CXG50

Revision of the Codex *General Guidelines on Sampling* (CXG 50-2004)

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Agenda

- Quiz
- Summary of progress on CXG50
- Risk and related definitions
- Introduction to the “How To” guide
- Worked examples

History of the process

CCMAS 37
2016

GL 50 difficult to understand
EWG to review GL 50 rationale and purpose

CCMAS 38
2017

General and technical Improvements
EWG to prepare project document

CCMAS 39
2018

Proposed new work, prioritisation list, and the use of 'apps'
CAC41
EWG to undertake revision of the guidelines

CCMAS 40
2019

Report on progress on revision of guidelines to design appropriate sampling plans, and e-book containing sampling plan 'apps'.
EWG re-established

2020
Continuation

Circular Letter
EWG re-established

CCMAS 41
2021

Step 5
EWG re-established

Where are we currently up to?

- NZ and Germany have worked closely (remote on-line meetings) to update the CXG 50 based on the discussion at CCMAS 41
- These updated CXG 50 documents now consist of the ‘How to Guide’ and a ‘Reference Document’ and will soon be going out to the EWG for comment
- The ‘How to Guide’ and some of the related information in the ‘Reference Document’ will be presented at this webinar
- The information document containing the apps is also under review and being updated
- A final version of these will be circulated prior to CCMAS 42 for final comment
- The full package will be discussed at CCMAS 42

Relationship between CXG54 and CXG50

	CXG54	CXG50
	Guidelines on Measurement Uncertainty	Guidelines on Sampling (Acceptance Sampling)
Conformity assessment	Single sample	Lot
	A single analytical sample	Multiple samples tested
Purpose of assessments	Does the true value of the sample comply?	Does the lot comply within allowable tolerances based on risk?
	Takes account only of measurement uncertainty	Takes account of both measurement uncertainty AND sampling uncertainty
	CXG54 contains principles regarding measurement uncertainty that relate to both documents	

FAQs

1. Why have we adopted the approach using apps?

- Agreed Project TOR included allowance for measurement uncertainty (MU)
- Allowing for MU means that we can no longer publish tables of sampling plans as hard copy, there are too many possibilities

2. Why have we not followed the ISO standards completely?

- The plans in the ISO standards do not allow for control of both consumer's and producer's risks in the design of plans, and may be unfair if used inappropriately
- We have followed ISO standards 2859-2 and 3951-6 for the inspection of isolated lots where only control of consumer's risk is required

Risk

Definition (AS/NZS 4360:1999)
The chance of something happening that will have an impact upon objectives. It is measured in terms of consequences and likelihood.

Risk acceptance
An informed decision to accept the consequences and the likelihood of a particular risk

Types of Risk

- Food safety
- Disease
- Complaints & Product liability
- Financial
- Economic
- Professional liability

- Human
- Environmental
- Natural hazards
- Property damage
- Security
- Technological
- Occupational health & safety

Fundamental Principle of Sampling Inspection

- All sampling plans have the potential to make incorrect decisions about the acceptance of a lot; there are two basic types of risk:
  - Consumer's risk (CR), the chance that a lot of unacceptable quality will be accepted
  - Producer's risk (PR), the chance that a lot of good quality will be rejected
- However, by using statistical principles based on random sampling, it is possible to design sampling plans that allow no more risk than required
- Therefore, to design a sampling plan, we need to specify how we want to control the consumer's risk and producer's risks
  - of incorrectly accepting or rejecting a lot (respectively.)

Specification of Risks

In sampling inspection, risks are specified by:

- A quality level usually expressed as a percentage nonconforming
- The chance of acceptance or rejection at that quality level

- Acceptance or rejection of a lot at a quality level corresponds to the ‘consequence’ in the general definition of risk, and
- The chance of acceptance or rejection corresponds to the ‘likelihood’

Setting Risks in Codex Sampling Plans

FOOD SAFETY	Risk Rating				
Type of Risk	Severe	Serious	Moderate	Low	
Pathogens					CCFH
Other micro					CCFH
Chemical contaminants					CCPR & CCRVDF
Composition					

Non-FOOD SAFETY	Risk Rating				
Type of Risk	Major	Moderate	Minor	Low	
Composition					CXG50
Commodity Defects					

Setting Risks for Sampling Plans Non-Food Safety

	Possible Risk Ratings				
Type of Risk	Major	Moderate	Minor	Low	
Composition					CXG50
Commodity Defects					
Possible CRQ values	To Be Decided				
Possible PRQ values					

- CXG50 is essentially restricted to composition and commodity defects
- Sampling plans will usually control both consumer's and producer's risks based on limited sample sizes (Holst et al.)

Specification of Risks

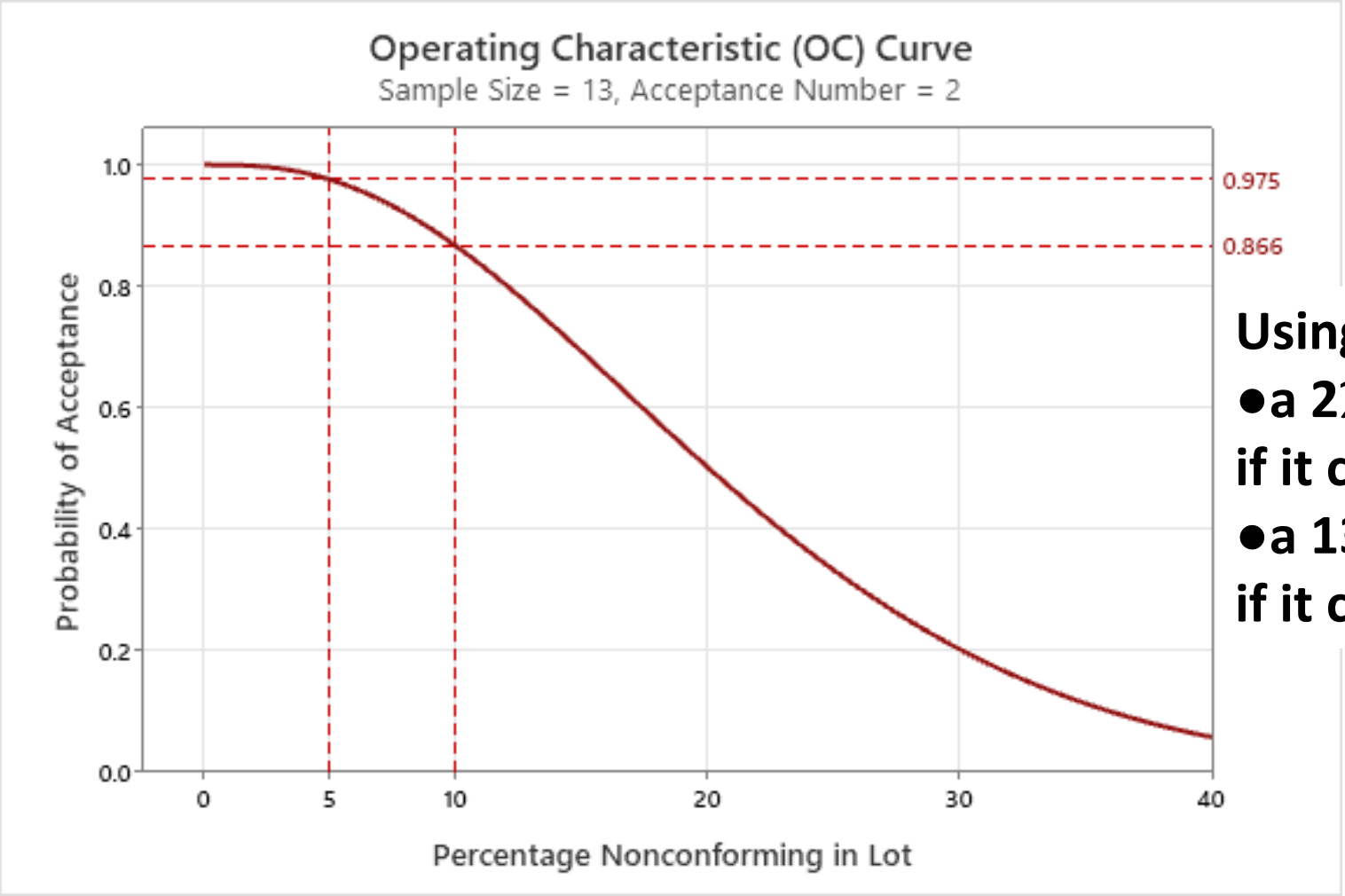
Firstly, to simplify the process, we can set:

