Eurachem
A focus for analytical chemistry in Europe
CITAC
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Consumer and producer risks in compliance assessment

PASS FAIL

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Eurachem/CITAC Workshop on Quality in Analytical Measurements: Uncertainty Evaluation and Results Interpretation

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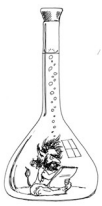
Outline

- Information needed for compliance
- Decision rules
- Eurachem guidance
- Risks
  - Producer and consumer risks
  - Specific and global risks
- Examples of specific risks
  - Simple acceptance (shared risk)
  - Guardband focusing on
    - Correct acceptance – low consumer risk – type II error
    - Correct rejection – low producer risk – type I error
- Global risk
- Summary



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Information needed to make an assessment of compliance

Information needed	Example
Measurand clearly specified	Cu content (mg/m^3) in impreganted wood – sampling is defined
Permitted upper or lower limit or both	Min 10 kg/m^3
Decision rule	Simple acceptance with demand on max expanded *U*
Measured value with uncertainty	9.95 kg/m^3 U = 25 %

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Decision rule

A decision rule should have a well-documented method of determining the location of acceptance and rejection zones, ideally including acceptable levels of probability, *P*, that the value of the measurand either

1) lies within the specification limit (correct acceptance) **or**
2) lies outside the specification limit (correct rejection)

Common decision rules are:

- pass/fail using **simple acceptance**
- pass/fail using **guard band**

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Decision rule in ISO/IEC 17025 7.8.6

When a statement of conformity* to a specification or standard is provided, the laboratory shall document the **decision rule** employed, taking into account the level of risk …

NOTE Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.

In ISO/IEC 17025 *Decision rul*e is mentioned 9 times and *Conformity assessment* 16 times

* Or compliance

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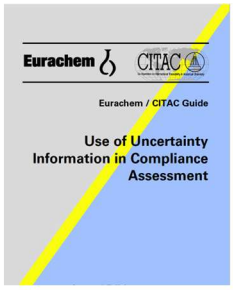
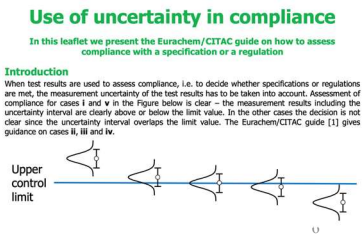
Eurachem guidance use compliance

- The Guide is concerned with whether a **measurement result complies with limits**, e.g. specifications, regulatory or legal limits – term used is **"compliance assessment".**
  - One chapter dedicated to producer and consumer risks



- The Leaflet introduces the Guide and give some examples



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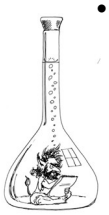
Producer and Consumer risks in compliance assessment

- Producer risk
  - Type I error
  - **Production**
    A product within spec is not accepted
  - **Environmental**
    A water sample below limit is non-compliant
- Consumer risk
  - Type II error
  - **Production**
    A product out of spec is accepted
  - **Environmental**
    A water sample above limit is compliant

- **Type** I
  - **Health care**
    The medical test shows a healthy person to be sick
  - **Court case**
    An innocent person is convicted
- **Type** II
  - **Health care**
    The medical test shows a sick person to be heathy
  - **Court case**
    A guilty person is not convicted



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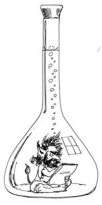
Specific and Global risks in compliance assessment

Specific risk

- The probability of incorrect decisions for a single measured value

Global risk

- The probability of incorrect decisions taken over the whole **production over time**



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Let's look at an example
- Specific risk with
- Decision rule - simple acceptance

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Examples with simple acceptance & specific risk

A consignment of wood with Cu as preservative

- Minimum is 10 kg/m^3
- Result
  - Value 9.95 kg/m^3
  - Expanded Uncertainty 25 %
- Is this result compliant?

Specific risk
The risk is based on measurement of a single item

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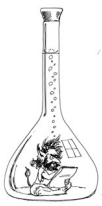
Example with a consignment of wood with Cu as preservative

Decision rule states*:

1. Round to 1 decimal place
   9.95 is then 10.0 kg/m^3

2. BUT maximum uncertainty *U* = 20 % relative
   U of 25 % is over the maximum uncertainty

No decision could be made since *U* was too large.



