets used to allow for non-negligible between laboratory MU.

$$p_{acc} = pr \left( Z \leq \frac{NORMSINV(1 - \theta) - k}{\sqrt{\sigma_b^2 + \frac{\sigma_r^2}{n} + \frac{\sigma^2}{n}}} \right) = NORMSDIST \left( \frac{NORMSINV(1 - \theta) - k}{\sqrt{\sigma_b^2 + \frac{\sigma_r^2}{n} + \frac{\sigma^2}{n}}} \right)$$

In this expression the uncertainty of the calculated mean value depends on the repeatability standard deviation  $\sigma_r$  and the between laboratory standard deviation  $\sigma_b$ .

If an offset ( $offset = q \cdot \sigma_b$ ) is applied to allow for between laboratory measurement uncertainty, the probability of acceptance becomes.

$$p_{acc} = pr \left( Z \leq \frac{NORMSINV(1 - \theta) - k - q \cdot \sigma_b}{\sqrt{\sigma_b^2 + \frac{\sigma_r^2}{n} + \frac{\sigma^2}{n}}} \right) = NORMSDIST \left( \frac{NORMSINV(1 - \theta) - k - q \cdot \sigma_b}{\sqrt{\sigma_b^2 + \frac{\sigma_r^2}{n} + \frac{\sigma^2}{n}}} \right)$$

where  $q$  is the multiplier of between laboratory standard deviation in the offset. Allowance for method biases can be made in the same way, subtracting the method bias from the numerator in the equation.

### 4.3 Calculating measurement uncertainty from precision estimates

The calculation of the probability of acceptance and the form of the acceptability criterion must take account of how the sampling and analytical components of measurement uncertainty are affected by any compositing, or by averaging of results performed as part of the overall sampling, subsampling, sample preparation and analytical procedures for the plan.

The following examples show the basic principles, where:

- $\sigma_r$  is the repeatability standard deviation
- $\sigma_L$  is the standard deviation representing the laboratory bias
- $\sigma_R$  is the reproducibility standard deviation
- $u$  is the standard measurement uncertainty
- $\sigma$  is the lot standard deviation

We distinguish the following 5 cases:

1. A single sample (increment) taken from a lot.

$$u = \sigma_R = \sqrt{\sigma_L^2 + \sigma_r^2}$$

This is the analytical component of measurement uncertainty.

2. A single taken from a lot, interpreting the result as the average level of the lot.

$$u = \sqrt{\sigma^2 + \sigma_L^2 + \sigma_r^2}$$

3.  $n$  samples taken from lot, and tested, and the results averaged to provide an estimate of the average level

$$u = \sqrt{\frac{\sigma^2}{n} + \sigma_L^2 + \frac{\sigma_r^2}{n}}$$

4. A composite of  $n$  subsamples is tested once to provide an estimate of the average level.

$$u = \sqrt{\frac{\sigma^2}{n} + \sigma_L^2 + \sigma_r^2}$$

5.  $n$  samples taken from the lot, each is tested  $m$  times, and results averaged to estimate the average level

$$u = \sqrt{\frac{\sigma^2}{nm} + \sigma_L^2 + \frac{\sigma_r^2}{nm}}$$

#### 4.4 Combined attributes-variables plans

It is possible to modify the acceptance criterion for variables plans by including an additional requirement on the individual analytical results, typically that none of the results should exceed the specification limit. This leads to a combined attributes-variables plan.

This additional requirement will reduce the probability of acceptance, the decrease is obviously greater at higher levels nonconforming.

Refer also to CXG 50-2004 section 5.2.9 Fractional Nonconformance plans that are another type of combined attribute-variables plans.

#### 4.5 Multi-stage plans

In multi-stage plans the inspection is carried out in several stages, most commonly two-stage plans are used. At each stage, a specified number of samples is taken and tested, although practically, a larger number of samples may be taken at the first stage in case they need to be tested at Stage 2:

- if the results meet the acceptance criterion for that stage, the lot is accepted without any further inspections needed.
- If the results meet the rejection criterion for that stage, the lot is rejected.
- If neither criterion is met, sampling continues to the next stage [if there is one].

The following example shows how a double attributes sampling plan operates. This example is based on a producer's risk of 5% at a quality level of 1% nonconforming and a consumer's risk with a 10% at a quality level of 5% nonconforming.

##### Stage 1:

$n_1 = 88$  samples are taken at random from a lot.

- If at most one nonconforming item was found, then accept the lot.
- If four or more nonconforming items were found, then reject the lot.
- If two or three nonconforming items were found, proceed to Stage 2.

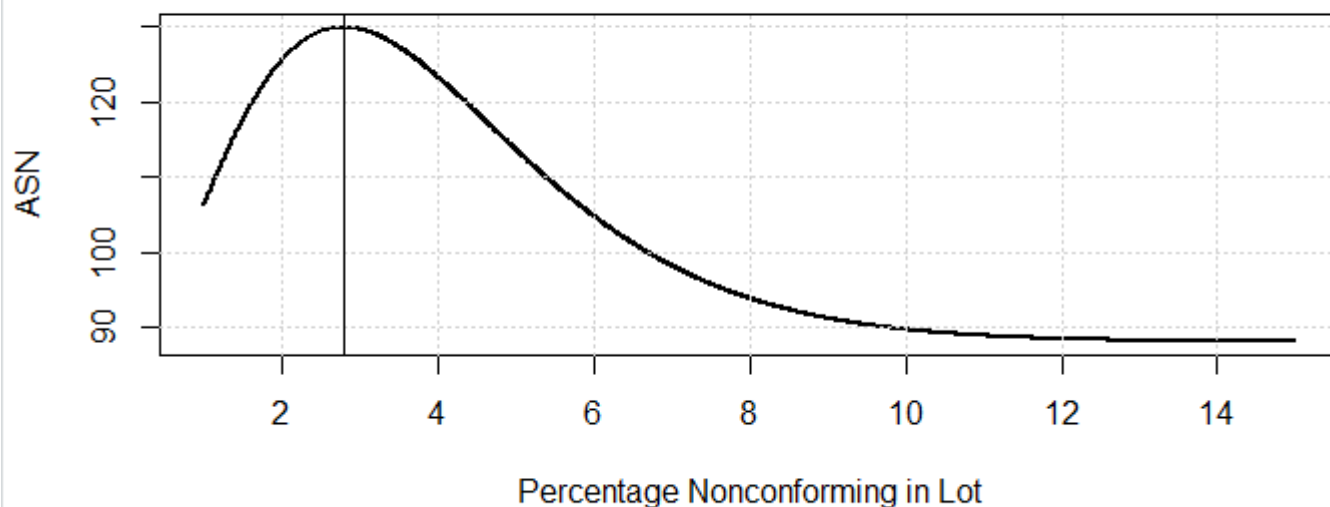
##### Stage 2:

$n_2 = 88$  additional samples are taken at random from a lot.

- If at most four nonconforming items were found in both stages, then accept the lot.
- If five or more nonconforming items were found in both stages, then reject the lot.

The main advantage of multi-stage plans is the reduction in the overall average sample size relative to the sample size for a single stage plan for the same control of producer's and consumer's risks; lots of very good quality lots are accepted, and lots of very poor quality are rejected, at the first stage. However, a disadvantage of multi-stage plans is the increased administrative and other costs and the possible delay making a final decision on the disposition of marginal lots.

The maximum Average Sample Number (ASN) for the double sampling plan is  $n_1 + n_2 = 130$  approximately, at a quality level of about 2.8% nonconforming, but the ASN is considerably less at other levels nonconforming.

**Figure 33: Two stage plan – expected average sample number (ASN) by level nonconforming**

The corresponding single sample plan is ( $n=132$ ,  $c=3$ ).

#### 4.6 Lots consisting of bulk materials

This section provides information on the design of plans for bulk materials, particularly relating to plans to assess compliance of the average level to a maximum or minimum limit that are often used for chemical contaminants. In particular, this section provides:

- The scope, some understanding, few basic properties of sampling plans for bulk materials, and 'motivation' for their use.
- Review of ISO 10725, Acceptance sampling plans and procedures for the inspection of bulk material, for assessment of the average level.
- Acceptance sampling for aflatoxins, in particular, the plans described in Whitaker's work, including explanation of tables from the *General standard for contaminants and toxins in food and feed* (CXS193-1995).

Detailed guidance is not provided on the following topics because of the statistical complexity involved; it is recommended that users seek assistance from a statistician:

- Characterizing the heterogeneity in bulk sampling, partitioning total heterogeneity in various components.
- The design of sampling plans for bulk materials to assess compliance against a minimum or maximum limits.

Note: plans for bulk materials are generally one-off i.e. applicable to a specific situation or a limited range of situations, so are not necessarily transferable to other matrices or characteristics.

Bicking (1970) defines the following process for the design of sampling plans for bulk materials:

1. State the problem for which an estimate of the average value is required.
2. Collect information on the relevant properties of the material (averages and components of variance of the properties)
3. Identify the components of variation in the overall sampling and testing process that might be relevant to the intended sampling plan options.
4. Estimate these components using a suitable statistical design (often 'hierarchical' designs are used)



5. Consider various approaches, taking account of cost, precision and difficulties.
6. Evaluate these plans in terms of the cost of sampling and testing, delay, supervisory time and convenience.
7. Calculate the standard deviations associated with the estimates of the average levels for these plans and their uncertainty (degrees of freedom).
8. Provisionally, select a plan from one of these approaches.
9. Reconsider the preceding steps.

The acceptance criterion will be of the form:  $\bar{x} + k \cdot S \leq USL$  for upper specification limit  $USL$  for the average level, where  $S$  is the standard error (standard deviation) of the estimate  $\bar{x}$  of the mean level and  $k$  is the multiplier<sup>5</sup> of the standard error in the acceptance criterion. Note that this multiplier is different from the acceptability constant used with variables plans used to control the percentage nonconforming.

If the cost associated with the initial sampling step was low the plan could be economized by taking more increments to improve the precision of the estimate of the average level.

#### 4.6.1 Example: Variables Plans for homogeneous lots—negligible MU

As an alternative to the sampling plan discussed in section 4.2.1, the contents of the cans in the lot could be considered as a bulk material so that the assessment relates to the contents of the lot as a whole rather than to compliance at the can level. This approach would also allow plans for the beta distribution to be used, with the possible benefit of being able to carry out an inspection based on a single test of a composite sample, if the characteristic inspected was a compositional proportion.

If both producer's and consumer's risks are specified in the design of the sampling plan, the design process is the same as in section 4.2.1, noting that the sample size does not depend on the lot size if both risks are specified.

To avoid repetition, the full details of the plan in section 4.2.1 are not repeated here, but in summary that plan was based on the following assumptions:

The CRQ was chosen as 10% and the PRQ as 2.5%, with the CR and PR at 10% and 5% respectively. This means that the plan will have:

- A 10% chance of accepting a lot in which 10% of the product is nonconforming.
- A 5% chance of rejecting a lot in which 2.5% of the product is nonconforming.

The lot standard deviation was assumed to be  $\sigma = 0.3$  and the measurement uncertainty was considered negligible, leading to the plan ( $n=43$ ,  $k=1.59$ ), i.e. 43 samples need to be taken from the lot and tested, with the lot is accepted with respect to milkfat provided the average and the standard deviation of the results meet the acceptance criterion:

$$\bar{x} - 1.59 \times s \geq 26$$

where:

- $\bar{x}$  is the average of the 43 individual results and 's' their standard deviation,

#### 4.6.2 Example: Variables plan with non-negligible MU with no laboratory bias

Refer to section 4.2.2 – the process for the design of the sampling plan is the same.

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<sup>5</sup> The multiplier is based on the Student's T-distribution for which the number of degrees of freedom has to be determined using a statistical procedure. See Schilling for an example and the CXG 54 Information Document for more information, but the details of this procedure are outside the scope of these guidelines.

### 4.6.3 Example: Variables plan with non-negligible MU with laboratory bias

Refer to section 4.2.3 – the process for the design of the sampling plan is the same as described in that section.

### 4.6.4 ISO 10725

This standard follows the work by Schilling & Neubauer and is discussed in their book [3], available on-line [5].

ISO10725 describes procedures for the design of sampling plans for the assessment of the average levels of lots, based on a three-component model:

- A number of increments are taken from the lot and combined to form composite samples.
- Test portions are taken from each of the well-mixed composite samples.
- Each test portion is tested a number of times.

As well as the variation of each component, the standard also allows for the actual (or relative) costs of each step to be taken into account to obtain cost optimal plans for specified levels of producer's and consumer's risks.

It is assumed that the standard deviations and the costs of each of the steps are known but the standard contains procedures to deal with situations where the costs or the standard deviations are not known.

### 4.6.5 Aflatoxin sampling plans

#### Introduction

The sampling plans for mycotoxins derived by Whitaker et al. are special cases of plans for bulk materials. Whitaker used 46 years of laboratory data, including some from contaminated lots, to derive Horwitz-type equations for the sampling, subsampling and analytical components of the total variation.

This method cannot be applied for the design of plans for new matrices or for new contaminants for which limited, or possibly unsuitable, historical data is available. In this case the classical approach described in Schilling, that underpins the ISO10725 standard, would be applied. A first step is to quantify the components of variation relevant to the intended sampling procedure using a suitable experimental design.

However, there are potential problems in that not every lot will be contaminated, and contamination might not be found in those lots that are actually contaminated, so that a considerable number of lots might be required for this exercise. Bayesian approaches might provide a way forward.

Following that, a sampling plan can be developed in terms of:

- the number of segments sampled
- the number of samples taken from each segment
- compositing and subsequent subsampling of those samples
- compositing of the subsamples
- the number of laboratory samples taken for testing
- analytical measurement uncertainty

The usual approach involves experimentation with the number of segments sampled, number of 'samples' taken at each stage and the number of results that are produced, the results from which are averaged. These numbers might also be chosen taking account of the cost involved in each operation. The statistical objective of the design process is the find the acceptability constant  $K$  in the acceptance criterion:

$$\bar{X} + t \cdot S \leq U$$

where:

$U$  is the average test result

$\bar{X}$  is the average test result, that will be an estimate of the overall average level in the lot

$S$  is the standard deviation of the estimate of the average level, usually referred to as the 'standard error'

$t$  is the multiplier of the standard error in the acceptance criterion, a percentage point on the "t-distribution", obtained using a statistical procedure by taking account of the uncertainties of the components of the sampling and measurement variation.

There may be other considerations in the design of plans, not taken into account in Whitaker's work, such as:

- Whether one can make use of an assumed distribution for the characteristic in the lot considering that the behaviour of heterogeneous materials cannot normally be explained in terms of a single standard deviation or distribution.
- Is it necessary to use discrete distributions to describe this behaviour given that the composite sampling will cause averaging?
- Does the use of cluster sampling need to be allowed for?

Other issues:

Designers of plans should consider what contamination scenarios they wish to detect, that is, the required probabilities of detection of detecting 'spikes' of contamination that contain certain levels of contamination and are of certain durations.

Compositing strategies should be developed to ensure that 'important' spikes of contamination are not averaged out to the extent that they cannot be found.

### Aflatoxin sampling plans

The Horwitz type equations were derived for the three variance components (sample to sample, subsampling and the analytical components of variation) in terms of the average concentration of aflatoxin.

CXS 193 shows the breakdown of the total variation for aflatoxins in tree-nuts, for example, into components  $S_s^2$ ,  $S_{sp}^2$  and  $S_a^2$ , due to sampling, subsampling and testing respectively. It should be noted that provisions for aflatoxins are expressed in terms of the average levels in a lot; these plans employ large offsets between the limits and the levels at which the foods become unsafe to consume in order to provide consumer protection (refer CXG 50-2004 4.3.5 Plans for the average level in the lot).

**Table 1. Variances<sup>a</sup> associated with the aflatoxin test procedure for each treenut**

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

The sampling plan is defined in terms of laboratory sample size  $n_s$ , test portion size  $n_{ss}$  and the number of aliquots  $n_a$ , the number of analytical samples taken from each subsample. The information in this table can be used to calculate the uncertainty of the estimated average value obtained using the sampling procedure and thereby the probability of acceptance. For example, the variance of the estimate of the average level for almonds is given by:

$$S^2 = \frac{7730 \times 5.759}{n_s} C^{1.561} + \frac{100 \times 0.170}{n_{ss}} C^{1.646} + \frac{0.048}{n_a} C^2$$

This equation implies the following sampling and testing procedure:

1.  $n_s$  samples are taken from the lot under consideration.
2. A composite sample is formed.
3. A laboratory sample of size  $n_{ss}$  grams is taken from that well-mixed composite.
4.  $n_a$  aliquots are taken from that subsample for testing.

In the FAO Mycotoxin plans this procedure can be carried out on more than a single sample, but the results for the different samples are not averaged but compared with the limit separately.

This criterion differs from the usual acceptance criterion for the assessment of compliance of the average level for bulk materials in general that would be of the form:

$$\bar{X} + t \times S \leq USL$$

where S is the uncertainty of the average level, t is the multiplier of the standard deviation in the criterion and USL is the upper limit for the mean.

This is a further example of the use of offsets that, in this case, allow simplification of the acceptance criterion.

CXS 193-1995 describes the operational details of the sampling and testing procedure:

1. A 20kg sample taken (1000 [shelled] almonds per kg) from a lot or part lot (sublot), with a 25-tonne limitation on lot size. These samples should be formed from many smaller increments, each no less than 200g. CXS 193-1995 provides guidance on the number of increments, in terms of sample size.
2. The entire sample is ground to a uniform particle size and thoroughly mixed.
3. A test portion of no less than  $n_{ss} = 50g$  is taken from the composite sample
4. A number ( $n_a$ ) of aliquots is taken for testing.
5. The results from these  $n_a$  tests are averaged. However, it appears that CXS 193-1995 assumes only single tests are performed ( $n_a = 1$ ) and that usually one or two different samples might be tested with the lot accepted provided no result exceeds the limit. This leads to different probabilities of acceptance, depending on the number of samples that are taken.

### Example – Shelled Almonds for further processing

Suppose the average concentration of aflatoxins in the lot was  $C = 8 \mu g/kg$  and  $n_s = 20000$ , 20 kg @ 1000 shelled nuts per kg, were taken as a sample, and this sample was ground, and well-mixed composite formed. If a subsample of 50g was taken and a single aliquot ( $n_a = 1$ ) tested, the standard deviation  $S$  representing the uncertainty of the average level would be:

$$S^2 = \frac{7730 \times 5.759}{20 \times 1000} 8^{1.561} + \frac{100 \times 0.170}{50} 8^{1.646} + \frac{0.048}{1} 8^2 = 70.67$$

Giving  $S = 8.41$ . The first component representing the sample-by-sample variation is much larger than the other two.