- The Producer's Risk (PR) level at 5% nonconforming
- The Consumer's Risk (CR) at 10% nonconforming

This reduces the task to specifying:

- The Producer's Risk Quality Level (PRQ) corresponding to the (PR)
- The Consumer's Risk Quality Level (CRQ) corresponding to the (CR)

Principle:
A 5% chance of accepting a lot at one quality level is the same as a 10% chance of accepting the lot at another quality level.



Using this sampling plan there is:

- **a 2½% chance of rejecting the lot if it contains 5% nonconforming, and**
- **a 13.4% chance of rejecting the lot if it contains 10% nonconforming**

Specification of Risks – a possible approach

Secondly, the producer's risk quality levels and consumer's risk quality levels are percentages:

We can simplify setting of these risks by:

- Grouping characteristics having similar risks
- Assigning risk ratings to each group
- Assigning a single PRQ and CRQ to each risk rating

Principle:
Small changes in the PRQ or CRQ values will not cause large changes in the performance of the sampling plan

Sample Size Considerations

- Choice of sampling plans for non-food safety characteristics will also be dictated by sample size (practicality and cost)
- Sample size is influenced most by the difference between the consumer's risk quality level (CRQ) and the producer's risk quality level (PRQ)

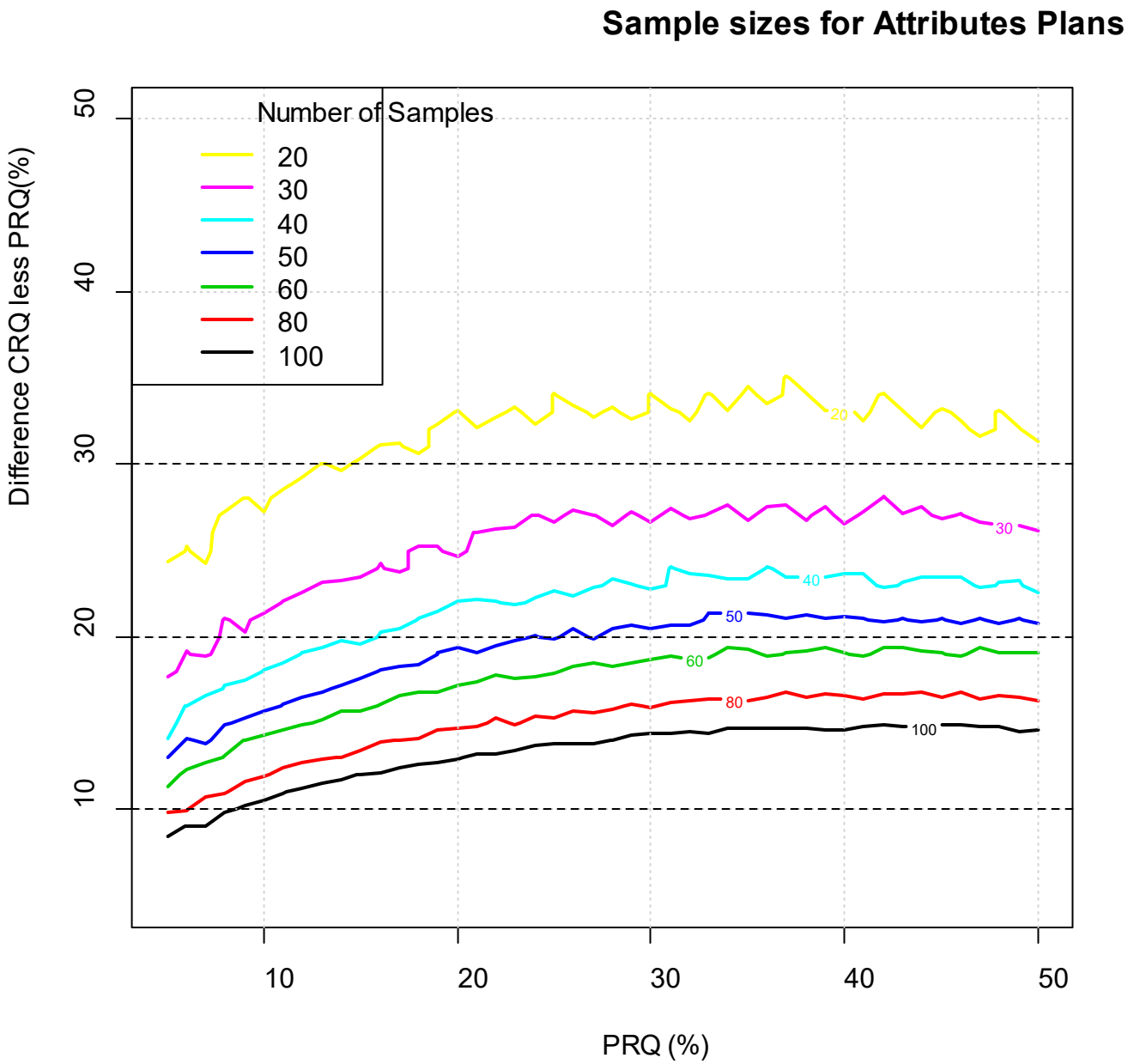
Sample Sizes - Attributes Plans

To keep sample sizes reasonable (say less than 30):

- If PRQ <10% then CRQ-PRQ > 10%

- If PRQ 10-15% then CRQ-PRQ>20%

- If PRQ >15% or more then CRQ-PRQ>25%



A Possible Approach to Setting Risks in Design of Sampling Plans?