*NWPC No3:2017 states rounding, shared risk (simple acceptance) and U ≤ 20 %
www.ntr-nwpc.com

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Comment on simple acceptance rule

UKAS report* LAB 48 Edition 5 page 44

- *Conformity statements under ISO/IEC 17025:2017 require a decision rule (3.7) that takes account of measurement uncertainty. Some might argue that it is possible to 'take account' by ignoring it …*

Recommendations for simple acceptance

- Tell client: not possible to state any level of confidence or risk associated with the decision, but
- **you** need to set a maximum allowable uncertainty or usE an approved test method with known performance

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*Decision rules and statements of conformity

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Specific and Global risks in compliance assessment

Specific risk

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Global risk

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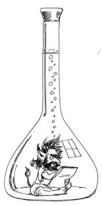

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Let's look at an example
- Specific risk
- Decision rule using Guard band focusing on low consumer risk- correct acceptance

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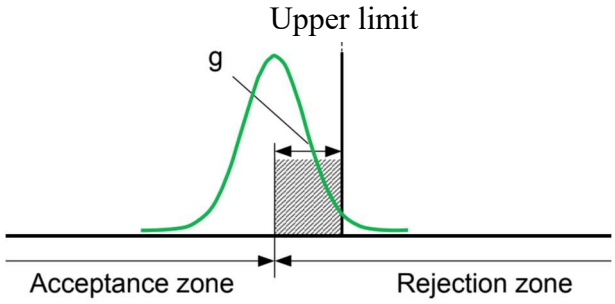
Guard band (*g*) and low specific consumer risk



For results in the acceptance zone there is

- a high probability of correct acceptance
- low probability of false acceptance - items actually above limit
- BUT several results within specification close to the upper limit will be rejected – high probability of false rejection

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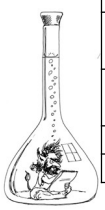
Example – batch of steel (1)

Measurand	Mass fraction of nickel, Ni in a batch of steel delivered to a customer.
Uncertainty	The expanded uncertainty (analysis and sampling), *U*, is 0.2 % Ni, $k = 2$ (95 %). Standard uncertainty, $u = 0.1$ % Ni.
Specification	The specification zone is from 16.0 % Ni to 18.0 % Ni.
Decision rule *High confidence of correct acceptance*	*The acceptance zone is the interval where it can be decided with a confidence > 95 % (α=0.05) that the batch has a mass fraction above the lower limit and below the upper limit.*
Distribution	The distribution is assumed to be Normal.
⇩	
Guard band	Guard band is calculated as $1.64u \approx 0.17$ % with *k* value 1.64 from the one-tailed 95 % upper quantile for the normal distribution.
Acceptance zone	16.2 % Ni to 17.8 % Ni, after rounding to one decimal place.
Measured value	16.1 % Ni



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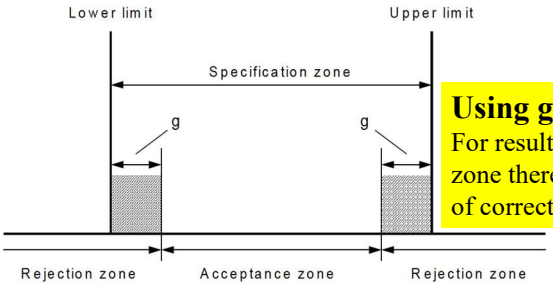
Example – batch of steel (2)



Guard bands (g), and acceptance and a rejection zones based on a lower and upper limit and a decision rule stating high confidence of correct acceptance

Using guard band
For results in the acceptanmce zone there is a high confidence of correct acceptance

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The measured value, 16.1 % Ni is below the lower acceptance limit of 16.2 %, i.e. it is in the rejection zone.
The batch is non-compliant.

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Specific and Global risks in compliance assessment

Specific risk

- The probability of incorrect decisions for a single measured value

Global risk

- The probability of incorrect decisions taken over the whole production over time

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Let's look at an example
- Specific risk
- Decision rule using Guard band focusing on low producer risk – correct rejection

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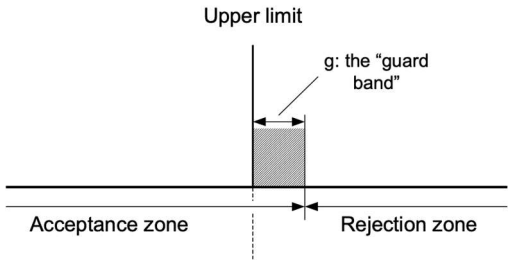
Decision rule using Guard band focusing on low specific producer risk – correct rejection



For results in the rejection zone there is

- a high probability of correct rejection
- BUT several results out of specification close to the upper limit will be accepted – high probability of false acceptance

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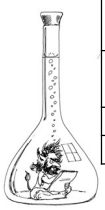
Example – banned substance in a food sample (1)

Measurand	Mass fraction of a banned substance in a food sample.
Uncertainty	The relative standard uncertainty *u* is 35 %.
Specification	Upper limit is 2 ng/g.
Decision rule *High confidence of correct rejection*	The mass fraction will be deemed to be above the limit if the probability of the value of the mass fraction being greater than the limit is 95 % or greater.
Distribution	The distribution is assumed to be close to log-normal – *u > 20 %*
	⇩
Guard band	Guard band for a lognormal distribution is is calculated to 1.6 ng/g with *k* value 1.64 from the one-tailed 95 % upper quantile.
Acceptance limit	3.6 ng/g
Measured value	3.3 ng/g