### Comments

The web-based FAO Mycotoxin Tool [2] for the evaluation of sampling plans is provided at <http://tools.fstools.org/mycotoxins/>.

This tool allows for only a single component of measurement uncertainty; there is no allowance for bias when multiple tests are performed. The tool allows users to select whether “within lab” or “among lab” variation is used, with the among laboratory variation equal to twice the within laboratory figure. The tables below show the within laboratory variance.

The sampling component is included using an assumed distribution, most often the negative binomial, a discrete distribution to allow contamination at the individual particle (e.g. grain) or sample level to be modelled - due to the small percentages (typically less than 1%) of contamination and the extreme distribution of contamination within lots very large sample sizes are needed to estimate the distribution.

The decision rule for Almonds for further processing in CXS 193 is that the lot is accepted “if the aflatoxin result is less than  $15 \mu g/kg$  in both samples...”, so that each individual result is classified as pass or fail with respect to the limit. However, as the analytical component is small relative to the sampling component, this does not seem to matter.

To calculate probabilities of acceptance (and the OC curve) we need to know the distribution of the sample-to-sample variation within a bulk lot. As above, Whitaker assumed, mostly, that the sample-to-sample variation follows a negative binomial distribution.

The negative binomial distribution is used in situations where the variation is more extreme than the binomial; it is defined in terms of an average value and a variance.

$$\text{Average} = \mu; \text{Variance} = S^2 = \mu + \frac{\mu^2}{k}$$

where  $k$  is the dispersion factor that allows for the extra variation.

To work out the theoretical probability of acceptance at a concentration  $C$  of aflatoxin Whitaker used the ‘method of moments’, equating the theoretical concentration  $C$  to the mean and the estimate of  $S^2$  to the variance, i.e.

$$\mu = C \text{ and } S^2 = C + \frac{C^2}{k}$$

The second equation is be solved to determine  $k$  and the probability of acceptance calculated. This process must be repeated for each value of  $C$ , as  $S^2$  depends on  $C$ .

## Components of Variance for Aflatoxin Sampling Plans

Study #	Mycotoxin	Commodity	References	Variance			Mycotoxin Test Procedure				Distribution Among Sample Test Results
				Sampling ( $S^2_n$ )	Sample Preparation ( $S^2_{sp}$ )	Analytical (Within Lab) ( $S^2_n$ )	Laboratory Sample Size (ns)	Comminuted Test Portion Size (nss)	Number of Aliquots (na)	Concentration (C)	
1	Aflatoxin	Shelled Peanuts	1, 2, 3, 34	(10,644/ns)9.19C <sup>1.335</sup>	(275/nss)0.294C <sup>1.729</sup>	(1/na)0.083C <sup>1.664</sup>	Number of shelled kernels (1,952ker/kg)	Mass (g) Dry Comminution USDA mill powder	Number of aliquots quantified by HPLC from Ref 34	ng/g (ppb) aflatoxin total	Negative Binomial
2	Aflatoxin	Cottonseed	4, 5, 6, 34	(43,200/ns)6.776C <sup>1.344</sup>	(200/nss)0.180C <sup>1.3598</sup>	(1/na)0.086C <sup>1.567</sup>	Number of seed (Hull removed) (19,031ker/kg)	Mass (g) Dry Comminution USDA mill powder	Number of aliquots quantified by HPLC from Ref 34	ng/g (ppb) aflatoxin either total or B1	Negative Binomial
3	Aflatoxin	Harvested Inshell Peanuts (Farmer's Stock)	7, 8, 9	(3713/ns)37.607C <sup>1.161</sup>	(100/nss)2.887C <sup>1.401</sup>	(1/na)0.083C <sup>1.664</sup>	Number of inshell pods (882pods/kg)	Mass (g) Dry Comminution VCM Paste	Number of aliquots quantified by HPLC from Ref 34	ng/g (ppb) aflatoxin total	Negative Binomial
4	Aflatoxin	Shelled Corn	10, 11, 12	(3,390/ns)11.36C <sup>0.98</sup>	(50/nss)1.254C <sup>1.27</sup>	(1/na)0.143C <sup>1.16</sup>	Number of shelled kernels (3,000ker/kg)	Mass (g) Dry Comminution Romer Powder	Number of aliquots quantified by HPLC	ng/g (ppb) aflatoxin total	Compound Gamma Used Negative Binomial
5	Aflatoxin	Shelled Almonds	13, 14, 15	(7,730/ns)5.759C <sup>1.581</sup>	(100/nss)0.170C <sup>1.648</sup>	(1/na)0.0041C <sup>1.988</sup>	Number of shelled kernels (773ker/kg)	Mass (g) Dry Comminution VCM Paste	Number of aliquots quantified by HPLC	ng/g (ppb) aflatoxin either total or B1	Negative Binomial
6	Aflatoxin	Inshell Almonds	13, 14, 15	(7,730/ns)5.759C <sup>1.581</sup>	(100/nss)0.170C <sup>1.648</sup>	(1/na)0.0041C <sup>1.988</sup>	Number of Inshell Nuts (309nuts/kg) Shell/ker Ratio = 60/40	Mass (g) Dry Comminution VCM Paste	Number of aliquots quantified by HPLC	ng/g (ppb) aflatoxin either total or B1	Negative Binomial
7	Aflatoxin	Shelled Hazelnuts	15, 16, 17	(10,000/ns)4.291C <sup>1.609</sup>	(50/nss)0.021C <sup>1.645</sup>	(1/na)0.0028C <sup>1.990</sup>	Number of shelled kernels (1,000ker/kg)	Mass (g) Dry Comminution VCM Paste	Number of aliquots quantified by HPLC	ng/g (ppb) aflatoxin either total or B1	Negative Binomial
8	Aflatoxin	Inshell Hazelnuts	15, 16, 17	(10,000/ns)4.291C <sup>1.609</sup>	(50/nss)0.021C <sup>1.645</sup>	(1/na)0.0028C <sup>1.990</sup>	Number of Inshell nuts (500Nuts/kg) Shell/Ker Ratio = 50/50	Mass (g) Dry Comminution VCM Paste	Number of aliquots quantified by HPLC	ng/g (ppb) aflatoxin either total or B1	Negative Binomial
9	Aflatoxin	Shelled Pistachios	15	(8,000/ns)7.913C <sup>1.475</sup>	(25/nss)2.334C <sup>1.622</sup>	(1/na)0.0368C <sup>1.598</sup>	Number of Shelled Kernels (1,600ker/kg)	Mass (g) Dry Comminution VCM Paste	Number of aliquots quantified by HPLC	ng/g (ppb) aflatoxin either total or B1	Negative Binomial
10	Aflatoxin	Inshell Pistachios	15	(8,000/ns)7.913C <sup>1.475</sup>	(25/nss)2.334C <sup>1.622</sup>	(1/na)0.0368C <sup>1.598</sup>	Number of Inshell Nuts (800nuts/kg) Shell/Ker Ratio = 50/50	Mass (g) Dry Comminution VCM Paste	Number of aliquots quantified by HPLC	ng/g (ppb) aflatoxin either total or B1	Negative Binomial



Study #	Mycotoxin	Commodity	References	Variance			Mycotoxin Test Procedure				Distribution Among Sample Test Results
				Sampling ( $S^2_s$ )	Sample Preparation ( $S^2_{sp}$ )	Analytical (Within Lab) ( $S^2_a$ )	Laboratory Sample Size (ns)	Comminuted Test Portion Size (nss)	Number of Aliquots (na)	Concentration (C)	
11	Aflatoxin	Shelled Brazil Nuts	15	(1,850/ns)4.862C <sup>1.889</sup>	(50/nss)0.0306C <sup>0.632</sup>	(1/na)0.0164C <sup>1.117</sup>	Number of Shelled Kernels (185ker/kg)	Mass (g) Slurry (Water/Ker 1/1) Comminution	Number of aliquots quantified by HPLC	ng/g (ppb) aflatoxin either total or B1	Negative Binomial
12	Aflatoxin	Inshelled Brazil Nuts	15	(1,850/ns)4.862C <sup>1.889</sup>	(50/nss)0.0306C <sup>0.632</sup>	(1/na)0.0164C <sup>1.117</sup>	Number of Inshelled Nuts (93Nuts/kg) Shell/Ker Ratio=50/50	Mass (g) Slurry (Water/Ker 1/1) Comminution	Number of aliquots quantified by HPLC	ng/g (ppb) aflatoxin either total or B1	Negative Binomial
13	Aflatoxin	In Field Ear Corn	18	(600/ns)8.919C <sup>2.230</sup>	(50/nss)1.254C <sup>1.27</sup>	(1/na)0.143C <sup>1.16</sup>	Number of shelled kernels per ear 200 g ker/ear (3,000ker/kg)	Mass (g) Dry Comminution Romer Powder	Number of aliquots quantified by HPLC	ng/g (ppb) aflatoxin B1	Negative Binomial
14	Aflatoxin	In Field Farmer's Stock Peanuts	19	(116/ns)17.056C <sup>1.6686</sup>	(100/nss)2.887C <sup>1.401</sup>	(1/na)0.083C <sup>1.654</sup>	Number of inshell pods (882pods/kg)	Mass (g) Dry Comminution VCM Paste	Number of aliquots quantified by HPLC from Ref 34	ng/g (ppb) aflatoxin total	Negative Binomial
15	Aflatoxin	Powdered Ginger in Capsules	20	(5/ns)0.138C <sup>1.0</sup>	No Test Portion, Entire Sample Extracted	(1/na)0.0178C <sup>1.70</sup>	5 g Laboratory Sample is also the 5 g Test Portion	No Test Portion, Entire Sample Extracted	Number of aliquots quantified by HPLC	ng/g (ppb) aflatoxin total	Normal
16	Aflatoxin	Powdered Ginger in 1-Lb Bags	21	(5/ns)4.218C <sup>1.0</sup>	No Test Portion, Entire Sample Extracted	(1/na)0.00349C <sup>1.70</sup>	5 g Laboratory Sample is also the 5 g Test Portion	No Test Portion, Entire Sample Extracted	Number of aliquots quantified by HPLC	ng/g (ppb) aflatoxin total	Normal
17	Aflatoxin	Dried Figs	Not Published	(590/ns)2.219C <sup>1.433</sup>	(55/nss)0.012C <sup>1.465</sup>	(1/na)0.006C <sup>1.368</sup>	Number of dried Figs (59 Figs/kg)	Mass (g) Slurry (Water/Ker 1/1) Comminution	Number of aliquots quantified by HPLC	ng/g (ppb) aflatoxin total	Negative Binomial
18	Fumonisin	Shelled Corn	22, 23, 24	(3,390/ns)0.033C <sup>1.75</sup>	(25/nss)0.011C <sup>1.59</sup>	(1/na)0.014C <sup>1.44</sup>	Number of shelled kernels (3,000ker/kg)	Mass (g) Dry Comminution Romer Powder	Number of aliquots quantified by HPLC	ug/g (ppm) Fumonisin either B1, B2, B3 or total	Compound Gamma Used Lognormal
19	Deoxynivalenol (DON)	Shelled Corn	25	(3,000/ns)0.202C <sup>1.923</sup>	(50/nss)0.0193C <sup>1.140</sup>	(1/na)0.0036C <sup>1.507</sup>	Number of shelled corn kernels (3,000ker/kg)	Mass (g) Dry Comminution Romer - 25 g	Number of aliquots quantified by Romer - Malone HPLC	ug/g (ppm) DON	Lognormal (not published)
20	Deoxynivalenol (DON)	Wheat	26	(13,620/ns)0.026C <sup>0.833</sup>	(25/nss)0.066C <sup>0.833</sup>	(1/na)0.026C <sup>0.833</sup>	Number of raw wheat kernels (30,000ker/kg)	Mass (g) Dry Comminution Romer 25 g	Number of aliquots quantified by Romer FluoroQuant	ug/g (ppm) DON	Lognormal (not published)

Study #	Mycotoxin	Commodity	References	Variance			Mycotoxin Test Procedure				Distribution Among Sample Test Results
				Sampling ( $S^2_s$ )	Sample Preparation ( $S^2_{sp}$ )	Analytical (Within Lab) ( $S^2_a$ )	Laboratory Sample Size (ns)	Comminuted Test Portion Size (nss)	Number of Aliquots (na)	Concentration (C)	
21	Deoxynivalenol (DON)	Barley	27	(77,000/ns)0.0122C <sup>0.947</sup>	(50/nss)0.003C <sup>1.956</sup>	(1/na)0.0108C <sup>1.005</sup>	Number of raw barley kernels (30,800ker/kg)	Mass (g) Dry Comminution Rorer 50 g	Number of aliquots quantified by Rorer FluoroQuant	ug/g (ppm) DON	Lognormal (not published)
22	Ochratoxin A (OTA)	Green Coffee Beans	28, 29, 30	(1,500/ns)1.350C <sup>1.090</sup>	(25/nss)0.272C <sup>1.646</sup>	(1/na)0.008C <sup>1.605</sup>	Number of beans (1,500ker/kg)	Mass (g) Dry Comminution VCM Paste	Number of aliquots quantified by HPLC	ng/g (ppb) OTA total	Lognormal
23	Ochratoxin A (OTA)	Powdered Ginger in Capsules	20	(5/ns)0.108C <sup>1.0</sup>	No Test Portion, Entire Sample Extracted	(1/na)0.00654C <sup>1.70</sup>	5 g Laboratory Sample is also the 5 g Test Portion	No Test Portion, Entire Sample Extracted	Number of aliquots quantified by HPLC	ng/g (ppb) OTA total	Normal
24	Ochratoxin A (OTA)	Powdered Ginger in 1-Lb Bags	21	(5/ns)1.336C <sup>1.0</sup>	No Test Portion, Entire Sample Extracted	(1/na)0.00146C <sup>1.70</sup>	5 g Laboratory Sample is also the 5 g Test Portion	No Test Portion, Entire Sample Extracted	Number of aliquots quantified by HPLC	ng/g (ppb) OTA total	Normal
25	Ochratoxin A (OTA)	Oats	Not Published	(55,796/ns)1.440C <sup>1.278</sup>	(100/nss)0.0074C <sup>1.638</sup>	(1/na)0.0103C <sup>1.58</sup>	Number of raw oat kernels (27,898ker/kg)	Mass (g) Dry Comminution Retsch SR300 #20 Screen	Number of aliquots quantified by HPLC	ng/g (ppb) OTA total	Negative Binomial
26	Ochratoxin A (OTA)	Wheat	Not Published	(60,180/ns)1.557C <sup>1.132</sup>	(5/nss)0.207C <sup>1.152</sup>	(1/na)0.0204C <sup>1.896</sup>	Number of raw wheat kernels (30,090ker/kg)	Mass (g) Dry Comminution Retsch SR300 #20 Screen	Number of aliquots quantified by HPLC	ng/g (ppb) OTA total	Negative Binomial
27	FAPAS among lab variability		31			(1/na)0.0484C <sup>2.000</sup>					
28	Horwitz among lab variability (ppb)		32,33			(1/na)0.2048C <sup>1.70</sup>					
29	Whitaker, Horwitz, Analytical Variances - TLC, Immuno, HPLC		34			Among Lab = 2*Within Lab					
<p>Study 3 the sampling variance was calculated by subtracting analytical and sample prep variances from total variances for each of the three (2.26, 4.21, and 6.91 kg) sample sizes.</p> <p>Studies 13 and 14 measured only total variance. Used sample prep and analytical variances from studies 4 and 3, respectively.</p> <p>Study 28 analytical variance was determined for various methods, mycotoxins, and commodities using data base from Horwitz Ref 32</p>											



#### 4.6.6 General plans for assessment against minimum or maximum levels

One approach, more suited to food safety than commercial characteristics on the grounds of fairness, is to use offsets and assess compliance of lots against the average level. This has the considerable advantage of simplicity.

However, these plans are also important in a commercial context where one might, for example, wish to provide assurance about the average level of protein in a lot of grain that is to be further processed, for example to make flour.

In general, however, the design of sampling plans for bulk materials to assess compliance against a minimum or maximum limit is difficult statistically and no information is included in this Information Document.

#### 4.7 Plans for microbiological assessment

Plans used for the assessment of lots for microbiological characteristics, often referred to as *Microbiological Criteria*, frequently employ 2-class attributes plans that require  $n=5$  samples to be taken. These plans are suitable only for characteristics where the measurements are counts and there are adequate offsets between the limits used in these plans and the levels at which foods are considered to be unsafe.

If the offsets are not adequate there could be a higher rate of acceptance of contaminated product. Testing of pathogens is usually carried out using detection tests that produce presence or absence outcomes; in this case there are no offsets between the limits (zero) and the levels at which foods become unsafe to consume. For this reason, the use of ( $n=5$ ,  $c=0$ ) plans for pathogens is inadvisable; this is also the reason why sampling plans for pathogenic characteristics require much larger sample numbers and a greater total amount of sample is tested. Use of a larger numbers of samples also provides some safeguard against potentially inhomogeneous contamination within lots. Some examples of microbiological criteria are given in the *Code of hygienic practice for powdered formulae for infants and young children* (CXC 66-2008) that contains the following microbiological criteria (see Codex definition at the end of the section) along with some points on the Operating Characteristic:

Microorganism	n	c	m	Class Plan
Cronobacter sp.	30	0	0/10g	2
Salmonella	60	0	0/25g	2

Points on the operating characteristic have been calculated by *Zweiterung et al.* [10] assuming a Poisson-lognormal distribution, being a Poisson distribution whose mean varies according to a lognormal distribution.

*Cronobacter*:

- At a mean concentration of 1 cfu/340g, the probability of detection is 95%, assuming a standard deviation [for the lognormal distribution] of  $sd = 0.8$ .
- At a mean concentration of 1 cfu/100g, the probability of detection is 99%, assuming a standard deviation of  $sd = 0.5$ .

*Salmonella*:

- At a mean concentration of 1 cfu/526g, the probability of detection is 95%, assuming a standard deviation of  $sd = 0.8$ .