	Risk Ratings			
Type of Risk	Major	Moderate	Minor	Low
Composition				
Commodity Defects				
Possible CRQ values	CRQ only?	PRQ+10%	PRQ+20%	PRQ+30%
Possible PRQ values		TBD	TBD	TBD

Summary

Sample Sizes present a challenging issue, however:

- **Plans designed using statistical design principles are preferred to ad hoc plans**

Other possible mitigations to reduce sample size include:

- **Managing average non-compliance rates over the medium to long term, rather than possibly paying a high premium in terms of testing costs for high levels of assurance on a lot-by-lot basis**
- **The use of 'indifference' plans that are designed around the 'Indifference Quality Level' (IQL), the level of defects at which there is 50% acceptance, rather than based on PRQ, CRQ.**
- **Use of offsets, subject to considerations of fairness**
- **Use of plans based on the beta distribution for compositional characteristics**
- **Two stage sampling plans**
- **Use of rapid methods such as NIR instruments for compositional and other testing**

The CXG50 "How To" Guide

Identifies appropriate options for sampling plans based on inputs:

Type of data:

- Attributes (pass/fail outcomes)
- Variables (measured characteristics)

Measurement uncertainty

- Negligible, the presence of measurement uncertainty has no effect on the probability of acceptance, or
- Non-negligible

Introduction to the CXG50 How To Guide

Guidance on the choice of sampling plans and references to CXG50 and the appropriate apps to design those plans.

Step 1: Determine the type of Sampling Plan Attributes or Variables?

Guide to the Selection and Design of Sampling Plans

A Determine Sampling Plan Options

1. Type of data

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

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

2. Attributes data

Is the inspection error negligible or non-negligible?

Negligible	CXG50 4.2	PR & CR	App1 (attributes)	
		CR only	App1 (attributes)	ISO2859-2
Non-negligible	CXG50 5.2.1		App4	Retesting
	CXG50 5.2.2		App7	Known errors

Step 2: Variables plans – purpose of plan

3. Variables data	
Does the provision relate to compliance of the distribution or to the average level of the characteristic?	
3.a. Plans to assess compliance of the distribution	
Is the characteristic normally distributed, a compositional characteristic or does it follow some other distribution?	
Normally distributed	Go to step 4
Compositional Proportion	Go to step 6
Some other distribution	Go to step 7
3.b. Plans for the average level	
Plans for the Average level	Go to step 8

Step 3: Variables plans: Non-negligible MU

4. Variables plans, normally distributed characteristics				
Is measurement uncertainty negligible or non-negligible?				
Negligible	CXG50 4.3.3	PR & CR	App1 (Variables)	
		CR only	App1 (Variables)	ISO3951-6
Non-negligible	Go to step 5			
5. Variables plans, normally distributed characteristics, non-negligible measurement uncertainty				
Is the measurement uncertainty normally distributed or does it follow some other distribution?				
Normally distributed	CXG50 5.3.1	PR & CR	App15	
		PR only	App15	ISO3951-1 Annex O (repeatability only)
	CXG50 5.3.2	CR only	AppX	ISO3951-6 (general measurement error)
	CXG50 5.3.2	PR & CR	App16	Fractional nonconformance plans
Some other distribution	CXG50 5.3.2	PR & CR	App16	Fractional nonconformance plans

Step 4: Special plans

6. Compositional Proportions				
Is measurement uncertainty negligible or non-negligible?				
Negligible	CXG50 4.3.1	PR & CR	App10	
Non-negligible	Go to step 5		Use normal approximation	
7. Characteristic is neither normally distributed nor a compositional proportion				
Is the measurement uncertainty negligible or non-negligible?				
Negligible	CXG50 4.2.6	PR & CR	App1	Classify measurements to attributes
Non-negligible	CXG50 5.3.2	PR & CR	App16	Fractional Nonconformance Plans
8. Provision is expressed in terms of the average level in a lot				
Is the measurement uncertainty negligible or non-negligible?				
Negligible	CXG50 4.3.2	PR & CR	App3	
Non-negligible				

Step 5: Specification of Risks

B	**Specify Stringency for the Sampling Plan (plans to assess compliance to minimum or maximum levels)**		
	Consumer's Risk Quality level (CRQ)		
	What percentage nonconforming (quality level?) would you allow in lots that you would want to reject most of the time?	6.5%	Enter the allowable CRQ level
	Consumer's Risk (CR)		
	What consumer's risk are you prepared to allow, i.e. how often would you want to accept lots containing 6.5% nonconforming?	10%	Enter the allowable consumer's risk (CR) or use 10% as the default value
	If the characteristic is a 'serious' food safety (or other) concern		
	• It might not be appropriate to control producer's risks explicitly		
	• Use ISO plans (or alternatives) that control only the consumer's risk		
	• If the characteristic is not a 'serious' food safety or other concern, it is appropriate to also control the producer's risk		
	Producer's Risk Quality level (PRQ)		
	What percentage nonconforming (quality level?) would need to be present in lots that you would want to accept most of the time?	5.0%	Enter the allowable PRQ level
	Producer's Risk (PR)		
	What producer's risk are you prepared to allow, i.e. how often would you want to reject lots containing 5.0% nonconforming?	5%	Enter the allowable producer's risk (PR) or use 5% as the default value

Examples

Use of the How To Guide

Example 1: Blemishes on apples

A	Determine Sampling Plan Options			
	1. Type of data			
	Are the test results expressed as pass/fail outcomes (or equivalent) or are they measurements?			
	Blemishes on apples are visual defects, they are present on the skin of apples or not present. This is therefore an example of attributes data.			
	Pass/Fail outcomes (Attributes	Go to step 2		
	Measurements (Variables)	Go to Step 3		
	2. Attributes data			
	Is the inspection error negligible or non-negligible?			
	Negligible	CXG50 4.2	PR & CR	App1 (attributes)
			CR only	App1 (attributes)
	Non-negligible	CXG50 5.2.1		App4
		CXG50 5.2.2		App7

Step 1: Identify the type of data. Blemishes on apples are visual defects, they are either present or not present; they are an example of attributes data.