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Example – banned substance in a food sample (2) Calculation of acceptance limits

- Specification max 2.0 ng/g
- Standard relative uncertainty, *u* = 35 %
- Normal distribution
  - $2.0 + 2.0 \cdot 0.35 \cdot 1.64 = 3.15 \approx 3.2\ ng/g$
- Log-normal distribution
  - $\frac{2.0}{\exp(-k \cdot u_{rel})} = \frac{2.0}{0.56} \approx 3.6\ ng/g$

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Let's look close to the normal and log-normal distributions

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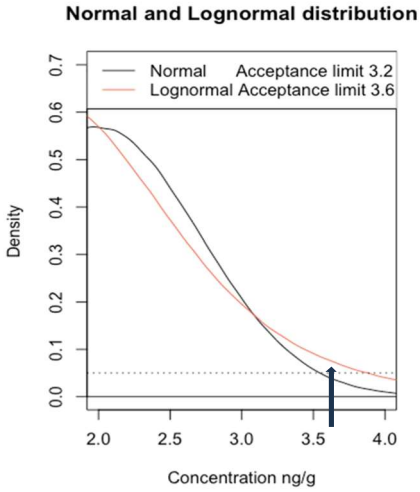
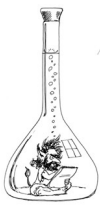
Example – banned substance in a food sample (3) Calculation of acceptance limits





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With a lognormal distribution the
- upper acceptance limit will be higher
- lower acceptance limits will be higher

compared to a normal distribution

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Specific and Global risks in compliance assessment

Specific risk

- The probability of incorrect decisions for a single measured value

Global risk

- The probability of incorrect decisions taken over the whole production over time

Let's look at Global risk

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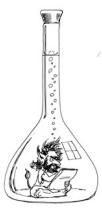
Global risk – ILAC G8

Global Risk

- is the **average probability** that an accepted item is non-conforming, or that a rejected item does conform.
- It does not directly address the probability of false accept to any single item.

NOTE
For global risk we also need to know the process distribution



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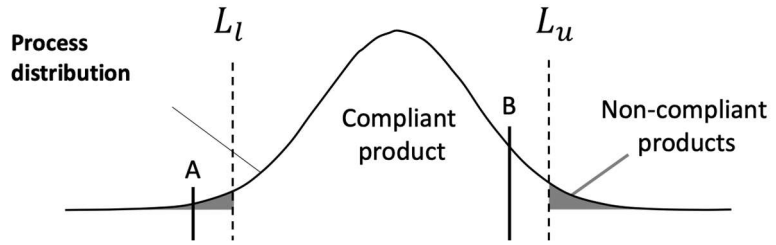
Global risk - process distribution



Item A – outside specification
Item B – within specification

Item B – probability of false rejection with simple acceptance

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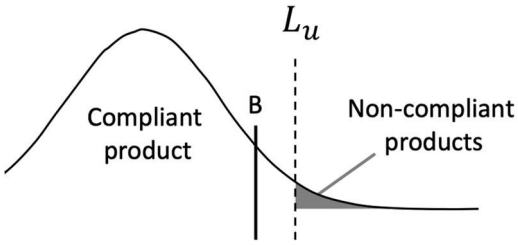
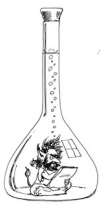
False rejection for a value B within specification





Conclusion
Specific risk Item B – high probability of false rejection
Global risk depends on process distribution and uncertainty.
We need to integrate over all compliant values and calculate the over-all frequency of false rejection – that is the global risk

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Compliance assessment in a testing laboratory

- A testing laboratory normally evaluates the specific risk.
  Only if the process distribution is known a global risk can be evaluated
- Keeping the **uncertainty low** will reduce both the specific and global risk – **important for a producer or a regulator**
- Low uncertainty?
  - At least a Test Uncertainty Ratio (TUR) of 3
  - TUR = Tolerance /U
  - For Ni in steel the TUR is 5
    - Specification 16 – 18 % Ni. Tolerance TL is ± 1 % Ni
    - U = 0.2 %

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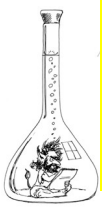
Summary
Risks in compliance assessment

Specific risk

- Probability of incorrect decisions for single item
- Decision rules
  - Simple acceptance
  - Focus on correct acceptance
  - Focus on correct rejection

Globa risk

- Probability of incorrect decisions over time for e.g. the whole production



A testing lab can only evaluate the specific risk using a decision rule.
Important to consider expanded uncertainty, *U*.
For a given Tolerance Limit (TL) the **Test Uncertainty Ratio**
TUR = TL/U should be at least > 3.
Ex limit = 100 ± 3, U =1 then TUR = 3

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Thanks for listening – looking forward to ?

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