##### 4.7.1 3-class attribute plans

Refer CXG 50-2004 section 4.2.6

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

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

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

Lots are accepted provided:

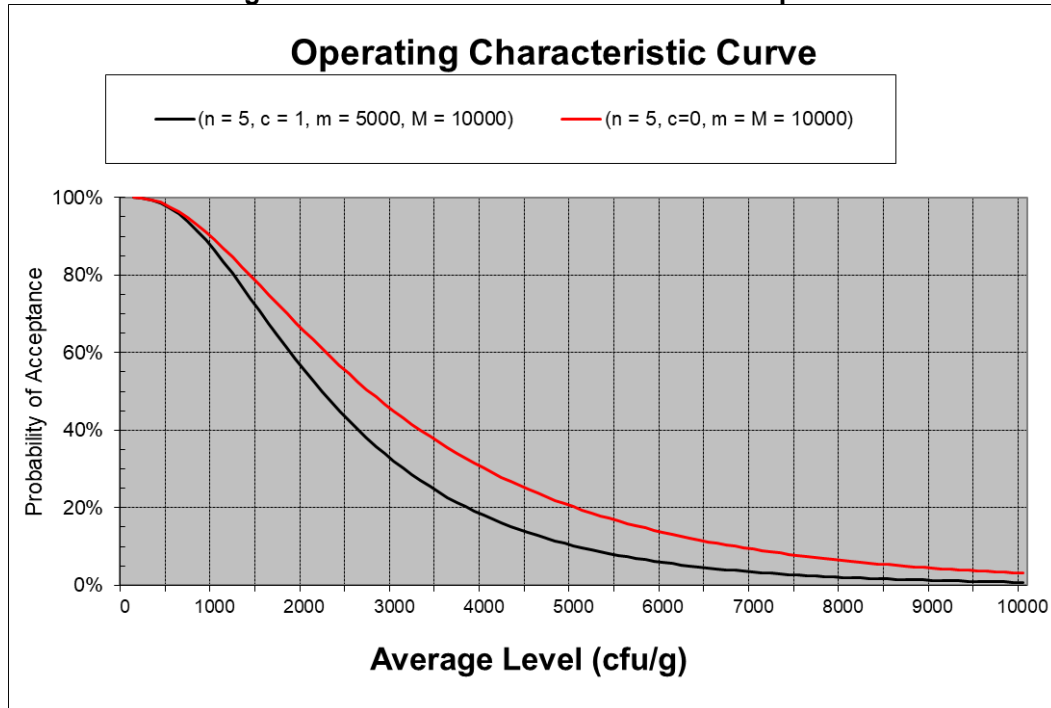
- None of the  $n$  samples is poor, having levels exceeding  $M$
- At most  $c$  of the samples are marginal, with levels between  $m$  and  $M$ .

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

Evaluation of these plans generally requires an assumption about the underlying distribution of the identified characteristic, the lognormal distribution is commonly used for microbiological characteristics for counts occurring at higher levels, whereas the Poisson distribution is often used for counts at lower levels.

The following plot shows the operating characteristic curves for a two-class plan ( $n=5$ ,  $c=0$ ,  $m=10000$ ) and a three-class plan ( $n=5$ ,  $c=1$ ,  $m=5000$ ,  $M=10000$ ); it shows that the three-class plan is more stringent despite allowing one result to be marginal.

**Figure 34 OC curves - three class attributes plans**



Although the plans mentioned in this section are used primarily in microbiological inspections, they are nevertheless useful in other applications such as those where acceptance is decided in terms of the total defects found in the sample, with the possibility that an item selected in the sample may contain more than one defect. One possible application of these plans is to the inspection of herbs and spices for insects or insect parts.

## 5 Statistical appendix

### 5.1 Background for the main (attributes & variables) sampling plans

#### 5.1.1 Calculating acceptance probabilities – attributes plans

Attributes Plans are based on the binomial distribution (two-class plans) or the multinomial distribution, an extension of the binomial distribution, for three or more class plans.

The probability of acceptance for the two-class binomial model is given by:

$$prob\_acceptance = \sum_{k=0}^c \binom{n}{k} p^k (1-p)^{n-k}$$

where:

$n$  is the sample size, the number of items or samples taken

$c$  is the acceptance number, the maximum number of nonconforming items permitted for acceptance of the lot

$p$  is the percentage nonconforming in the lot

For any given expression which depends on a variable  $k$ , the symbol

$$\sum_{k=value_1}^{value_n} expression(k)$$

means ‘the sum of’ the expression evaluated at

$$k = value_1, k = value_1 + 1, k = value_1 + 2, \dots, k = value_n$$

For example

$$\sum_{k=1}^5 k^2 = 1^2 + 2^2 + 3^2 + 4^2 + 5^2$$

The symbol  $\binom{n}{k}$  is the binomial coefficient, i.e. it is the number of ways of choosing  $k$  items from a total of  $n$  items. For example,  $\binom{5}{1} = 5$  since there are 5 ways of choosing one item from 5 items, viz. Aaaaa, aAaaa, aaAaa, aaaAa and aaaaA, where A represents the item selected.

The design of an attributes sampling plan involves finding the values of the number of samples  $n$  and the acceptance number  $c$  from the probabilities of acceptance at two specified points on the operating characteristic curve. Typically, these points are chosen as the producer’s and the consumer’s risk quality levels.

In the case  $p = PRQ$ , the probability of acceptance is equal to “one minus the producer’s risk”

$$Prob\ acceptance = 1 - PR = \sum_{k=0}^c \binom{n}{k} p^k (1-p)^{n-k}$$

and when  $p = CRQ$ , the probability of acceptance CR is equal to the consumer’s risk

$$Prob\ acceptance = CR = \sum_{k=0}^c \binom{n}{k} p^k (1-p)^{n-k}$$

These two equations are usually solved iteratively in a statistical package or using a computer program following the algorithm due to Hailey [15]:

1. Start by setting  $n = 0$  and  $c = 0$
2. If the probability of acceptance at the CRQ exceeds the specified maximum allowable consumer’s risk CR, then increase  $n$  by one, and go back to step 2.
3. If the probability of rejection at the PRQ exceeds the specified maximum allowable producer’s risk PR, then increase  $c$  by one, and go to step 2.

Note that because  $n$  and  $c$  are integers, and can only increase in steps of one, the actual producer's and consumer's risks in the final plan might not be exactly equal to the producer's and consumer's risks specified in the design of the plan.

Calculation of confidence intervals

Section 3.1.2 discussed ZAN plans and their use in applications such as inspections for foreign matter. The final part of that section described the calculation of confidence intervals for the percentage nonconforming or the number of defects in a lot when at least one nonconforming item or defect has been found in the samples examined.

For the binomial case that relates to the percentage of defective items in the lot overall, the lower and upper limits are calculated using the Excel formulas:

$$LCL = BETA.INV(0.025, c, n - c + 1)$$

and

$$UCL = BETA.INV(0.975, c + 1, n - c)$$

where  $n$  is the number of items or samples examined and  $c$  is the number of nonconforming items found among those  $n$  items.

For the Poisson case that relates to the percentage of defective items in the lot overall, the lower and upper limits are calculated using the Excel formulas:

$$LCL = 2 * GAMMA.INV(0.025, c, 0.5)$$

and

$$UCL = 2 * GAMMA.INV(0.975, c + 1, 0.5)$$

where  $n$  is the number of items or samples examined and  $c$  is the number of defects found during the inspection.

### 5.1.2 Derivation of formulas for variables plans

The formulas for  $k$  and  $n$  are derived as follows for the case of a known lot standard deviation  $\sigma$  and an upper specification limit  $U$ .

We use the notation  $z_p$  to denote the one-sided quantile of a standard normal distribution, i.e.

$$\mathcal{P}(X \leq z_p) = p$$

for

$$X \sim \mathcal{N}(0, 1).$$

The acceptance limit  $A$  is defined as

$$A = U - k\sigma$$

We thus have

$$\begin{aligned} U - A &= k\sigma \\ &= \mu_{PRQ} + z_{1-PRQ} \cdot \sigma - \left( \mu_{PRQ} + z_{1-PR} \cdot \frac{\sigma}{\sqrt{n}} \right) \end{aligned} \quad \text{Eq. 1}$$

$$= \mu_{CRQ} + z_{1-CRQ} \cdot \sigma - \left( \mu_{CRQ} + z_{CR} \cdot \frac{\sigma}{\sqrt{n}} \right) \quad \text{Eq. 2}$$

The following example and figure illustrate these two equations. Consider the case that we are asked to design a plan with

$$PRQ = 6.5\%$$

$$PR = 5\%$$

$$CRQ = 26\%$$

$$CR = 10\%$$

The corresponding standard normal quantiles are:

$$z_{1-PRQ} = 1.514$$

$$z_{1-PR} = 1.645$$

$$z_{1-CRQ} = 0.643$$

$$z_{CR} = -1.282$$

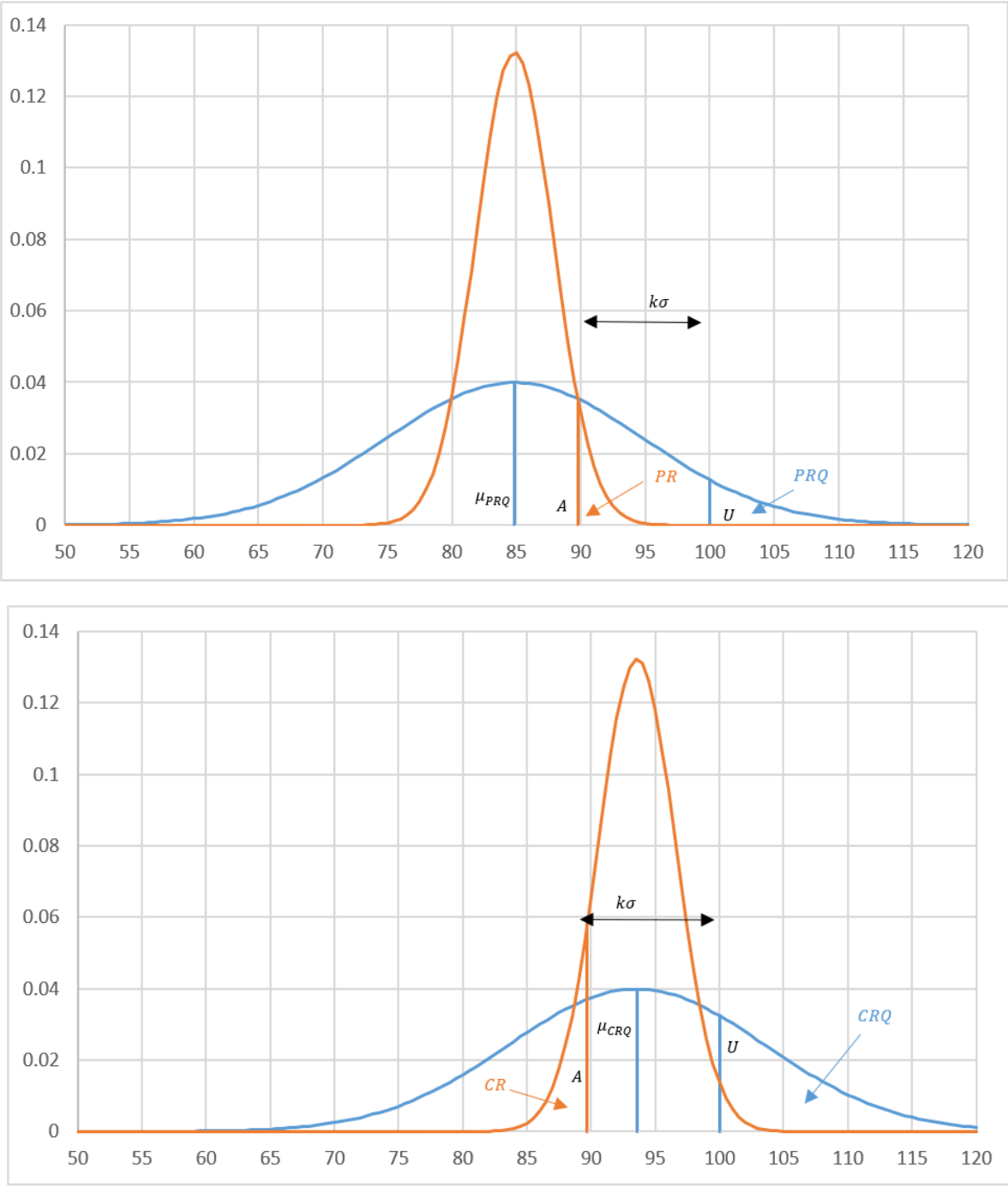
Applying the formulas for  $n$  and  $k$  (known  $\sigma$ ), we obtain

$$n = 11.3$$

$$k = 1.025$$

This is illustrated in the following diagrams. We consider the situation that  $U = 100$  (generic unit) and that the lot standard deviation is known with  $\sigma = 10$ . A lot with quality  $PRQ$  will have a mean value (across items)  $\mu_{PRQ} \approx 85$ . The sample size is  $n = 11$ . The acceptance limit (for the decision to accept or reject the lot) is calculated as  $A = U - k\sigma \approx \mu_{PRQ} + z_{1-PR} \cdot \frac{\sigma}{\sqrt{n}} \approx 90$ .

**Figure 35:** The blue curve represents the distribution of the property of interest in a lot with quality PRQ (top diagram) and in a lot with quality CRQ (bottom diagram) and lot standard deviation  $\sigma = 10$ . The red curve represents the statistical distribution of the arithmetic mean.



It follows from Equation 1 and Equation 2 that

$$\frac{1}{\sqrt{n}}(z_{CR} - z_{1-PR}) = z_{1-CRQ} - z_{1-PRQ}$$

And hence

$$\sqrt{n} = \frac{z_{1-PR} - z_{CR}}{z_{1-PRQ} - z_{1-CRQ}}$$

As far as  $k$  is concerned, it follows from Equation 1 and Equation 2 that

$$k = z_{1-PRQ} - \frac{z_{1-PR}}{\sqrt{n}}$$

$$k = z_{1-CRQ} - \frac{z_{CR}}{\sqrt{n}}$$

Hence, we have

$$\frac{k\sqrt{n}}{z_{1-PR}} = \frac{\sqrt{n} \cdot z_{1-PRQ}}{z_{1-PR}} - 1$$

and

$$\frac{k\sqrt{n}}{z_{CR}} = \frac{\sqrt{n} \cdot z_{1-CRQ}}{z_{CR}} - 1$$

It follows that

$$\frac{k\sqrt{n}}{z_{1-PR}} - \frac{k\sqrt{n}}{z_{CR}} = \frac{\sqrt{n} \cdot z_{1-PRQ}}{z_{1-PR}} - \frac{\sqrt{n} \cdot z_{1-CRQ}}{z_{CR}}$$

and thus

$$k \cdot \left( \frac{z_{CR} - z_{1-PR}}{z_{1-PR} \cdot z_{CR}} \right) = \frac{z_{1-PRQ} \cdot z_{CR} - z_{1-PR} \cdot z_{1-CRQ}}{z_{1-PR} \cdot z_{CR}}$$

From which we obtain

$$k = \frac{z_{1-PR} \cdot z_{1-CRQ} - z_{1-PRQ} \cdot z_{CR}}{z_{1-PR} - z_{CR}}$$

### 5.1.3 Within-item variability

In general, for a lot consisting of discrete items, there are two sources of variation: between-item variation and within-item variation. In “classical” acceptance sampling plans, there is a tacit assumption that within-item variation is negligible, and that one test result per item is thus sufficient. If non-negligible within-item variation is expected, then it may be necessary to modify the acceptance sampling plan. In particular, it may be necessary to correct the estimate of the lot standard deviation by “subtracting” the within-item component.

At low concentrations and for certain types of products (more specifically, when the presence or absence of the analyte is modelled via a discrete statistical distribution, as may be the case for sufficiently coarse-grained powders), within-item variation may be present even in the case of a “perfect” mixing process. This is due to an irreducible component of variation which remains even in the case of a perfectly homogenous item. This irreducible component is called the fundamental variability and is modelled via the Poisson distribution.

In the presence of fundamental variability, it may be necessary to apply specially developed models to distinguish between- from within-item variation. In particular, two different cases must be distinguished:

Case 1: the exact same quantity of analyte (corresponding to the property of interest, e.g. vitamin D in milk powder) is added separately to each item. Hence, there is no between-item variation, only within-item variation.

Case 2: the analyte is added to the mixing tank and then mixed with the pre-blend powder prior to filling the individual item recipients. In this case there is both between- and within-item variation.

Models for these two cases are discussed in Uhlig et al. (2025) [27].

## 5.2 Understanding ISO plans

The ISO standards apply a risk-based approach to the design of acceptance sampling plans. In inspection by attributes, it is the product AQL (PRQ)  $\times$  sample size which informs the design of the plans. In inspection by variables, the plans indexed by AQL (PRQ) aim to achieve a producer's risk which depends on the lot size.

### 5.2.1 Attributes plans constructed in terms of unity value

In the ISO 2859-1 standard, the plans are constructed in such a manner as to have constant acceptance number values across the diagonals of the sampling plan tables. This section provides a short rationale for this approach.

ISO 2859-1, the AQL (PRQ) values and the sample size values are “approximate” geometric series. The following table shows a selection of sample size values along with the ratio between consecutive values.

**Table 1: Sample size values from ISO 2859-1 as a geometric series**

Sample size	Ratio between consecutive sample sizes
5	-
8	1.60
13	1.63
20	1.54
32	1.60
50	1.56

As can be seen, the ratio between two consecutive sample size values is always close to 1.6. The ratio between consecutive AQL (PRQ) values is also approximately 1.6, as shown in the following table.

**Table 2: AQL (PRQ) values from ISO 2859-1 as a geometric series**

AQL	Ratio between consecutive AQL values
0.010	-
0.015	1.50
0.025	1.67
0.040	1.60
0.065	1.63
0.100	1.54

As a result, the product AQL (PRQ)  $\times$  sample size remains “near constant” across the diagonals of the sampling plan tables. This is illustrated in the following table, for a selection of AQL values.