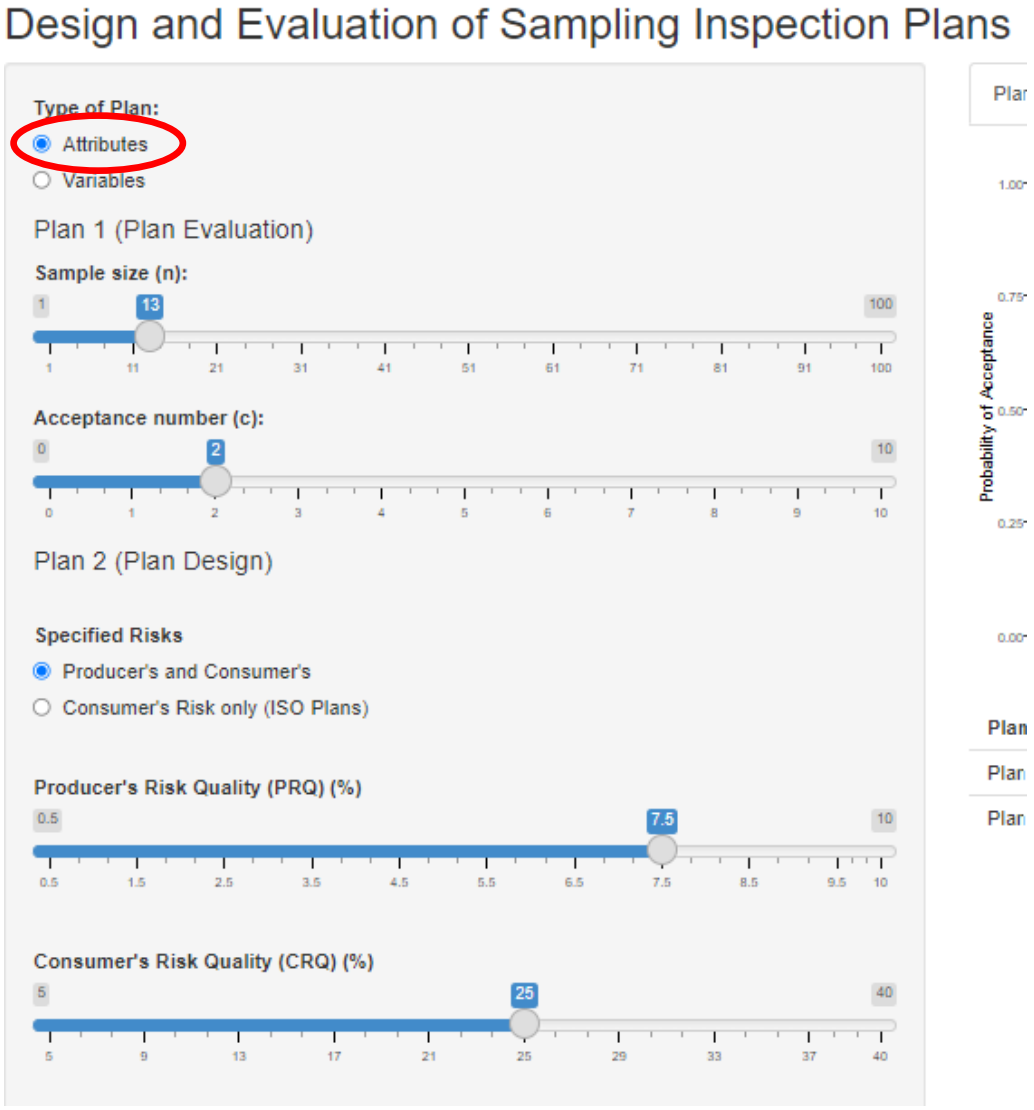
Step 2: For the purposes of this example, we have assumed there is no measurement uncertainty.

Therefore, we must use App1 (Attributes plans) to design a sampling plan.

- In App1 we select “Attributes” plans and then specify the allowable risks in the Plan Design section (Plan 2)
- Blemishes on apples is a minor defect so it is appropriate to control both producer’s and consumer’s risks

For this example, we chose risks as follows:

- Consumer’s risk: 10% chance of accepting lots in which 25% of the apples have blemishes
- Producer’s risk: 5% chance of rejecting lots in which 7½% of apples have blemishes



Blemishes on Apples (continued)

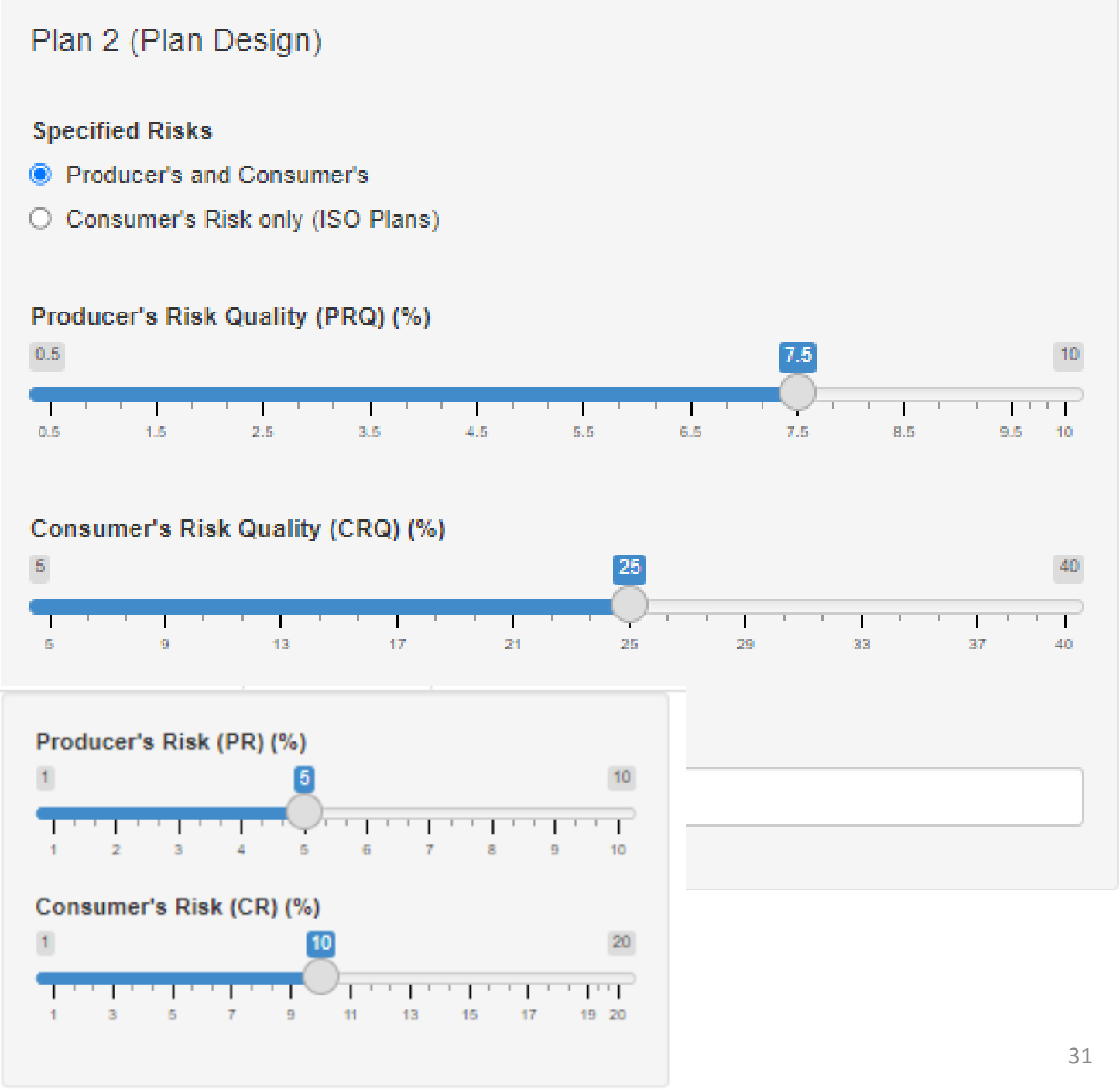
Risks were specified as follows:

Producer’s risk:

- 5% chance of rejecting a lot in which 7½% (PRQ level) of apples have blemishes

Consumer’s risk:

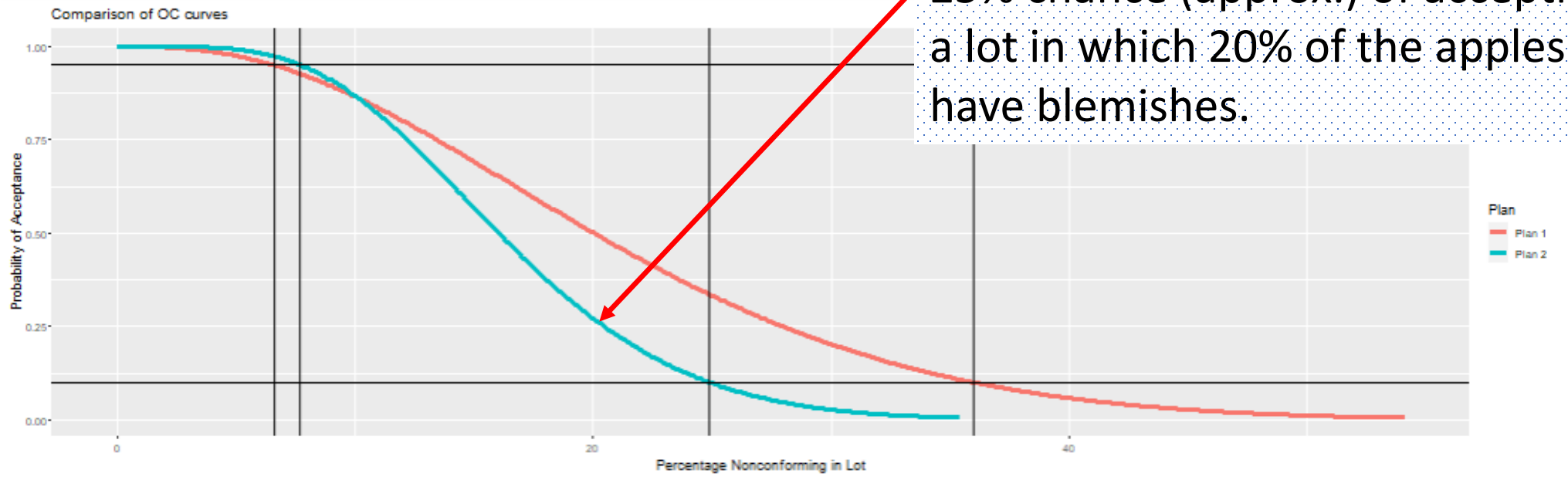
- 10% chance of accepting a lot in which 25% (CRQ level) of apples have blemishes.



The output shows that in order to control the risks to the specified levels, one must examine 35 apples taken at random from a lot, and accept the lot provided no more than 5 of those apples have blemishes.

OC curve also shows e.g. there is 25% chance (approx.) of accepting a lot in which 20% of the apples have blemishes.

Plan Details and OC | Risk Settings | Measurement Uncertainty



Plan	n	c	PRQ	PR	CRQ	CR
Plan 1	13.00	2.00	6.60	0.05	36.00	0.10
Plan 2	35.00	5.00	7.50	0.05	25.00	0.10

Demo of App – Example 1

Example 2: Fat levels in wholemilk powder (WMP)

A	Determine Sampling Plan Options	
	1. Type of data	
	Are the test results expressed as pass/fail outcomes (or equivalent) or are they measurements?	
	Pass/Fail outcomes (Attributes	Go to step 2
	Measurements (Variables)	Go to Step 3
	3. Variables data	
	Does the provision relate to compliance of the distribution or to the average level of the characteristic?	
	3.a. Plans to assess compliance of the distribution	
	Is the characteristic normally distributed, a compositional characteristic or does it follow some other distribution?	
	Normally distributed	Go to step 4
	Compositional Proportion	Go to step 6
	Some other distribution	Go to step 7

Step 1: Identify the type of data. Fat levels in WMP is a measured parameter, so this is an example of variables data.

Step 3a: For the purposes of this example, we have assumed that fat levels are normally distributed (the default assumption).

Therefore, we use App1 (Variables plans) to design a sampling plan.