Table 3: The product PRQ  $\times$  sample size remains “near constant” across the diagonals of the sampling plan tables

Sample size	AQL (PRQ)										
	0.001	0.0015	0.0025	0.004	0.0065	0.01	0.015	0.025	0.04	0.065	0.1
<b>2</b>	0.002	0.003	0.005	0.008	0.013	0.02	0.03	0.05	0.08	0.13	0.2
<b>3</b>	0.003	0.005	0.008	0.012	0.020	0.03	0.05	0.08	0.12	0.20	0.3
<b>5</b>	0.005	0.008	0.013	0.020	0.033	0.05	0.08	0.13	0.20	0.33	0.5
<b>8</b>	0.008	0.012	0.020	0.032	0.052	0.08	0.12	0.20	0.32	0.52	0.8
<b>13</b>	0.013	0.020	0.033	0.052	0.085	0.13	0.20	0.33	0.52	0.85	1.3
<b>20</b>	0.020	0.030	0.050	0.080	0.130	0.20	0.30	0.50	0.80	1.30	2.0
<b>32</b>	0.032	0.048	0.080	0.128	0.208	0.32	0.48	0.80	1.28	2.08	3.2
<b>50</b>	0.050	0.075	0.125	0.200	0.325	0.50	0.75	1.25	2.00	3.25	5.0
<b>80</b>	0.080	0.120	0.200	0.320	0.520	0.80	1.20	2.00	3.20	5.20	8.0
<b>125</b>	0.125	0.188	0.313	0.500	0.813	1.25	1.88	3.13	5.00	8.13	12.5
<b>200</b>	0.200	0.300	0.500	0.800	1.300	2.00	3.00	5.00	8.00	13.00	20.0
<b>315</b>	0.315	0.473	0.788	1.260	2.048	3.15	4.73	7.88	12.60	20.48	31.5
<b>500</b>	0.500	0.750	1.250	2.000	3.250	5.00	7.50	12.50	20.00	32.50	50.0
<b>800</b>	0.800	1.200	2.000	3.200	5.200	8.00	12.00	20.00	32.00	52.00	80.0
<b>1250</b>	1.250	1.875	3.125	5.000	8.125	12.50	18.75	31.25	50.00	81.25	125.0
<b>2000</b>	2.000	3.000	5.000	8.000	13.000	20.00	30.00	50.00	80.00	130.00	200.0

The product AQL (PRQ)  $\times$  sample size is called the *unity value* and can be understood as the number of expected nonconforming items in the sample for lot quality AQL. For example, for lot quality 1% percentage nonconforming and a sample size of 20 items, we can expect 0.2 nonconforming items. This is the rationale for having constant acceptance number values across diagonals in ISO 2859-1.

### 5.2.2 Variables plans constructed in terms of the producer's risk

The “philosophy” of ISO acceptance sampling plans for inspection by variables is as follows.

First, the ISO plans are designed in such a manner as to ensure either a high probability of acceptance at the acceptance quality limit (AQL) i.e. at the producer's risk quality level (PRQ) or a low probability of acceptance at the limiting quality (LQ) i.e. at the consumer's risk quality level (CRQ).

Secondly, the ISO plans indexed by AQL are constructed in such a way that the producer's risk decreases as the lot size increases. The following table, taken from the Mathematical and Statistical Principles underlying Military Standard 414 [30], the forerunner of the ISO 3951 standard, shows the producer's risk in terms of the sample size code letter (reflecting lot size):

**Table 4: Lot size in the ISO standards**

Sample size code letter	Producer's risk
B	0.11
C	0.10
D	0.10
E	0.10
F	0.10
G	0.09
H	0.08
I	0.07
J	0.06
K	0.06
L	0.05
M	0.05
N	0.04
O	0.03
P	0.02
Q	0.01

As can be seen the “target” PR of 5 % is only achieved from code letter L onwards. Indeed, the PR is better than 5 % from code letter N onwards, achieving 1 % for code letter Q.

In the plans in ISO 3951-2, the producer's risk remains “near constant” along the diagonals (from bottom left to top right).

The principle behind the ISO 3951-6 plans (which are indexed by LQ) is different: here the aim is to design plans whose OC curves correspond to the OC curves in ISO 2859-2.

### 5.3 Acceptance sampling versus conformity assessment

There is an extensive normative body of work on conformity assessment: the ISO 17000 series, JCGM 106, etc. The question thus arises to what extent this normative literature is relevant for acceptance sampling. In particular, the question arises whether conformity assessment procedures can be used in acceptance sampling.

In this section, the following abbreviations will be used:

- AS = acceptance sampling
- CA = conformity assessment

It is important to note that the question addressed here cannot currently be answered definitively one way or another. This section can thus be considered to provide basic orientation and considerations which may prove useful in untangling these various concepts in a given context.

#### 5.3.1 Definitions

##### JCGM 106

In JCGM 106, conformity assessment is defined (definition 3.3.1) as

*Activity to determine whether specified requirements relating to a product, process, system, person or body are fulfilled.*

Note that this definition is so general as to allow lot inspection to fall under its scope. Indeed, in many cases a lot can be considered the product output of a process.

##### ISO 3534

In ISO 3534-2, in section 4 Inspection and general acceptance sampling, we find definition 4.1.1

*Conformity evaluation*

*Systematic examination of the extent to which an item/entity fulfills specific requirements.*

If conformity evaluation is taken as synonymous with conformity assessment, then the fact this definition is found in the section on acceptance sampling is an indication that the CA normative literature is indeed relevant for AS.

##### ISO 17025

It seems useful to recall the definition of a “decision rule” (for use in conformity assessment) in ISO 17025. (This definition highlights the central role which measurement uncertainty plays in conformity assessment.)

*Rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.*

#### 5.3.2 Positions in ISO standards

##### ISO 10576 (Guidelines for the evaluation of conformity with specified requirements)

On the other hand, the following paragraph from ISO 10576 would seem to indicate that a resounding no is the correct answer:

*Because of the apparent similarity to acceptance sampling procedures, it is sometimes seen that acceptance sampling plans are used in conformity testing activities. Acceptance sampling and conformity testing activities both utilize elements of hypothesis testing (see e.g. ISO 2854). It is, however, important to realize that the objectives of the two activities are fundamentally different and in particular the two activities imply different approaches to the risk involved (see ISO 2854 and Holst).*

##### ISO 2859 and ISO 3951

In the standards from both series, the following phrase is found in the forward:

*For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL:*  
[http://www.iso.org/iso/home/standards\\_development/resources-for-technical-work/foreword.htm](http://www.iso.org/iso/home/standards_development/resources-for-technical-work/foreword.htm)

This phrase seems to imply that there is a connection between acceptance sampling and conformity assessment.

### 5.3.3 Positions in the literature

#### Paper by Holst, Thyregod and Wilrich (On conformity testing and the use of two stage procedures)

This paper draws the following distinction:

- Acceptance sampling plans are used in the context of transactions between two parties and should provide unambiguous rules for accepting or rejecting the lot. Both parties are aware of the risks involved.
- On the other hand, in conformity testing, “it is crucial that the user can have confidence in a declaration of conformity”. Thus, when an item meets the conformity criterion, this means that “the test has demonstrated beyond any reasonable doubt that the entity conforms to the requirements.”

### 5.3.4 Discussion

The following distinctions between CA and AS seem to be clear:

- in CA, testing is performed on the basis of one single item, and measurement uncertainty is taken into account
- in AS, there are many cases where testing is performed on the basis of several items (sampled from the lot). In inspection by variables, it is not the conformity of each item which is determined, but rather, one test result is obtained per item and the decision to accept or reject the lot is made on the basis of calculations performed on these test results.
- The outcome of CA may be inconclusive whereas in AS there is always an acceptance or rejection outcome.

A related difference between the two is as follows:

- In CA, measurement uncertainty is taken into account in the decision rule. Thus, in CA, the focus is on the measurand (in the strict metrological sense).
- In AS, the rule for lot acceptance or rejection takes into account the lot standard deviation, which describes how the property of interest varies in the lot, rather than variation between *test results*, which may reflect other effects such as analytical uncertainty, effects due to the sampling procedure, etc. Thus, in AS, the acceptance rule is expressed in terms of the statistical properties of the lot.

The following points highlight conceptual similarities between conformity assessment and acceptance sampling:

- Acceptance sampling can be “re-interpreted” in such a way that the entire framework is formulated in terms of a “measurand” – thus achieving a common conceptual framework with conformity assessment. In this re-interpretation it is the statistical parameters of the lot (e.g. lot mean and lot standard deviation) which constitute the measurand. See Uhlig et al. (2022) [28].
- In the classical CA framework, conformity often requires the measurement uncertainty to be sufficiently low, e.g. in the case of a decision rule such as  $y_m + U < USL$ . Similarly, in AS, one could formulate requirements regarding sufficiently low specific producer or consumer risks.
- for both CA and AS, one can define both “parametric” and “specific” risks (see section 6.5.1).

## 5.4 The role of measurement uncertainty in acceptance sampling

The criterion for lot acceptance or rejection is often expressed in terms of statistical parameters such as lot mean and lot standard deviation. If the measurement uncertainty is non-negligible, then the estimates of these statistical parameters may be affected. Accordingly, in some cases, it may be appropriate to apply a correction for measurement uncertainty. Naturally, such a correction presupposes that a reliable estimate of measurement uncertainty is available.

The reader is referred to the *Guidelines on measurement uncertainty* (CXG 54-2004) and the information document for information about the estimation of measurement uncertainty; another key reference is ISO 5725 Parts 1 & 2.

The Eurachem Guide on *Measurement Uncertainty arising from sampling* provides guidance regarding the estimation of the sampling component of uncertainty. The duplicate method can also be applied to estimate the lot standard deviation. Such a method would be appropriate if within-item variation is expected. If an estimate of repeatability precision is available, then Hahn's method (see Section 4.2.1 and Section 4.2.2) can be used to adjust the estimate of the lot standard deviation, avoiding the need to test items in duplicate. The Eurachem Guide also provides information regarding the use of control charts for the monitoring of consistency.

The following questions are discussed in this section:

- How is the measurand specified?
- Terminological clarification: sampling uncertainty versus acceptance sampling
- What effect does analytical uncertainty have on the producer's risk?

### 5.4.1 Specifying the measurand

In determining measurement uncertainty, the first question is: *what is the measurand?*

The term *measurand* has a very specific definition in metrology. The full definition ("Quantity intended to be measured") ~~which is based on the definition of another term, namely quantity~~ can be found in VIM (JCGM 200:2012). ~~These definitions are~~ The definition of quantity is rather technical. For our purposes here, it is sufficient to highlight 2 aspects of the definition of *measurand*.

In order to specify a measurand, it is necessary to define both

- the property of interest (e.g. analyte concentration)
- ~~where in what material/sampling target~~<sup>6</sup> this property of interest is being measured

For instance: measuring a given analyte concentration *in an individual item* and measuring the mean analyte concentration *in the lot* correspond to two different measurands.

It should also be noted that a measurand is by definition a property whose characterization is quantitative rather than qualitative.

The question which sources of uncertainty are relevant is answered by considering the definition of the measurand. For instance, if the measurand is defined in terms of the laboratory sample, then only analytical sources are relevant. ~~However, if~~ if the measurand is defined in terms of a population/lot/container ("sampling target") from which the laboratory sample was obtained, then both sampling and analytical sources are relevant.

In connection with acceptance sampling, the concept of measurand can be understood in two different ways.

#### 5.4.1.1 Classical definition of measurand

Insofar as test results are obtained (whether on the basis of discrete items, or on the basis of a composite sample), these test results involve the specification of a measurand. The question arises whether the measurand is specified in relation to the laboratory sample, or in relation to the lot. Two separate cases must be considered: lots consisting of discrete items and lots consisting of bulk material.

##### Lots consisting of discrete items

In the case of lots consisting of discrete items, acceptance is often based on a characterization of percentage nonconforming. The acceptance criterion is expressed in terms of the lot standard deviation (estimated from the item-specific test results) and the mean value across items. For a given item, the aim is to characterize the

<sup>6</sup> A sampling target is defined in Eurachem UfS Guide (2019) as *the portion of material, at a particular time, that the sample is intended to represent*. The reader is also referred to AMC(2005), Technical Brief 19.

item-specific mean value—not the lot mean. Accordingly, the measurand is defined in relation to the laboratory sample<sup>7</sup>, and only analytical sources of measurement uncertainty need be considered. *In particular, there is no sampling component of measurement uncertainty.*

Note: the mean value across the item-specific test results may be considered an estimate of the lot mean. Nonetheless, for lots consisting of discrete items, the measurand is the item-specific mean—not the lot mean.

### **Lots consisting of bulk material**

By contrast, in the case of bulk materials, the aim is to obtain an estimate of the mean concentration in the lot. Accordingly, the measurand is specified in terms of the lot, *and both analytical and sampling sources of uncertainty apply.*

#### **5.4.1.2 Reinterpretation of the concept of measurand for acceptance sampling**

Insofar as acceptance is based on a criterion expressed in terms of the statistical parameters of the lot under inspection, it is useful to take a step back and to generalize the concept of measurand as follows:

- In acceptance sampling, the measurand can be defined in terms of the statistical parameters of the lot (e.g. for a lot consisting of discrete items, the lot mean and the, lot standard deviation). ~~play the role of the measurand.~~
- The measurement uncertainty can then be considered to ~~be reflected in the producer's and consumer's risks~~ the statistical uncertainty of the estimates of these parameters.

This reinterpretation is particularly relevant in connection with Bayesian approaches to acceptance sampling. See Uhlig et al. (2022) [28].

#### **5.4.2 Sampling uncertainty versus acceptance sampling (terminological clarification)**

##### **Sampling uncertainty** (Uncertainty from Sampling, UfS)

Sampling uncertainty is a component of measurement uncertainty.

If the measurand is specified in terms of a larger population such as a lot/container/area, then the laboratory sample must be considered the result of a sampling procedure which may contribute to the uncertainty of the test result. The larger population from which the laboratory sample was obtained is often referred to as the sampling target.

If the total measurement uncertainty is too large, it may be necessary to improve the sampling procedure.

If the measurand is specified in terms of the laboratory sample, there is no contribution to measurement uncertainty due to sampling.

##### **Acceptance sampling**

In acceptance sampling, the aim is not to obtain an estimate of measurement uncertainty. The only connection between acceptance sampling and measurement uncertainty is the possible effect of the latter on the calculation of statistical parameters such as lot mean value and lot standard deviation in terms of which the acceptance criterion is expressed.

##### **Lot standard deviation versus sampling component of measurement uncertainty**

The concept of the lot standard deviation may seem to be closely related to the concept of the sampling component of measurement uncertainty, namely as a measure of the variation of the property of interest within the lot (where the lot is interpreted as a sampling target). However, this similarity is merely superficial; at a more fundamental level, the two concepts must be carefully distinguished.

In order to clarify the distinction between the lot SD and the sampling component of measurement uncertainty, consider the following hypothetical scenario—case: if all items in the lot ~~are were~~ tested ~~(one test result per item)~~, then there ~~is would be~~ no sampling component of the uncertainty of the lot mean (assuming homogeneity within the items). Nonetheless, variation between the items ~~may could~~ be small or large.

##### **Note regarding lots consisting of bulk material**

<sup>7</sup> A given laboratory sample may correspond to an entire item or may correspond to a subsample from the item. In the latter case, if the measurand is defined in relation to the item, there may be a within-item sampling component of measurement uncertainty.

For lots consisting of bulk material, the acceptance criterion is often expressed in terms of the lot mean (rather than in terms of the proportion non-conforming). The estimate of the lot mean can be obtained from a composite sample. If the acceptance criterion also involves the uncertainty of the lot mean, and the calculation of this uncertainty includes contributions reflecting the sampling procedure, then this procedure may be indistinguishable from the procedures typically applied in connection with conformity assessment. In such cases, there may thus be no useful distinction between acceptance sampling and conformity assessment. In particular, in such cases, measurement uncertainty takes on a completely different role: rather than a “nuisance parameter” which must be corrected for (if non-negligible), it now plays a central role.

### 5.4.3 Effects of analytical and sampling uncertainty in acceptance sampling

In this section, we consider the case that the lot consists of discrete items. The criterion for lot acceptance is thus expressed in terms of the percentage nonconforming.

Notation: let  $n$  denote the sample size (i.e. the sample consists of  $n$  items). For item  $i$ , the corresponding test result is denoted  $x_i$ . Proposed model for test result  $x_i$ :

$$x_i = \mu_i + B + e_i$$

where

$\mu_i$  is the “true” mean value for item  $i$ . The “true” lot standard deviation  $\sigma$  characterizes the variation of the  $\mu_i$  in the lot. If sigma is unknown, it is estimated on the basis of the  $x_i$  values obtained from the items in the sample.

$B$  is the bias (systematic effect). First and foremost, this term reflects laboratory bias or analytical method bias, but there may be other contributions to bias, e.g. from the sampling procedure.

$e_i$  is the random effect for item  $i$ . First and foremost, this term reflects analytical measurement uncertainty (repeatability effects), but there may be contributions from sampling uncertainty.

For lots consisting of discrete items, the acceptance criterion typically has the following form:

$$\bar{x} + ks \leq U \text{ (or } \bar{x} \leq A := U - ks)$$

where

$\bar{x}$  is the mean value across the item-specific test results  $\bar{x} = \frac{1}{n} \sum_{i=1}^n x_i$

$s$  is the standard deviation across the item-specific test results  $s^2 = \frac{1}{n-1} \sum_{i=1}^n (x_i - \bar{x})^2$

Analytical uncertainty will manifest itself in the term  $e_i \sim \mathcal{N}(0, u_{\text{analytical}})$  and will always **inflate** the estimate of the lot standard deviation  $s$ :

$$s^2 = \sigma^2 + u_{\text{analytical}}^2$$

where

$\sigma$  is the “true” lot standard deviation

$u_{\text{analytical}}$  is the analytical measurement uncertainty

If left uncorrected, the presence of analytical uncertainty will increase producer and consumer risks.