Example 2: Fat levels in WMP (continued)

4. Variables plans, normally distributed characteristics			
Is measurement uncertainty negligible or non-negligible?			
Negligible	CXG50 4.3.3	PR & CR	App1 (Variables)
		CR only	App1 (Variables)
Non-negligible	Go to step 5		
5. Variables plans, normally distributed characteristics, non-negligible measurement uncertainty			
Is the measurement uncertainty normally distributed or does it follow some other distribution?			
Normally distributed	CXG50 5.3.1	PR & CR	App15
		PR only	App15
	CXG50 5.3.2	CR only	AppX
	CXG50 5.3.2	PR & CR	App16
Some other distribution	CXG50 5.3.2	PR & CR	App16

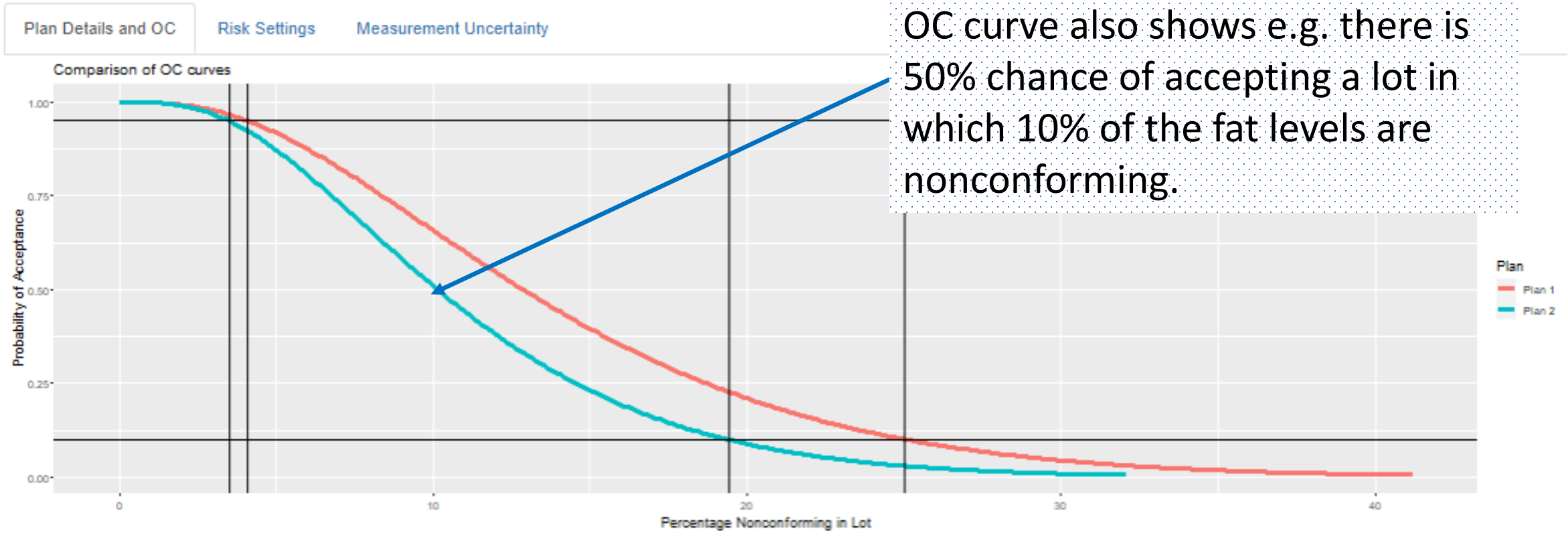
Step 4: Further, in this example we assume that measurement uncertainty is negligible.

In addition, there is not a food safety risk for fat in WMP, so it seems reasonable that any sampling plan should control both consumer's and producer's risks

This means that we can use App1 (Variables plans) to design a sampling plan.

- Using App1 we first select “Variables” plans.
- Then we must select whether the standard deviation is known from previous work or unknown, calculated from the inspection data. Here it is assumed unknown.
- We have already decided that it is appropriate to control both producer’s and consumer’s risks as follows:
- Consumer’s risk: (CR) 10% chance of accepting lots in which (CRQ) 20% of the fat levels are nonconforming
- Producer’s risk: (PR) 5% chance of rejecting lots in which (PRQ) 3½% of fat levels are nonconforming

The output shows that in order to control the risks to the specified levels, one must test 18 samples taken at random from a lot, and accept the lot provided $\bar{x}_{fat} - 1.295 \times sd_{fat} \geq 26$



OC curve also shows e.g. there is 50% chance of accepting a lot in which 10% of the fat levels are nonconforming.

Plan	n	k	PRQ	PR	CRQ	CR
Plan 1	13.00	1.16	4.10	0.05	25.00	0.10
Plan 2	18.00	1.29	3.50	0.05	20.00	0.10

Demo of App – Example 2

The acceptance criterion (n=18, k=1.295)

$$\bar{x}_{fat} - 1.295 \times sd_{fat} \geq 26$$

The average of the fat results

The standard deviation of the fat results

The lower specification limit for fat (26%) (Codex standard CXS 207-1999)

The equivalent attributes plan having the same consumer's and producer's risks is (n, c) = (32, 3), almost twice as many samples

Worked example

Fat results from 18 samples a lot:

26.4	26.4	26.6	26	26.3	26.3
25.9	26.1	26	25.9	26.2	26
26.3	26.4	26.4	26.6	25.9	25.9

- Average result = 26.20 (using the AVERAGE function in Excel)
- sd= 0.24 (using the STDEV function in Excel)

$$average - 1.295 \times sd = 25.8892 < 26$$

- Fat levels in this lot do not meet the requirements within the allowable risk levels (specified in the design of the plan).

Example 3

Variables plans with non-negligible measurement uncertainty.

How to decide whether measurement uncertainty is non-negligible?

How do we allow for the measurement uncertainty?

How to decide whether measurement uncertainty is non-negligible?

Approximate Rule:

The measurement uncertainty can be considered negligible if the measurement uncertainty standard deviation is less than 30% of the sampling uncertainty standard deviation:

$$\frac{sd(measurement\ uncertainty)}{sd(sampling\ uncertainty)} \leq 30\%$$

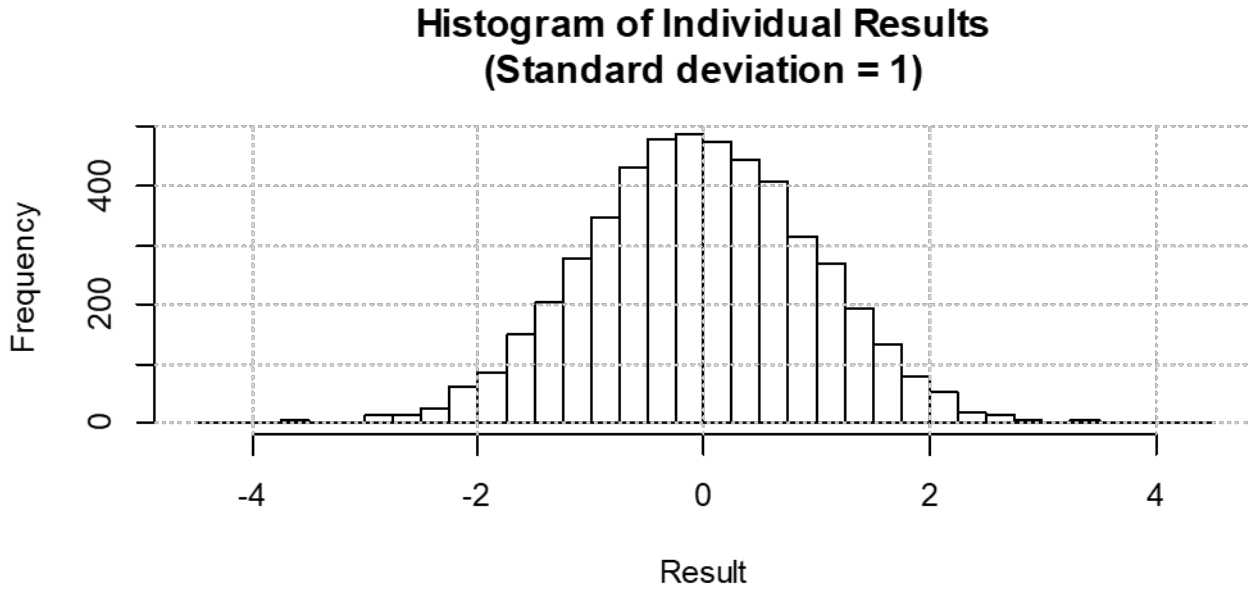
NB: The ISO standards use 10% rather than 30%

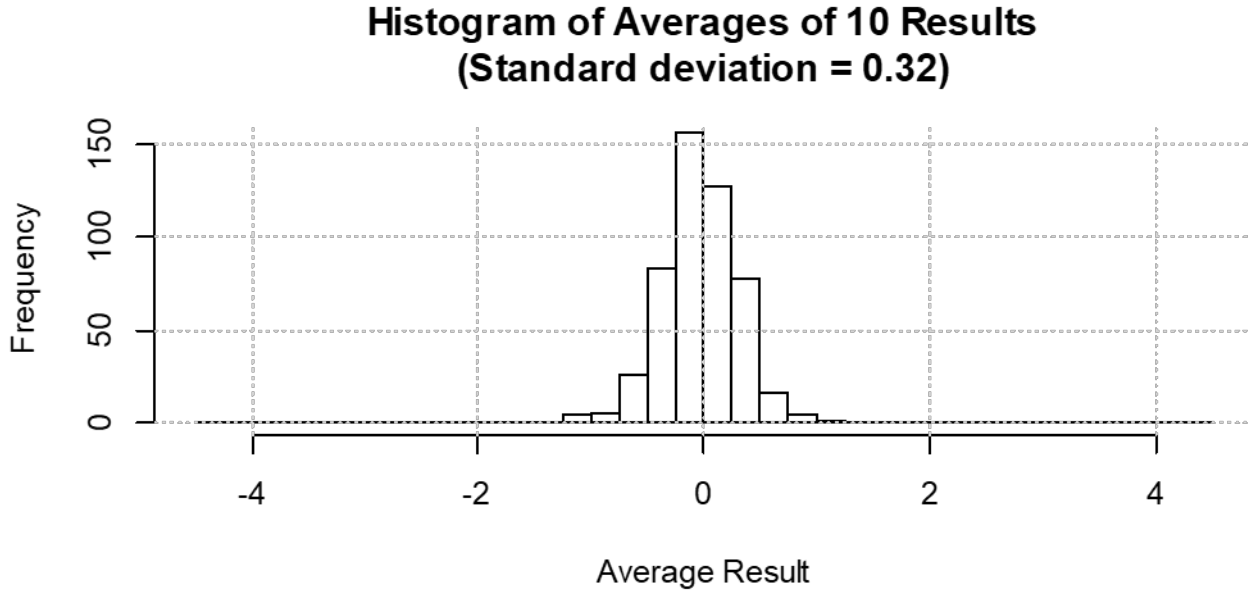
However, the apps work out the required allowance for measurement uncertainty automatically.

How to allow for measurement uncertainty

- Variables plans use the average result $\bar{x}$ as a key part of the acceptance criterion: $\bar{x} + k \times \sigma \leq USL$
- To calculate the probability of acceptance we must allow for the uncertainty of the calculated average $\bar{x}$
- When we calculate an average result, the sampling uncertainty and the random components of measurement uncertainty are reduced by the averaging, but the systematic components are not.
- (There might also be uncertainty in the standard deviation)

- The effect of the random components of measurement and the sampling uncertainty will be reduced by averaging of results.
- In practice, we do not need to worry about the details, all the calculations are done within the apps.





Example 3: Variables plans with non-negligible measurement uncertainty.

Possible Options from CXG50 How To Guide:

1. Fractional Nonconformance plans
2. ISO3951-6 plans

Option 1
Fractional Nonconformance (FNC) plans

- FNC plan controlling risks to these quality levels and allowing for measurement uncertainty:

  (n=28, Ac=3.02)

- n=28 samples with maximum acceptance number Ac=3.02

Plan Parameters:
Producer's Risk Quality = 5%
Producer's risk = 5%
Consumer's Risk Quality = 20%
Consumer's risk = 10%
Uncertainty Information:
Sampling Uncertainty sd = 0.2
Measurement Uncertainty:
Random component (repeatability) sd = 0.025
Systematic component sd = 0.05
Error variance ratio = 6.25%

OC Curve (App 16)

FNC Inspection Plan

Plan parameters

Sample size:

5 | 28 | 100

5 15 25 35 45 55 65 75 85 95 100

k-constant (Variables Plan):

1 | 1.21 | 3

1 1.2 1.4 1.6 1.8 2 2.2 2.4 2.6 2.8 3

Error Variance Ratio:

0.063 | 0.5

0.05 0.095 0.14 0.185 0.23 0.275 0.32 0.365 0.41 0.455 0.5

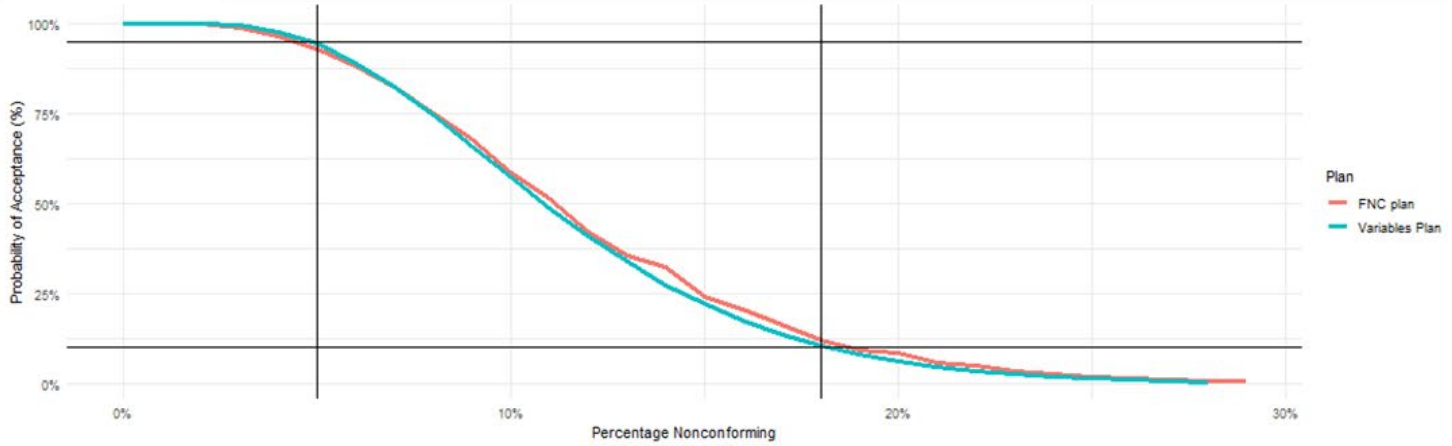
Fractional acceptance number (FNC Plan):

0.1 | 3.02 | 5

0.1 0.59 1.08 1.57 2.06 2.55 3.04 3.53 4.02 4.51 5

This tool may take about 2 minutes to show the OC curves because the simulations involved.

Plan Details and OC | Risk Settings | Notes



Plan	AQL	AQL.risk	LQL	LQL.risk
Variables Plan	5	5	18	10
FNC plan	4	5	19	10

Option 2
ISO3951-6 plans

Issues:

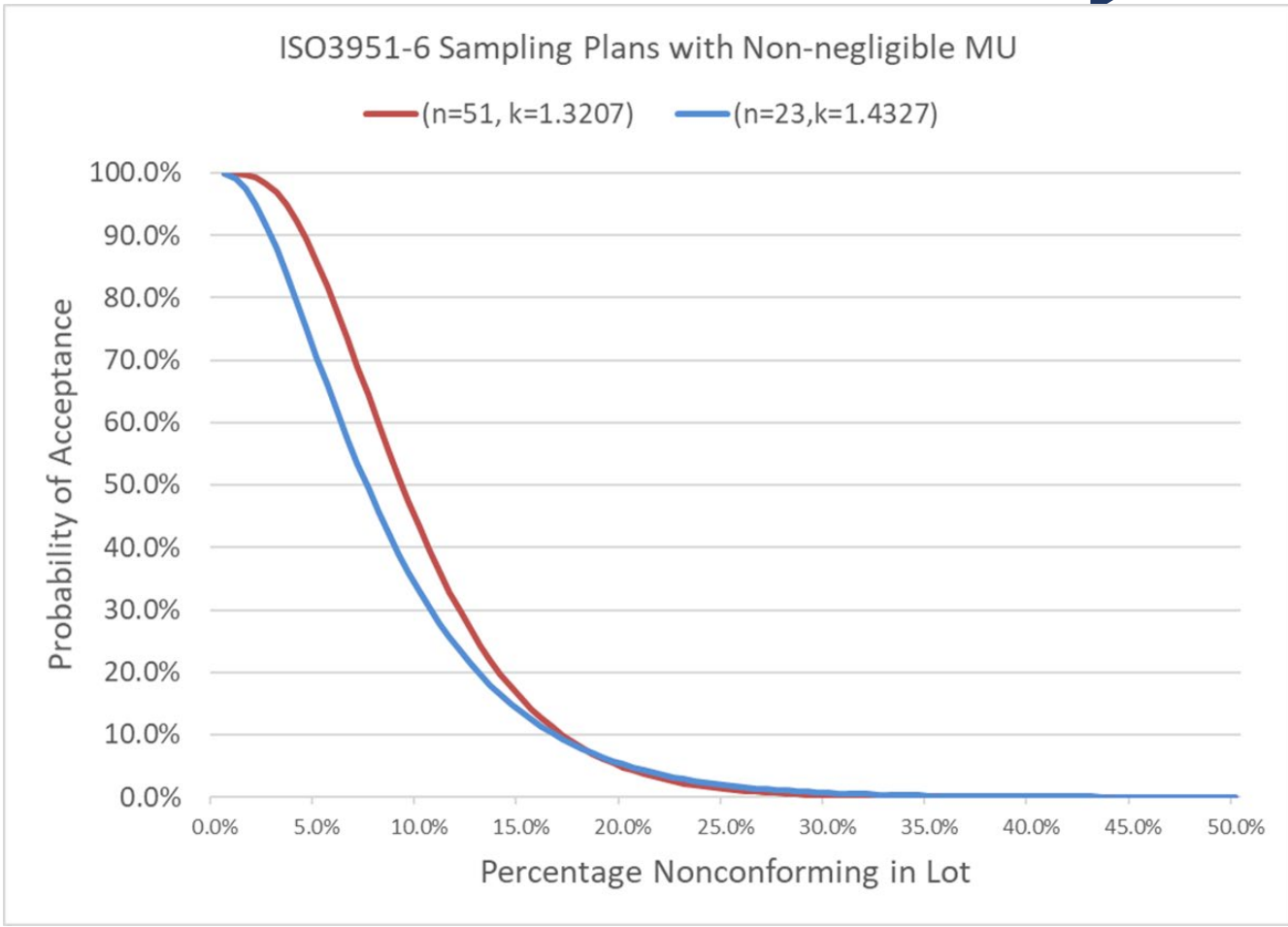
- ISO3951-6 plans assume that lots consist of discrete items
  - Due to sample size vs lot size relationship
  - Are there any provisions in Codex where such plans would be useful?
  - NB: For a bulk material the number of packages in a lot is not the lot size, e.g. for compositional characteristics such as fat and protein
  - ISO3951-6 plans control only consumer's risk (explicitly)
- Possible solution - Disregard sample size lot size relationship

Option 2
ISO3951-6 plans

Two options for plans controlling the consumer's risks to these quality levels and allowing for measurement uncertainty:

1. (n = 51, k = 1.331)
2. (n = 23, k = 1.431)

The producer's risk will differ between the two plans



End of Presentation