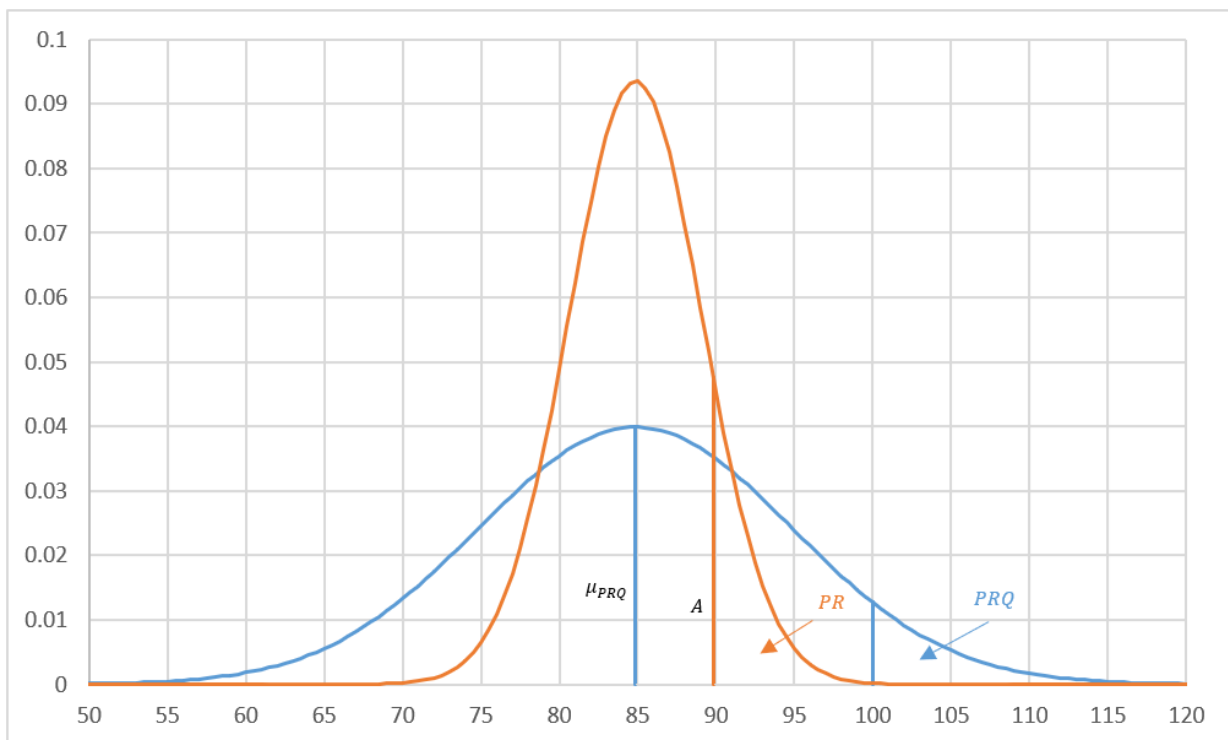
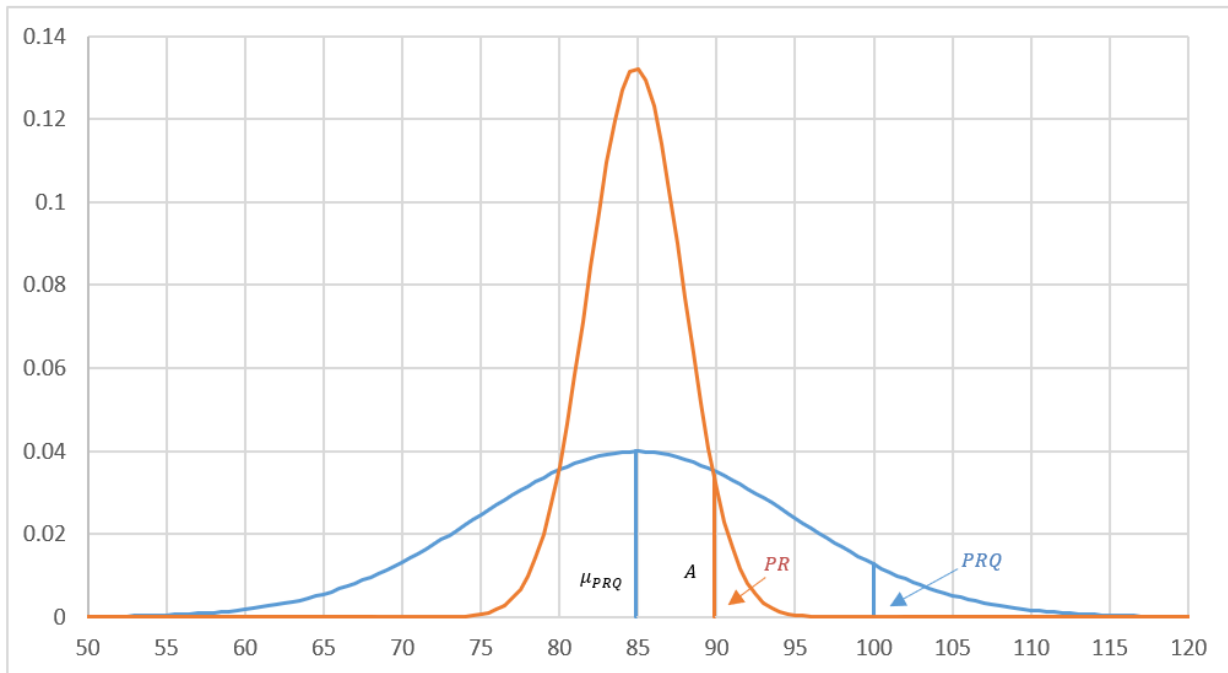
This is illustrated on the basis of two scenarios.

**Scenario 1: known  $\sigma$ , increase in producer risk**

In this scenario, the upper specification limit is  $U = 100$  and the lot standard deviation  $\sigma = 10$  is known. The following acceptance sampling plan is applied:  $n = 11$ ,  $k = 1.025$  ( $A = U - k \cdot \sigma = 90$ ). However, the analytical uncertainty is nonnegligible, with  $u_{analytical} = 10$  (the analytical uncertainty is the equal to the lot SD, and hence can be considered considerable). As a result of the analytical uncertainty, for a lot with quality  $PRQ = 6.5\%$ , the PR is over 11% (instead of 5%) due to the inflated variation of the  $x_i$ .



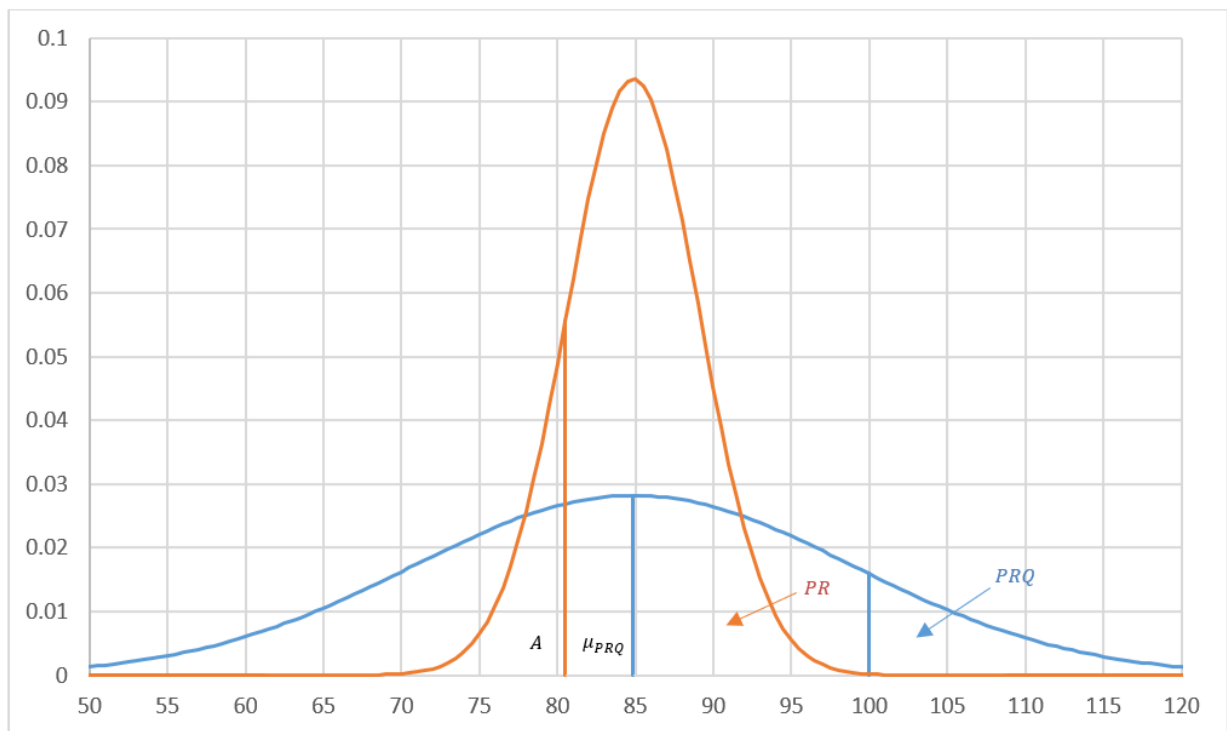
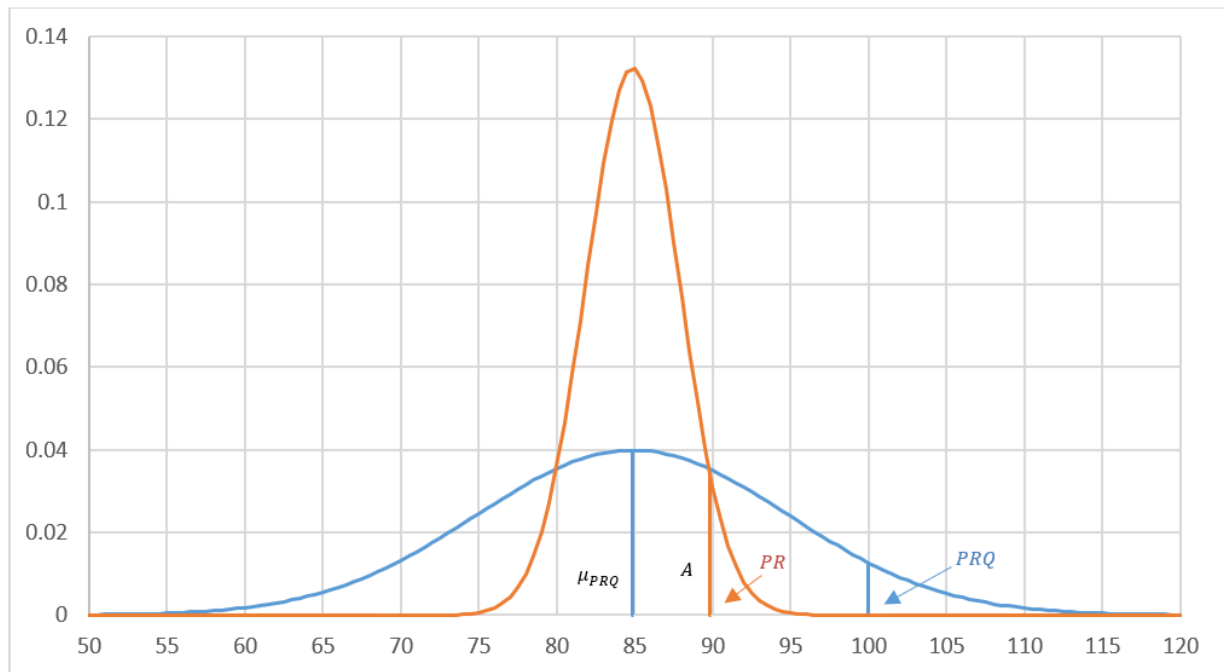
**Figure 36:** The blue curve represents the distribution of the property of interest in the lot. The area of the blue curve above  $U = 100$  is  $PRQ = 6.5\%$ . The red curve represents the statistical distribution of the arithmetic mean. In the top diagram, there is no analytical uncertainty, so the PR is 5%. In the bottom diagram, the analytical uncertainty is non-negligible, resulting in an increase in PR to over 11%.



**Scenario 2**

In this scenario, the upper specification limit is  $U = 100$  and the lot standard deviation is unknown and estimated from the  $x_i$ . At this point, various things can happen. For instance, the producer could notice that the lot quality is now 8.5 % percentage nonconforming instead of 6.5 %. If this discrepancy is ignored, and the same plan as originally contemplated is applied (in particular:  $k = 1.025$ ), the acceptance limit is now 80.5 (instead of 90) due to the inflated estimate  $s$ , and the PR is now over 85 %.

**Figure 37:** The blue curve represents the distribution of the property of interest in the lot. The area of the blue curve above  $U = 100$  is  $PRQ = 6.5\%$ . The red curve represents the statistical distribution of the arithmetic mean. In the top diagram, there is no analytical uncertainty, so the PR is 5%. In the bottom diagram, the analytical uncertainty is non-negligible, resulting in an increase in a much wider blue curve and a distorted value for A, resulting in a PR of nearly 85 %.



# PART THREE

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## Bayesian Sampling Plans

## 6 Bayesian plans

This section presents an overview on Bayesian plans that are the subject of new and on-going work in ISO and other forums.

It is often the case that prior information regarding lot quality is available. For instance, the consumer may have previously purchased lots from the producer of the lot currently under inspection. It is thus sensible to ask the following question: is it possible to propose a Bayesian framework for the design of acceptance sampling plans which mobilizes prior information in order to achieve a reduction in sample size? In the following, this question will be discussed in relation to *inspection by attributes*.

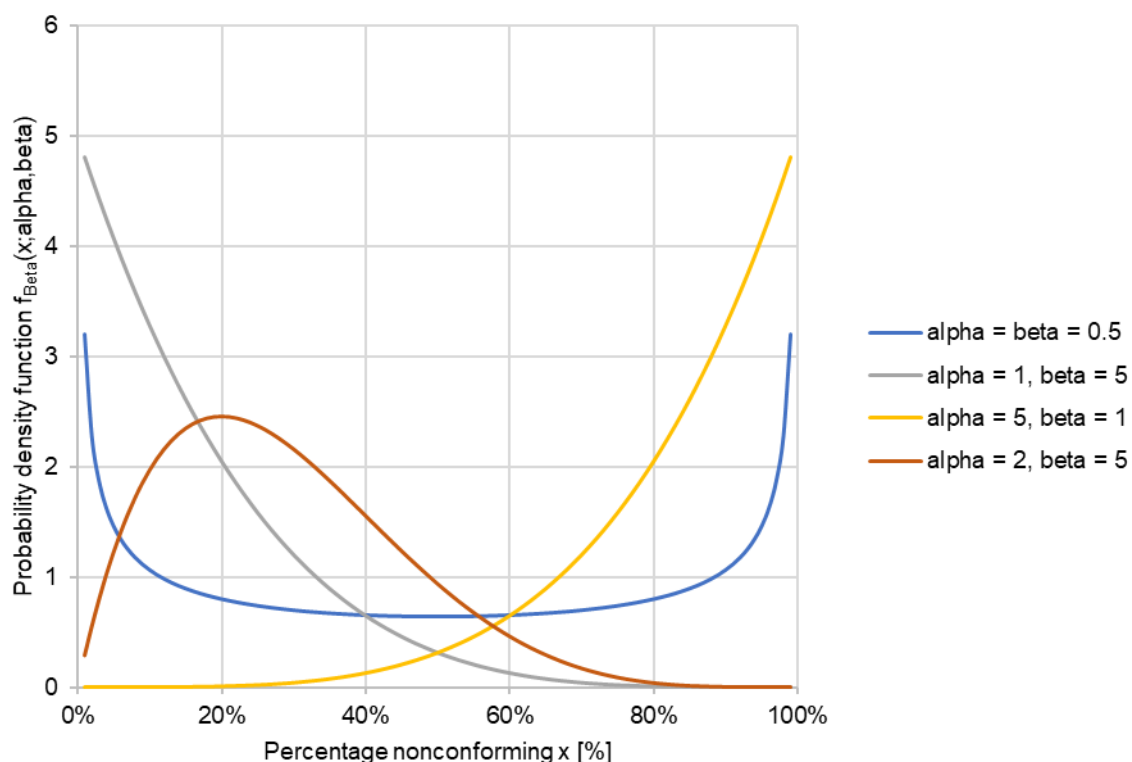
### 5.56.1 Prior distributions

The consumer's or producer's prior information regarding the percentage nonconforming  $x$  is encapsulated in the prior distribution. In the case of inspection by attributes, the simplest assumption regarding the prior for  $x$  is that it follows a beta distribution.

The beta family of distributions is generated via two hyperparameters  $\alpha$  and  $\beta$ . For a given choice of  $\alpha$  and  $\beta$ , the corresponding beta distribution is denoted  $\text{Beta}(\alpha, \beta)$  and the probability density function is denoted  $f_{\text{Beta}}(x; \alpha, \beta)$ .

The following diagram shows different beta distributions. As can be seen, this family of distributions is quite versatile, allowing very different curves to be mapped via the choice of  $\alpha$  and  $\beta$ .

Figure 38 Different beta distributions



Note: The case that no prior information is available can be represented by the choice  $\alpha = \beta = 0.5$ .

Once items from a lot have been tested, the prior distribution can be updated to obtain a posterior distribution.

If the prior is a beta distribution, the posterior is also a beta distribution and the posterior hyperparameters  $\alpha_1$  and  $\beta_1$  are obtained from the prior hyperparameters  $\alpha_0$  and  $\beta_0$  and from the number of nonconforming items  $y$  as follows:

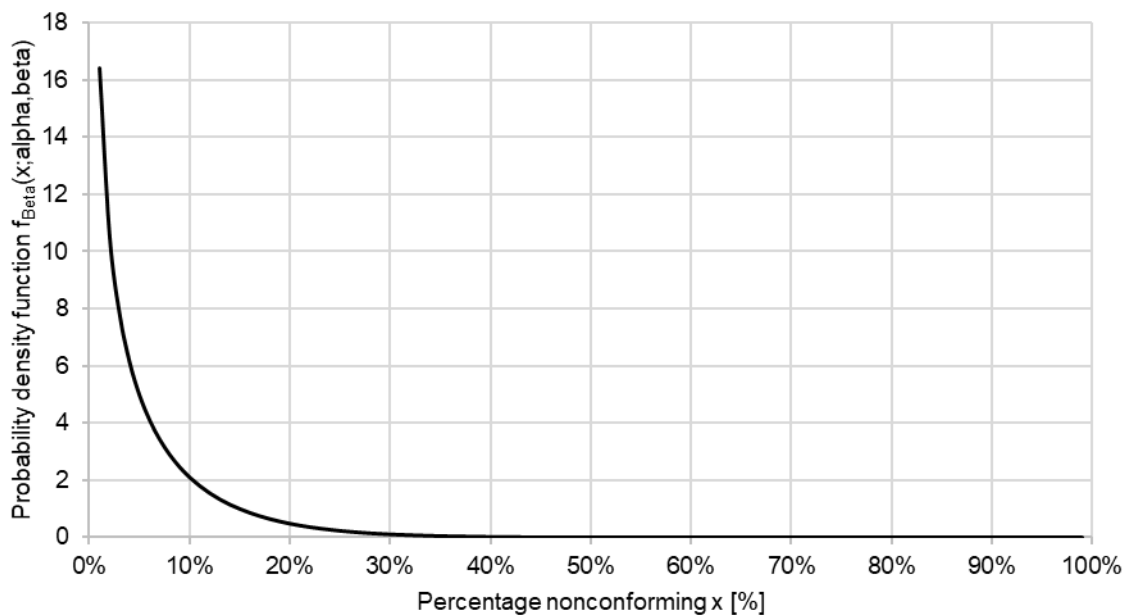
$$\begin{aligned}\alpha_1 &= \alpha_0 + y \\ \beta_1 &= \beta_0 + n - y\end{aligned}$$

For example, if 10 items from a given lot have been inspected and all 10 have been found to be conforming (i.e.  $y = 0$ ), the  $\alpha_0 = \beta_0 = 0.5$  prior is updated as follows:

$$\begin{aligned}\alpha_1 &= 0.5 + 0 = 0.5 \\ \beta_1 &= 0.5 + 10 - 0 = 10.5\end{aligned}$$

The following diagrams shows the beta distribution corresponding to  $\alpha = 0.5$  and  $\beta = 10.5$ .

**Figure 39 Probability density for Beta distribution  $\alpha=0.5$ ,  $\beta=10.5$**



As can be seen, the Beta(0.5,10.5) density function falls steeply in the range  $x = 0\%$  to  $x = 30\%$  and is near 0 for all percentage nonconforming values above  $x = 30\%$ . This means that—on the basis of the prior Beta(0.5,0.5) and the test outcome  $y = 0$  (out of 10 tests)—it is now expected that the percentage nonconforming will be no greater than 30%.

### 5.66.2 Conformance probability approach

In this section, an approach is presented for specifying acceptance sampling plans on the basis of the concept of conformance probability from JCGM 106. The approach described in the ISO 2859 and ISO 3951 standards asks the following question: given a certain quality level (expressed e.g. as percentage nonconforming) what is the probability that the lot is accepted? By contrast, the conformance probability approach asks the following question: given that a lot is accepted, what is the probability that it is actually conforming? Insofar as the conformance probability approach starts from lot acceptance or rejection (i.e. information which is known), this approach can be considered more pragmatic. In the conformance probability approach, probabilities and risks are calculated via the Bayesian approach. The starting point is a prior distribution, which encapsulates all available knowledge regarding the property of interest prior to lot inspection. Once tests have been performed, the prior distribution is updated on the basis of the test results. The updated distribution is called the posterior distribution.

#### Definition of conformance probability

The definition of conformance probability found in JCGM 106 can be adapted to lot inspection and acceptance sampling as follows.

Conformance probability is the probability that the lot quality actually lies in the conformance region  $\mathcal{C}$ . This probability is calculated on the basis of the *posterior* distribution.

As can be seen from the definition, a conformance region for lot quality must be specified. This is a clear departure from the approach described in the ISO 2859 and ISO 3951 standards in which, even though the plans are indexed in terms of certain quality levels considered “good” (PRQ, AQL) or “poor” (CRQ, LQ), conformance regions for lot quality are not specified.

The conformance region  $\mathcal{C}$  can be specified via an upper limit for the percentage nonconforming. This upper limit is denoted  $x_c$ .

### Definition of parametric and specific consumer’s and producer’s risks

In the ISO 2859 and ISO 3951 standards., the consumer and producer risks are defined as follows:

- Producer risk = probability that a lot of good quality (e.g. PRQ or AQL) will not be accepted
- Consumer risk = probability that a lot of poor quality (e.g. CRQ or LQ) will be accepted

In the calculation of the ISO risks, lot quality is treated as the parameter of a statistical distribution. For this reason, the ISO risks are also called “parametric” risks.

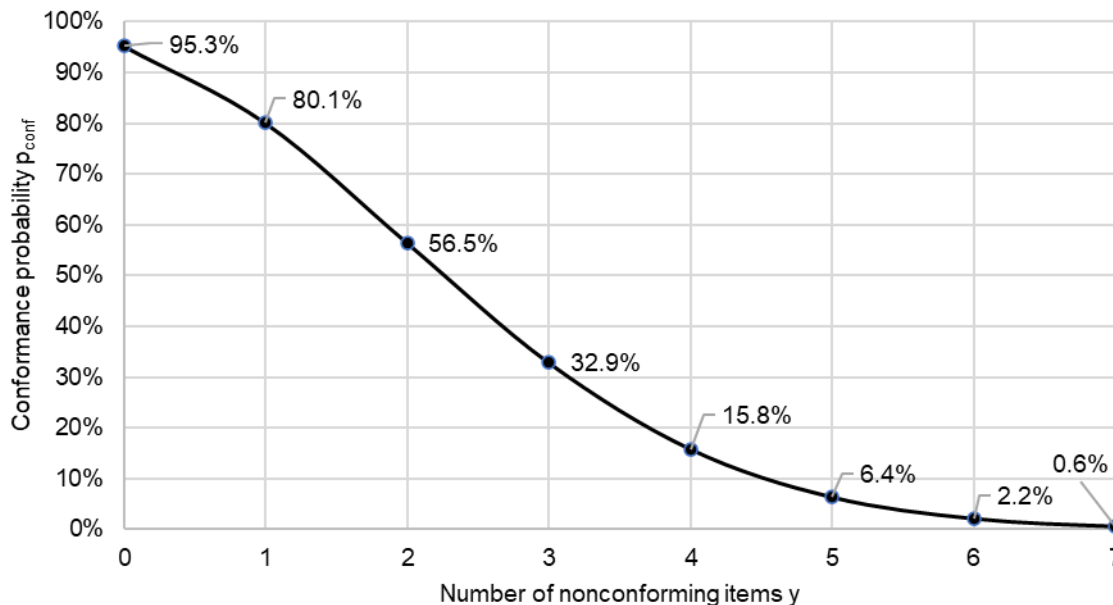
In JCGM 106, specific consumer and producer risks are defined by “going in the opposite direction” as compared to the ISO definitions:

- Specific producer risk = probability that a lot *which has not been accepted* actually has conforming quality
- Specific consumer risk = probability that a lot *which has been accepted* actually has nonconforming quality

### Conformance probability curves

The concept of conformance probability can be used to derive acceptance sampling plans. For a given sample size  $n$ , the conformance probability is calculated for each possible testing outcome  $y$  (e.g. number of nonconforming items in the sample). An acceptance sampling plan can then be determined by requiring that the specific consumer risk (the complement of the conformance probability) should be less than a certain threshold (e.g. 5 %). This procedure is illustrated in the following diagram which shows the conformance probability curve for a lot conformity region specified via the upper limit  $x_c = 10\%$  for the percentage nonconforming, the prior Beta(1,9) and the sample size  $n = 20$ .

**Figure 40: Conformance probability curve for upper limit of the lot conformity region  $x_c = 10\%$ , prior Beta(1,9) and sample size  $n = 20$**



As can be seen, the conformance probability is greater than 95 % at  $y = 0$ . Accordingly, the plan  $n = 20$ ,  $c = 0$  is a plan which allows a specific consumer risk less than 5 %.

### Consumer and producer risks

The Bayesian framework from JCGM 106 allows the definition of various risks. These risks address different questions, as summarized in the following tables.

**Table 5: Bayesian producer's risks – notation and interpretation**

Risk	Notation	Definition
Specific PR (evaluated for a specific test outcome $y$ resulting in rejection)	$SPR(y)$	How likely is it that a lot is conforming, given that it is rejected?
Conditional PR (conditioned on the lot quality $x$ )	$CPR_x$	How likely is it that a lot is rejected, given that it is conforming?
Conditional PR (conditioned on all test outcomes $y$ resulting in rejection)	$CPR_y$	How likely is it that a lot is conforming, given that it is rejected?
Global PR	$GPR$	How likely is it that a lot is both conforming and rejected?
Global probability of rejection	$GP_{rej}$	How likely is it that a lot is rejected – no matter whether it is conforming or not?

**Table 6: Bayesian consumer's risks – notation and interpretation**

Risk	Notation	Interpretation
Specific CR (evaluated for a specific test outcome $y$ resulting in acceptance)	$SCR(y)$	How likely is it that a lot is nonconforming, given that it is accepted?
Conditional CR (conditioned on the lot quality $x$ )	$CCR_x$	How likely is it that a lot is accepted, given that it is nonconforming?
Conditional CR (conditioned on all test outcomes $y$ resulting in acceptance)	$CCR_y$	How likely is it that a lot is nonconforming, given that it is accepted?
Global CR	$GCR$	How likely is it that a lot is both nonconforming and accepted?
Global probability of acceptance	$GP_{acc}$	How likely is it that a lot is accepted – no matter whether it is conforming or not?

More information regarding the conformance probability approach can be found in Uhlig et al. (2024) [21].

### 5.76.3 Utility approach

#### 5.7.16.3.1 Definition

The definition of utility is as follows:



Utility for a lot which has been **accepted** = benefit associated with an accepted lot (under the assumption that all items are conforming) i.e.  
 returns minus expenditures  
**minus** damages associated with nonconforming items in an accepted lot  
**minus** testing and sampling costs

Utility for a lot which has been **rejected** = **minus** testing and sampling costs

Depending on the context and the consumer, benefits may reflect profits from commercial sales, tax income, long-term environmental considerations, laying the foundations of new business opportunities, etc.; while damages may reflect commercial losses, negative health impacts, costs associated with recalling a lot and a tarnished public image.

### 5.7.26.3.2 The consumer

In acceptance sampling, the consumer is defined as the party which accepts or rejects the producer's lot. The consumer may be a retailer purchasing commodities at a wholesale market, a manufacturer acquiring parts or a customs officer or food safety agent checking that legal limits for contaminants are not exceeded before admitting a lot at the border, etc... The following table provides different interpretations of benefit and damages for three different types of consumers.

**Table 7: The meaning of benefit and damages for different types of consumers**

	Retailer	Manufacturer	State
<b>Benefit</b> associated with conforming items	Profit = <i>returns</i> minus <i>expenditures</i> of conforming items  <i>Returns</i> = income from selling the items in the lot  <i>Expenditures</i> = the lot's purchase price, transport costs, staff remuneration, retail outlet overhead, taxes	Profit from conforming items depends on aspects like cost efficiency, innovation, secure supply, flexibility, and sustainability	Benefit from conforming items could include: Positive impact on trade balance Benefits for the end-user Employment impact Tax revenue Innovation Positive environmental impact Positive health impact
<b>Damages</b> associated with nonconforming items	Income loss associated with nonconforming items, e.g. with items which were not sold, contractual penalties or legal fines, costs associated with containing and recalling items	Income loss from nonconforming items, associated with disruptions in the manufacturing process, quality issues and supply chain challenges	Damages from nonconforming items could include Negative health impact Loss in GDP Negative employment impact Financial losses (e.g. tax, extra expenditures) Negative environmental impact

### 5.7.36.3.3 Mathematical expression

The definition of utility makes it possible to apply a simple criterion in the design of acceptance sampling plans: select the plan which maximizes utility.

In order to express the utility function in mathematical terms, the following notation will be used:

$B$  = benefit associated with one conforming item in an accepted lot

$D$  = damages associated with one nonconforming item in an accepted lot (damages is understood here in a very general sense, see below. This parameter could also be called "losses".)

$T$  = the testing and sampling costs per item

All costs are expressed in terms  $B$  (the benefit associated with a conforming item in an accepted lot). In other words, the common unit in which all the terms in the utility function are expressed is  $B$ . For example, the damages associated with a nonconforming item  $D$  could be  $10 B$ ; and the testing and sampling costs per item  $T$  could be  $5 B$ . The values for  $D$  and  $T$  expressed in terms of  $B$  will be referred to the *cost structure*.

The quantity  $B$  thus has a dual role: on the one hand, it denotes the item-specific benefit and on the other hand, it functions as a unit in which to express  $D$  (damages) and  $T$  (testing costs). The values for  $D$  and  $T$  are thus *relative* to  $B$ . The advantages of expressing  $D$  and  $T$  in relation to  $B$  are twofold:

- on the one hand, it may be easier to provide values for  $D$  and  $T$  in relation to  $B$  rather than monetary values
- on the other hand, the fact that these values are relative highlights that it is the relation between the costs and benefits rather than the absolute or monetary values themselves which play a central role in the utility approach

Specifying the parameter  $B$  point of view of a state (the consumer is e.g. a food safety agency or a customs officer) is not always straightforward. Indeed, from the point of view of the state, some of the positive aspects of a successful commercial transaction may be intangible or difficult to assign a precise monetary value to. In such cases, as a rule of thumb, it is suggested to use the lot's purchase price.

The damages (or losses) parameter  $D$  can have different meanings. If there are no other costs and if there are no re-purposing options for items which are not sold, the value  $D = B$  corresponds to the case that the only cost associated with a nonconforming item is the *loss* in income caused its not being sold. A value such as  $D = 1.5 B$  corresponds to the scenario that, in addition to losses, there are additional costs associated with nonconforming items, such as costs associated with waste management. A value such as  $D = 10 B$  could reflect additional costs associated with environmental pollution, damage to the reputation of the retailer (dissatisfied customers taking their business elsewhere, tarnished public image) etc. Higher values such as  $D = 25 B$  or  $D = 100 B$  reflect substantial additional costs such as those associated with recalling a lot or healthcare costs. It may be difficult to quantify healthcare costs associated with nonconforming items (e.g. hospitalization costs due to the ingestion of contaminated meat). One approach could be to introduce an auxiliary unit such as  $W$  = wages corresponding to a day's work for an "average worker." For example, if a brief stay in a hospital is quantified as  $5 W$  and if the profit (benefit  $B$ ) associated with the item which caused the health issue (e.g. contaminated meat) is  $0.1 W$ , then  $D$  is calculated as  $50 B$ .

Finally, we also introduce the following notation:

$N$	Number of items in the lot
$M$	Number of nonconforming items in the lot
$n$	Sample size (i.e. number of items in the sample)

The utility function is defined as follows:

$$U(N, B, M, D, T, n) = \begin{cases} B \cdot N - D \cdot M - T \cdot n, & \text{if the lot is accepted} \\ -T \cdot n, & \text{if the lot is rejected} \end{cases}$$

In the case of an accepted lot, the utility function can be rewritten as

$$U(N, B, M, D, T, n) = N \cdot \left( B - D \cdot \frac{M}{N} - T \cdot \frac{n}{N} \right)$$

It should be noted that  $M$  is an integer which, in general, remains unknown. The aim of the acceptance sampling procedure is to obtain an estimate of  $U$  by means of a suitable (nonbiased) estimator for  $M$  (or for the proportion of nonconforming items  $\frac{M}{N}$ ), taking all prior information into account.

#### 5.7.46.3.4 Example

In order to illustrate the concept of utility as well as the coefficients for the benefit and damages discussed in the previous section, we consider the case where the utility is simply a given value rather than the expected value of a random variable.

Consider the scenario where a retailer has accepted and purchased a lot of 2000 apples (400 kg) at a wholesale price of 600 €. The retailer expects to sell all apples at an average retail price of 4 € per kg. Total sales (if all apples are sold) for the lot will thus be 1600 €. Transport costs were 20 €. The retailer paid a salesperson 100 € for the day's work.

The benefit for the entire lot (under the assumption that all the apples are sold) for the retailer is thus

$$1600 \text{ €} - 600 \text{ €} - 20 \text{ €} - 100 \text{ €} = 880 \text{ €}^8$$

A total of 100 apples (20 kg) had blemishes which resulted in being discarded (i.e. not sold). The retailer concludes that the damages caused by nonconforming items are 80 €.

#### Benefit, damages and testing costs for the example

Utility for a lot which has been <b>accepted</b>	=	benefit associated with an accepted lot (under the assumption that all items are conforming) i.e. returns minus expenditures	880 €
		<b>minus</b> damages associated with nonconforming items in an accepted lot	<b>minus 80 €.</b>
		<b>minus</b> sampling and testing costs	<b>minus 0 €.</b>

Accordingly, in this example, the utility for the lot is **800 €**. Now, let us calculate the parameters  $B$  and  $D$  (we already know that  $T = 0$ ). The benefit per conforming item (apple without blemishes)  $B$  expressed in Euros is

$$B = \frac{880 \text{ €}}{2000 \text{ apples in the lot}} = 0.44 \text{ € per apple}$$

The damages associated with nonconforming items are

$$D = \frac{80 \text{ €}}{100 \text{ apples with blemishes}} = 0.8 \text{ € per apple}$$

If the damages coefficient is expressed in terms of  $B$ , we have

$$D = \frac{0.8 \text{ € per apple}}{0.44 \text{ € per apple}} = 1.82 B \text{ per apple}$$

<sup>8</sup> For the sake of simplicity, neither overhead costs (associated with the retail outlet) nor taxes are included here.

The following table summarizes the example.

**Table 8: Summary of example of lot of 1000 apples**

<b>Lot size</b>	$N = 2000$
<b>Sample size</b>	$n = 0$
<b>Acceptance number</b>	$c$ Not applicable
<b>Sampling and testing costs</b>	$T = 0 \text{ B}$
<b>Damages per nonconforming item</b>	$D = 1.82 \text{ B}$
<b>Conversion of benefit per conforming item</b>	$B = 0.44 \text{ €}$
<b>Proportion of nonconforming items</b>	$x_0 = 5 \%$
<b>Utility</b>	$B \cdot N - D \cdot M - T \cdot n$ $= 0.44 \text{ €} \cdot 2000 - 1.82 \cdot 0.88 \text{ €} \cdot 100$ $= 800 \text{ €}$

**Note 1**

If the retailer purchases lemons instead of apples and if the lemons are displayed for purchase at the retail outlet during 10 days, then the retailer will worry about mold spread via contamination with neighboring spoilt lemons. If the lemons are sold individually and if the retailer observes that, on average, one spoilt lemon contaminates 5 neighboring lemons in the time span of 10 days, this state of affairs can be taken into consideration by multiplying the  $D$  coefficient by 5.

**Note 2**

If an intermediate distributor is involved in the purchase of a lot of 500 crates of 2000 apples ( $10^6$  apples), it is likely that the lot will be inspected prior to acceptance. In such a situation,  $T$  will be nonzero.

**Note 3**

If the aim is to use the utility in order to determine the acceptance sampling plan (sample size  $n$  and acceptance number  $c$ ), then the damages coefficient can be specified via the mean value of the prior distribution for the percentage nonconforming.

In order to illustrate this point, we start with the observation that, in the example above, at least 900 apples must be sold in order for the retailer to break even:

Expenditures (Purchase price of the lot + transport costs + sales person remuneration)	720 €
Retail price of apple	0.8 €
Income from the sale of 900 apples (180 kg)	720 €

Accordingly, 1 maximum of 1100 nonconforming items (1100 apples with blemishes leading to discarding) can be tolerated in order to break even. This corresponds to a maximum of 55% for the percentage nonconforming.

If the retailer works with a prior distribution for the percentage nonconforming whose mean value is 10% (i.e. well below the maximum of 55%), then  $D$  can be determined as follows. First, we note that the percentage nonconforming corresponds to  $\frac{M}{N}$ . In the absence of testing costs, the utility is simply

$$U = N \cdot B - D \cdot M$$

Setting  $U = 0$  (i.e. lot acceptance in the sense of breaking even), we obtain the following expression for the damages coefficient

$$D = \frac{N}{M} \cdot B$$

If  $D$  is expressed in terms of  $B$ , then this simplifies to

$$D = \frac{N}{M}$$

For  $\frac{M}{N} = 0.1$  (the prior which the retailer is working with), we thus obtain  $D = 10$ .

#### Note 4

It is important to understand the impact which  $D$  has on the utility. In particular, in the absence of sampling and testing costs, the value  $D = 1/B$  means that one single sold item is sufficient to have a positive utility.

Indeed, for  $M = N - 1$  and  $D = 1/B$  we have

$$U = N \cdot B - D \cdot M = N - M = N - (N - 1) = 1$$

### 5.7.56.3.5 The role of the prior

In the example from the previous section, the lot has already been accepted and purchased and the proportion of nonconforming items  $x_0$  can be empirically determined by 100% inspection of the lot. In other words, in such a case,  $x_0$  is an empirically determined value rather than a random variable (hence the notation with the subscript). However, the aim of the utility approach is to determine sample size and acceptance number—in other words to design the acceptance sampling plan—prior to lot inspection. For this reason, in the following, the empirically determined  $x_0$  value will be replaced with a random variable  $X$  whose distribution is called the *prior*. This gives a slightly different meaning to the utility: instead of an *empirical* value corresponding to a given lot, it is now an *expected* value, in the probabilistic sense. The expected utility for a given plan (sample size  $n$  and acceptance number  $c$ ) calculated on the basis of the prior distribution is denoted  $u_{prior}(n, c)$ .

### 5.7.66.3.6 Utility curves

The following diagrams show utility curves:

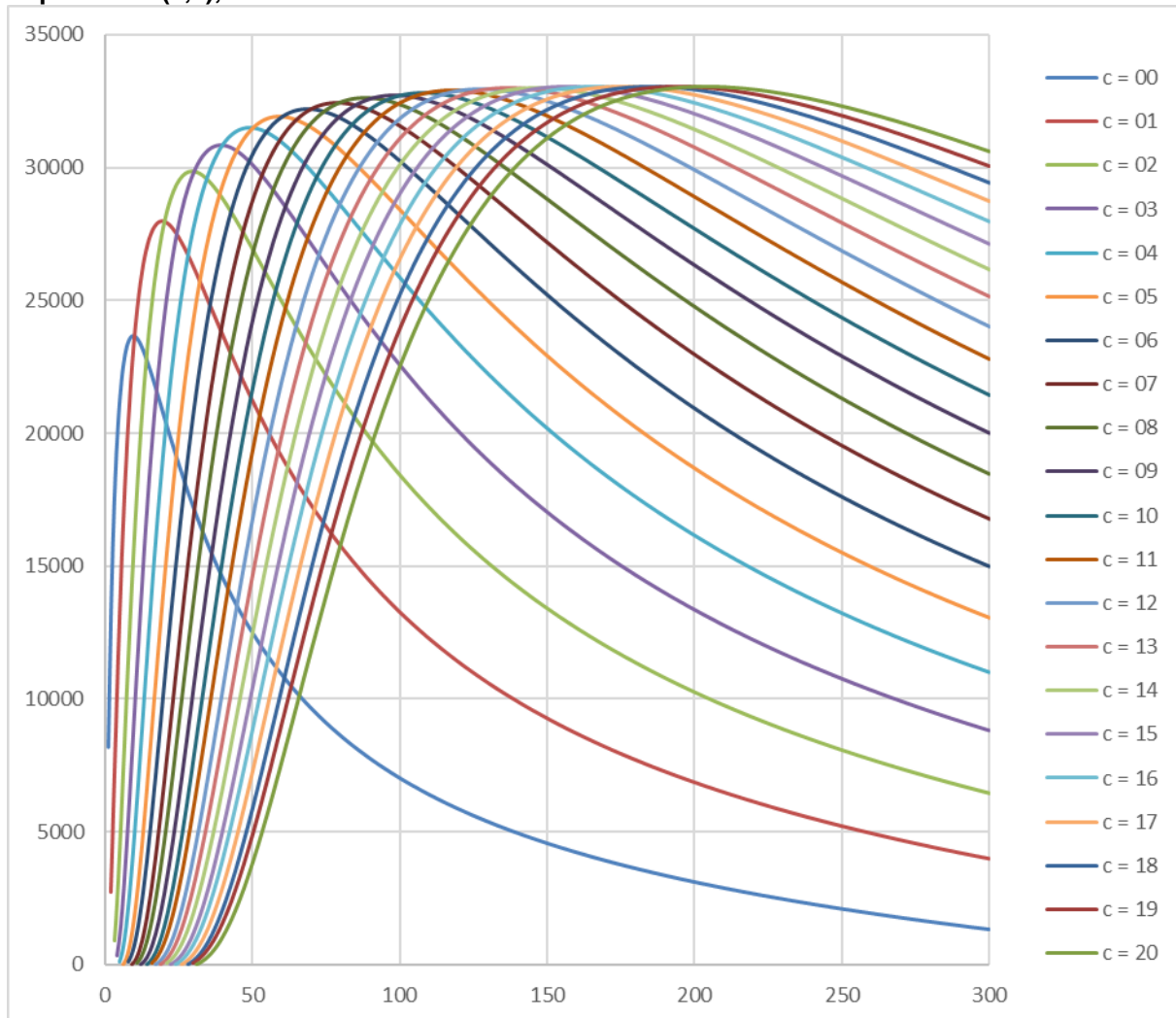
- for the prior Beta(1,9) with mean value 10% percentage nonconforming
- for the prior Beta(0.5,0.5) with mean value 50% percentage nonconforming (“non-informative” prior)

The  $x$ -axis shows the sample size  $n$  and the  $y$ -axis shows the expected utility  $u_{prior}(n, c)$ . There is a separate curve for each acceptance number  $c$ .

As can be seen, the utility values for the more optimistic prior are greater (maximum around 33000  $B$ ) than for the non-informative prior (maximum around 12600  $B$ ).

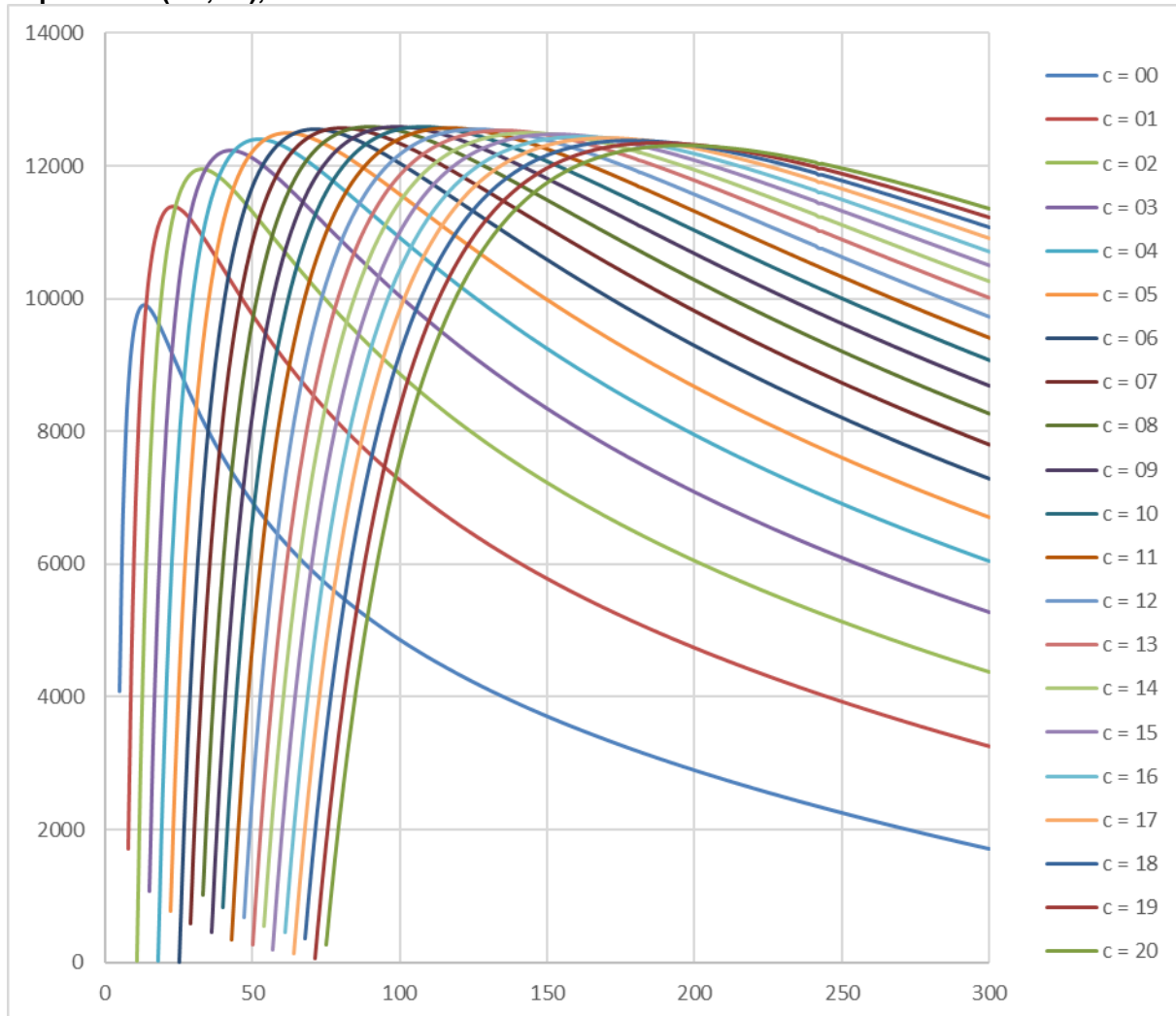
The following diagram shows utility curves for the prior  $\text{Beta}(1,9)$ , lot size  $N = 100000$  and cost structure  $D = 10B$  and  $T = 5B$ . The optimum plan is  $n = 175$ ,  $c = 17$  (utility = 33043  $B$ ).

**Figure 41: Utility curves for different acceptance number  $c$  values as a function of sample size  $n$  for the prior  $\text{Beta}(1,9)$ , lot size  $N = 100000$  and the cost structure  $D = 10B$  and  $T = 5B$**



The following diagram shows the utility curves for the Jeffreys prior  $\text{Beta}(0.5, 0.5)$ , which represents the case that no prior information is available (noninformative prior). As in the previous diagram, the lot size  $N$  is 100000 and the cost structure is  $D = 10 B$  and  $T = 5 B$ . The optimum plan is  $n = 99, c = 9$  (utility = 12592  $B$ ).

**Figure 42: Utility curves for different acceptance number  $c$  values as a function of sample size  $n$  for the prior  $\text{Beta}(0.5, 0.5)$ , lot size  $N = 100000$  and the cost structure  $D = 10 B$  and  $T = 5 B$**



As can be seen in the above diagrams, the utility curves appear to plateau around the maximum value. This motivates the following procedure: we propose to consider plans whose utility lies within 10% of the maximum utility. This will allow a considerable reduction in sample size while maintaining a negligible impact on utility.

For instance, the maximum utility for the  $\text{Beta}(1, 9)$  prior is 30457  $B$ . Subtracting 10% of this maximum value, we obtain 29739  $B$ . The  $c = 2$  curve exceeds this value at  $n = 27$ . Hence the  $n = 175, c = 17$  plan can be replaced with  $n = 27, c = 2$ .

### 5-7.76.3.7 Standard plans

This section provides tables with standard plans for the practitioner. It is assumed that there is no inspection error and that prior information is available in the form of results from previous testing performed on items from the producer of the lot currently under inspection. It is assumed that these previous tests have been performed recently—say, within the previous 2 or 3 months. In the tables, the results from previous testing are represented via the pair  $(n_0, y_0)$  with  $n_0$  denoting the number of items previously tested and  $y_0$  denoting the number of nonconforming items from these recent tests.

For a given pair  $(n_0, y_0)$ , the plans are calculated on the basis of a  $\text{Beta}(\alpha, \beta)$  prior for the percentage nonconforming where

$$\begin{aligned}\alpha &= y_0 + 0.5 \\ \beta &= n_0 - y_0 + 0.5\end{aligned}$$

The pair  $(n_0 = 0, y_0 = 0)$  stands for the absence of any prior information. This scenario is represented as the first row in each of the tables. The corresponding standard plans are based on the noninformative Jeffreys prior, i.e. the  $\text{Beta}(0.5, 0.5)$  distribution.

The standard plans can be used to answer two questions.

**Question 1: Given prior information, a cost structure and a lot size, which acceptance sampling plan should be applied?**

**Question 2: Given a cost structure and lot size, what type of prior information is required in order to achieve an acceptance sampling plan whose workload is acceptable (or indeed, for it to be worthwhile to perform acceptance sampling at all)**

In order to illustrate the use of the standard plans to answer these two questions, consider the following examples.

Example 1
A lot with size $N = 100\,000$ packages of grains was purchased at a price of 100 000 GCU (where GCU stands for generic currency unit). The retailer who purchased the lot intends to sell each package at 6 GCU. A simplified calculation (i.e. without taking overhead costs etc. into consideration) thus yields a benefit per item of $B = 5$ GCU. Say that sampling and testing costs are 25 GCU per package. The corresponding parameter is thus $T = 5B$ . Finally, if the damages associated with a nonconforming item consist in a dissatisfied customer who may no longer return to the retailer's outlet, the $D$ parameter can be specified as $D = 10B$ .
Answer to question 1: Given this background, if the retailer has recently purchased another lot and tested 20 packages, none of which were nonconforming, then the plan $n = 33, c = 1$ can be applied.
Answer to question 2: If the retailer would like to test, say, no more than 10 packages, then prior information based on at least 50 tested packages would be required.

Example 2
A lot of canned salmon is inspected following the item conformity criteria set out in Section 8 of CXS 3-1981. Say the lot size is $N = 1000$ items (cans) and that the sampling and testing costs per item are $T = 5B$ (as in Example 1). Finally, the damages associated with a nonconforming item consist in a dissatisfied customer who may no longer to the retailer's outlet, and the $D$ parameter can be specified as $D = 10B$ (as in Example 1).
Answer to question 1: Given this background, if the consumer has data from 5 recently tested cans from the same supplier, one of which was nonconforming, the decision would be to reject without testing.
Answer to question 2: The consumer would need to test an additional three cans prior to investing resources in inspecting a lot of 1000 cans. With prior information $n_0 = 8, y_0 = 1$ , the acceptance sampling plan would be $(10, 0)$ .

### Notation

The following notation is used in the tables:

$n_0$	Previous testing / prior information The number of items tested prior to the current lot inspection
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$y_0$	Previous testing / prior information The number of nonconforming items
$N$	Lot size
$D$	Damages/losses/costs per nonconforming item (expressed in terms of the benefit per item $B$ )
$T$	Sampling and testing costs per item (expressed in terms of the benefit per item $B$ )
$a$	Accept without testing
$r$	Reject without testing
$(n, c)$	Acceptance sampling plan with sample size $n$ acceptance number $c$

Table 9: Standard plans for testing and sampling costs  $T = 5B$ 

Prior test results		N	1000					10000					100000				
		D	1.5	3	10	30	100	1.5	3	10	30	100	1.5	3	10	30	100
		T	5					5					5				
n <sub>0</sub>	y <sub>0</sub>	T/N	0.500%					0.050%					0.005%				
0	0		(1,0)	(2,0)	(7,0)	r	r	(2,1)	(5,1)	(15,1)	(25,0)	r	(2,1)	(7,2)	(21,1)	(50,1)	(93,0)
1	0		a	(2,0)	(7,0)	r	r	a	(4,1)	(15,1)	(27,0)	(78,0)	a	(4,1)	(24,2)	(53,1)	(110,0)
2	0		a	(1,0)	(6,0)	r	r	a	(3,1)	(14,1)	(28,0)	(77,0)	a	(3,1)	(20,1)	(54,1)	(119,0)
3	0		a	(1,0)	(5,0)	(20,0)	r	a	(1,0)	(13,1)	(28,0)	(76,0)	a	(3,1)	(18,1)	(54,1)	(131,0)
4	0		a	(1,0)	(5,0)	(19,0)	r	a	(1,0)	(12,1)	(28,0)	(76,0)	a	(1,0)	(16,1)	(53,1)	(147,1)
5	0		a	(1,0)	(4,0)	(18,0)	r	a	(1,0)	(11,1)	(28,0)	(76,0)	a	(1,0)	(14,1)	(52,1)	(147,1)
8	0		a	(1,0)	(3,0)	(15,0)	r	a	(1,0)	(7,0)	(26,0)	(74,0)	a	(1,0)	(10,1)	(49,1)	(144,1)
10	0		a	(1,0)	(3,0)	(14,0)	r	a	(1,0)	(5,0)	(24,0)	(73,0)	a	(1,0)	(9,1)	(46,1)	(143,1)
13	0		a	(1,0)	(2,0)	(12,0)	r	a	(1,0)	(4,0)	(21,0)	(71,0)	a	(1,0)	(7,1)	(42,1)	(140,1)
20	0		a	(1,0)	(2,0)	(8,0)	r	a	(1,0)	(3,0)	(15,0)	(65,0)	a	(1,0)	(3,0)	(33,1)	(133,1)
30	0		a	(1,0)	(2,0)	(6,0)	r	a	(1,0)	(3,0)	(9,0)	(57,0)	a	(1,0)	(3,0)	(22,1)	(122,1)
50	0		a	(1,0)	(2,0)	(5,0)	(22,0)	a	(1,0)	(2,0)	(7,0)	(41,0)	a	(1,0)	(3,0)	(9,0)	(80,0)
80	0		a	(1,0)	(2,0)	(4,0)	(14,0)	a	(1,0)	(2,0)	(6,0)	(23,0)	a	(1,0)	(3,0)	(7,0)	(50,0)
100	0		a	(1,0)	(2,0)	(4,0)	(12,0)	a	(1,0)	(2,0)	(6,0)	(18,0)	a	(1,0)	(3,0)	(7,0)	(34,0)
1	1		(2,1)	(3,0)	r	r	r	(4,2)	(7,1)	(11,0)	r	r	(6,3)	(12,3)	(22,1)	(36,0)	(87,0)
2	1		a	(5,1)	r	r	r	(2,1)	(9,2)	(16,0)	r	r	(3,2)	(15,4)	(33,2)	(59,1)	r
3	1		a	(4,1)	r	r	r	a	(8,2)	(21,1)	r	r	a	(14,4)	(41,3)	(64,1)	r
4	1		a	(3,1)	r	r	r	a	(7,2)	(22,1)	r	r	a	(10,3)	(43,3)	(69,1)	r
5	1		a	(3,1)	r	r	r	a	(6,2)	(22,1)	r	r	a	(8,3)	(46,3)	(72,1)	r
8	1		a	(1,0)	(10,0)	r	r	a	(2,1)	(23,1)	r	r	a	(3,1)	(48,4)	(96,2)	r
10	1		a	(1,0)	(8,0)	r	r	a	(2,1)	(25,2)	(45,0)	r	a	(2,1)	(45,4)	(98,2)	r
13	1		a	(1,0)	(6,0)	r	r	a	(1,0)	(19,1)	(42,0)	r	a	(2,1)	(37,3)	(102,2)	(159,0)
20	1		a	(1,0)	(3,0)	r	r	a	(1,0)	(10,1)	(58,1)	r	a	(1,0)	(20,2)	(106,2)	(159,0)
30	1		a	(1,0)	(3,0)	r	r	a	(1,0)	(6,1)	(49,1)	r	a	(1,0)	(7,1)	(97,2)	(156,0)
50	1		a	(1,0)	(2,0)	(9,0)	r	a	(1,0)	(4,0)	(30,1)	r	a	(1,0)	(5,1)	(64,2)	(147,0)
80	1		a	(1,0)	(2,0)	(6,0)	r	a	(1,0)	(3,0)	(10,0)	r	a	(1,0)	(3,0)	(20,1)	(180,1)
100	1		a	(1,0)	(2,0)	(5,0)	r	a	(1,0)	(3,0)	(8,0)	(87,0)	a	(1,0)	(3,0)	(15,1)	(167,1)
8	2		a	(3,1)	r	r	r	a	(6,2)	(25,1)	r	r	a	(12,4)	(48,3)	(68,1)	r
10	2		a	(1,0)	r	r	r	a	(3,1)	(25,1)	r	r	a	(6,2)	(56,4)	(74,1)	r
13	2		a	(1,0)	r	r	r	a	(2,1)	(26,1)	r	r	a	(3,1)	(62,5)	(80,1)	r
20	2		a	(1,0)	(8,0)	r	r	a	(2,1)	(26,2)	r	r	a	(2,1)	(56,5)	(109,2)	r
30	2		a	(1,0)	(3,0)	r	r	a	(1,0)	(12,1)	r	r	a	(2,1)	(30,3)	(133,3)	r
50	2		a	(1,0)	(3,0)	r	r	a	(1,0)	(6,1)	(59,1)	r	a	(1,0)	(7,1)	(122,3)	r
80	2		a	(1,0)	(2,0)	(10,0)	r	a	(1,0)	(5,1)	(32,1)	r	a	(1,0)	(6,1)	(87,3)	r
100	2		a	(1,0)	(2,0)	(7,0)	r	a	(1,0)	(3,0)	(19,1)	r	a	(1,0)	(5,1)	(46,2)	(186,0)
20	3		a	(1,0)	r	r	r	a	(2,1)	(27,1)	r	r	a	(2,1)	(70,5)	(81,1)	r
30	3		a	(1,0)	(8,0)	r	r	a	(2,1)	(27,2)	r	r	a	(2,1)	(66,6)	(92,1)	r
50	3		a	(1,0)	(3,0)	r	r	a	(1,0)	(7,1)	r	r	a	(1,0)	(15,2)	(143,3)	r
80	3		a	(1,0)	(2,0)	r	r	a	(1,0)	(5,1)	(60,1)	r	a	(1,0)	(6,1)	(127,3)	r
100	3		a	(1,0)	(2,0)	r	r	a	(1,0)	(5,1)	(41,1)	r	a	(1,0)	(6,1)	(107,3)	r
50	4		a	(1,0)	(4,0)	r	r	a	(1,0)	(17,2)	r	r	a	(2,1)	(46,5)	(100,1)	r
80	4		a	(1,0)	(3,0)	r	r	a	(1,0)	(6,1)	r	r	a	(1,0)	(8,1)	(147,3)	r
100	4		a	(1,0)	(3,0)	r	r	a	(1,0)	(5,1)	r	r	a	(1,0)	(6,1)	(142,3)	r

Table 10: Standard plans for testing and sampling costs  $T = 25 B$ 

Prior test results		$N$	1000					10000					100000				
		$D$	1.5	3	10	30	100	1.5	3	10	30	100	1.5	3	10	30	100
		$T$	25					25					25				
$n_0$	$y_0$	$T/N$	2.500%					0.250%					0.025%				
0	0		(1,0)	(2,0)	r	r	r	(2,1)	(4,1)	(8,0)	r	r	(2,1)	(5,1)	(16,1)	(29,0)	(78,0)
1	0		a	(1,0)	r	r	r	a	(2,0)	(8,0)	(22,0)	r	a	(4,1)	(16,1)	(34,0)	(80,0)
2	0		a	(1,0)	(5,0)	r	r	a	(1,0)	(7,0)	(21,0)	r	a	(3,1)	(15,1)	(44,1)	(81,0)
3	0		a	(1,0)	(4,0)	r	r	a	(1,0)	(7,0)	(21,0)	r	a	(1,0)	(14,1)	(43,1)	(81,0)
4	0		a	(1,0)	(4,0)	r	r	a	(1,0)	(6,0)	(20,0)	r	a	(1,0)	(13,1)	(43,1)	(81,0)
5	0		a	(1,0)	(3,0)	r	r	a	(1,0)	(5,0)	(19,0)	r	a	(1,0)	(12,1)	(42,1)	(81,0)
8	0		a	(1,0)	(2,0)	r	r	a	(1,0)	(4,0)	(17,0)	r	a	(1,0)	(9,1)	(39,1)	(80,0)
10	0		a	(1,0)	(2,0)	r	r	a	(1,0)	(3,0)	(15,0)	r	a	(1,0)	(7,1)	(37,1)	(80,0)
13	0		a	(1,0)	(2,0)	r	r	a	(1,0)	(3,0)	(13,0)	r	a	(1,0)	(4,0)	(34,1)	(80,0)
20	0		a	(1,0)	(2,0)	(5,0)	r	a	(1,0)	(2,0)	(9,0)	(55,0)	a	(1,0)	(3,0)	(22,0)	(77,0)
30	0		a	(1,0)	(2,0)	(4,0)	r	a	(1,0)	(2,0)	(6,0)	(44,0)	a	(1,0)	(3,0)	(11,0)	(70,0)
50	0		a	(1,0)	(2,0)	(4,0)	r	a	(1,0)	(2,0)	(5,0)	(28,0)	a	(1,0)	(3,0)	(7,0)	(53,0)
80	0		a	(1,0)	(2,0)	(3,0)	r	a	(1,0)	(2,0)	(5,0)	(16,0)	a	(1,0)	(2,0)	(6,0)	(30,0)
100	0		a	(1,0)	(2,0)	(3,0)	(9,0)	a	(1,0)	(2,0)	(5,0)	(14,0)	a	(1,0)	(2,0)	(6,0)	(22,0)
1	1		(1,0)	r	r	r	r	(2,1)	(4,0)	r	r	r	(4,2)	(9,2)	(15,0)	(29,0)	r
2	1		a	(2,0)	r	r	r	(2,1)	(5,1)	r	r	r	(2,1)	(11,3)	(22,1)	(36,0)	r
3	1		a	(2,0)	r	r	r	a	(5,1)	r	r	r	a	(10,3)	(24,1)	(40,0)	r
4	1		a	(1,0)	r	r	r	a	(4,1)	(13,0)	r	r	a	(8,2)	(30,2)	(42,0)	r
5	1		a	(1,0)	r	r	r	a	(3,1)	(12,0)	r	r	a	(6,2)	(30,2)	(43,0)	r
8	1		a	(1,0)	r	r	r	a	(1,0)	(11,0)	r	r	a	(2,1)	(29,2)	(45,0)	r
10	1		a	(1,0)	r	r	r	a	(1,0)	(10,0)	r	r	a	(2,1)	(28,2)	(66,1)	r
13	1		a	(1,0)	r	r	r	a	(1,0)	(9,0)	r	r	a	(2,1)	(24,2)	(65,1)	r
20	1		a	(1,0)	(2,0)	r	r	a	(1,0)	(4,0)	r	r	a	(1,0)	(12,1)	(63,1)	r
30	1		a	(1,0)	(2,0)	r	r	a	(1,0)	(3,0)	(25,0)	r	a	(1,0)	(6,1)	(58,1)	r
50	1		a	(1,0)	(2,0)	r	r	a	(1,0)	(2,0)	(11,0)	r	a	(1,0)	(5,1)	(37,1)	r
80	1		a	(1,0)	(2,0)	(4,0)	r	a	(1,0)	(2,0)	(6,0)	r	a	(1,0)	(3,0)	(16,1)	(111,0)
100	1		a	(1,0)	(2,0)	(4,0)	r	a	(1,0)	(2,0)	(6,0)	r	a	(1,0)	(3,0)	(11,0)	(111,0)
8	2		a	(1,0)	r	r	r	a	(3,1)	r	r	r	a	(9,3)	(27,1)	r	r
10	2		a	(1,0)	r	r	r	a	(2,1)	r	r	r	a	(5,2)	(34,2)	r	r
13	2		a	(1,0)	r	r	r	a	(2,1)	r	r	r	a	(2,1)	(35,2)	r	r
20	2		a	(1,0)	r	r	r	a	(1,0)	(9,0)	r	r	a	(2,1)	(35,3)	r	r
30	2		a	(1,0)	(3,0)	r	r	a	(1,0)	(5,0)	r	r	a	(1,0)	(18,2)	(78,1)	r
50	2		a	(1,0)	(2,0)	r	r	a	(1,0)	(3,0)	r	r	a	(1,0)	(6,1)	(68,1)	r
80	2		a	(1,0)	(2,0)	r	r	a	(1,0)	(3,0)	(11,0)	r	a	(1,0)	(5,1)	(41,1)	r
100	2		a	(1,0)	(2,0)	(5,0)	r	a	(1,0)	(2,0)	(7,0)	r	a	(1,0)	(5,1)	(22,1)	r
20	3		a	(1,0)	r	r	r	a	(2,1)	r	r	r	a	(2,1)	(37,2)	r	r
30	3		a	(1,0)	r	r	r	a	(1,0)	(9,0)	r	r	a	(2,1)	(37,3)	r	r
50	3		a	a	(2,0)	r	r	a	(1,0)	(4,0)	r	r	a	(1,0)	(9,1)	r	r
80	3		a	(1,0)	(2,0)	r	r	a	(1,0)	(3,0)	r	r	a	(1,0)	(6,1)	(69,1)	r
100	3		a	(1,0)	(2,0)	r	r	a	(1,0)	(3,0)	(16,0)	r	a	(1,0)	(5,1)	(55,1)	r
50	4		a	(1,0)	(3,0)	r	r	a	(1,0)	(5,0)	r	r	a	(2,1)	(21,2)	r	r
80	4		a	(1,0)	(2,0)	r	r	a	(1,0)	(5,1)	r	r	a	(1,0)	(6,1)	r	r
100	4		a	(1,0)	(2,0)	r	r	a	(1,0)	(3,0)	r	r	a	(1,0)	(6,1)	(73,1)	r

## General notes

### Note 1

As the lot size  $N$  increases, the sample size also increases, but at the same time, it becomes “easier” to justify investing resources in lot inspection—i.e. plans are available at lower  $n_0$  values. This is due to the increase in benefit due to the increased lot size.

### Note 2

For a given cost structure and lot size, the sample size is less for  $T = 25 B$  than for  $T = 5 B$ . On the other hand, a higher  $n_0$  value is required prior to committing resources to acceptance sampling for  $T = 25 B$ .

### Note 3

The ‘r’ entries (highlighted in red in the table) indicate that the lot should be rejected without testing. This should be interpreted as follows: given the testing costs and the damages associated with nonconforming items, it only makes sense to invest resources in lot inspection given a minimum level of confidence in the lot quality. This minimum level of confidence is codified via the  $(n_0, y_0)$  pair. For example, for a relatively small lot ( $N = 1000$ ) and a very high value for  $D$  ( $D = 100$ , reflecting for example a health hazard in connection with nonconforming items), it only makes sense to conduct acceptance sampling if the prior information is based on at least 50 previously tested items with zero nonconforming results.

If the consumer rejects the lot without testing, the producer has the following options:

1. Increase the lot size  $N$ . As seen in the standard plans, a larger lot size translates to higher income for the consumer, thus lowering the threshold for investing resources in acceptance sampling.
2. Decrease the purchase price of the lot. This is tantamount to increasing the parameter  $B$ , which, in turn, will result in lower values for  $D$  and  $T$ . This will lower the threshold for investing resources in acceptance sampling.
3. Develop test methods which are cheaper to apply. This option will result in a decrease in the  $T$  parameter, thus lowering the threshold for investing resources in acceptance sampling. An important caveat here is that the performance of the new method must be at least as good as that of the original method.

## Technical notes

### Note 1

The standard plans were calculated via a hierarchical Bayesian model which “mixes” two priors: the “actual” prior corresponding to the prior information and the “non-informative” Jeffreys prior. The latter’s influence is increased the further the testing outcome deviates from the “actual” prior. See Uhlig et al. (2025) [25]. In addition, the 10% approximation (see discussion at the end of the previous section) is applied.

### Note 2

We define the ratio  $x_0 = B/D$  (or  $1/D$  if  $D$  is expressed in terms of  $B$ ). The probability that the percentage nonconforming exceeds  $x_0$  is an interesting pendant to the consumer’s risk in the ISO 2859 series of standards. See the discussion in Hald [23].

### Note 3

The sample size increases with  $n_0$  as long as the mean value of the beta distribution corresponding to  $(n_0, y_0)$  is less than the ratio  $x_0 = B/D$  (or  $1/D$  if  $D$  is expressed in terms of  $B$ ). When this mean value is greater than  $x_0$ , the sample size decreases as  $n_0$  increases. This can be explained as follows: if the mean value is less than  $x_0$ , it is unlikely that utility will be positive, and the natural tendency of the model is to resist investing resources in lot inspection. This resistance decreases as the prior becomes more optimistic. By contrast, if the mean value is greater than  $x_0$ , then it is likely that the utility will be positive, and the natural tendency of the model is to invest resources in lot inspection. As the prior becomes more optimistic, fewer resources are required.

### Note 4

The standard plan for  $N = 1000$ ,  $D = 3$ ,  $T = 25$ ,  $n_0 = 50$ ,  $y_0 = 3$  is “accept” rather than (1,0). This anomaly may possibly be related to rounding issues.

More information regarding this approach can also be found in Uhlig et al. (2025) [25].

### 5.7.86.3.8 Broader view of utility

As can be seen in the standard plans, the acceptance sampling plan depends very much on the lot size. Indeed, a large lot size translates to an increase in total benefit, thus impacting the calculation of utility. For example, for the cost structure  $D = 30 B$  and  $T = 25 B$ , and for the prior information ( $n_0 = 20, y_0 = 1$ ), there is an acceptance plan (i.e. it makes sense to invest resources in lot inspection) only for the lot size  $N = 100\,000$ . Indeed, for the lot size  $N = 1000$  and the lot size  $N = 10\,000$ , the utility approach results in the decision to reject the lot without testing. These considerations show the extent to which the acceptance samplings plans (including the decision to reject without testing) reflect the cost structure internalized in the parameters of the utility model.

There are three takeaways from this for the consumer.

The first is that the consumer can perform some preliminary calculations and inform the producer prior to the lot being shipped that, given the cost structure, the transaction is only commercially viable for a minimum lot size.

The second is that, in certain circumstances, it could lie in the interest of the consumer to “pretend” that the lot size is greater than it actually is in order to achieve a viable acceptance sampling plan. For instance, consider the case that an importing country is initiating commercial relations with a new supplier and that the first lot—intended as a trial—is smaller in size than subsequent “routine” lots would be.

The third and last takeaway is that an indispensable condition for achieving plans which successfully balance the producer’s and the consumer’s interests is transparency. For instance, the producer must be able to ascertain whether the consumer intends to reject without testing or to apply an acceptance sampling plan *prior to shipping the lot*. Indeed, this last take away leads directly to the question whether it is possible to combine utility functions representing the consumer’s and the producer’s perspectives so as to achieve a broader notion of utility representing, as it were, a win-win situation for both parties to the transaction. This is discussed in the following section.

### 5.7.96.3.9 Adversarial approach

The standard plans from the previous section were calculated on the basis of a utility concept which reflects the consumer’s perspective. However, the utility approach can be extended to include the producer’s perspective. This will be briefly described in this section.

If the consumer reaches the decision to reject without testing, then the producer has two possible courses of action.

1. Apply one of the options listed under **Note 3** in the **General notes**, at the end of Section 6.3.7
2. Offer to pay for testing and sampling costs. In such a case, the sampling plan can be calculated from the point of view of the producer. This is where the *adversarial* approach is applied. The aim of the adversarial approach is to calculate an acceptance sampling plan (sample size and acceptance number) by maximizing the producer’s utility. The latter in turn, takes into account the consumer’s decision to accept or reject the lot. In other words, the adversarial approach consists in combining the consumer’s and the producer’s utility functions.

The adversarial approach was first described in articles by Lindley and Singpurwalla [24]. For further information regarding the adversarial approach, the reader is referred to Uhlig et al. (2025) [26].

### 5.86.4 Bayesian plans: glossary of terms

Percentage nonconforming	The proportion of nonconforming items in the lot, expressed as a percentage. In the ISO 2859 and ISO 3951 standards, this is called percentage nonconforming.
Prior distribution (short: prior)	Statistical distribution which encapsulates information regarding the lot quality which is available prior to the lot inspection
Posterior distribution (short: posterior)	Statistical distribution which combines the prior and the testing outcomes
Hyperparameter	Parameter of the prior or posterior distribution
Beta distribution	Typical choice of prior for the percentage nonconforming in the case of inspection by attributes
Parametric risk ("classical" or "ISO" risk)	The producer's and consumer's risks as defined in the ISO 2859 and ISO 3951 standards. These risks start from a given quality level and calculate the corresponding probability of acceptance or rejection. In other words, the quality level is treated as the parameter of a statistical distribution.
Bayesian risk	These risks are calculated via a prior distribution for the parameter which characterizes the lot quality. For example, in the case of inspection by attributes, the risks are calculated via a prior distribution for the percentage nonconforming. See Section 6.2.
Lot conformity	In the case of inspection by attributes: a lot is conforming if the percentage nonconforming lies within a conformance region $\mathcal{C}$ for lot quality specified via an upper limit $x_c$ for the percentage nonconforming (e.g. upper limit $x_c = 10\%$ ). Lot conformity must be carefully distinguished from item conformity.
Conformance probability	The probability that a lot is conforming, given a test outcome.
Specific consumer risk	A type of Bayesian risk. The probability that a lot is nonconforming given a test outcome resulting in lot acceptance.
Global producer risk	A type of Bayesian risk. The probability that lot is both conforming and rejected.
Utility	A value reflecting benefits and costs associated with an acceptance sampling plan and a lot.
Expected prior utility	Insofar as the utility is calculated from a prior for the percentage nonconforming, the utility is a random variable. The expected value of the utility is called the expected prior utility.

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