DECISION RULES FOR STATING THE CONFORMITY OF THE RESULTS:

In the **'Customer Panel'**, the customer can choose from among the following rules:

1. **Simple acceptance rule acc. to ILAC-G8/2019**
2. **Rule acc. to SANTE/12682/2019** (for pesticide residue testing)
3. **Rule acc. to ILAC G8:03/2009**
4. **Other rules that will be indicated in the offer and order** (required by applicable standards, legal acts, specified by the ordering party, etc.).

If the customer does not select any of the rules or if the legal regulations do not define a specific conformity rule, the simple acceptance rule is adopted (1.) for all parameters and (2.) for pesticide residue testing.

The risks associated with the choice of a decision rule:

SIMPLE ACCEPTANCE RULE ACC. TO ILAC-G8/2019 (binary rule):

- the measurement result is **compliant** if the measured value is below the tolerance limit.

The risk of false accept is **up to 50%** for results close to the tolerance limit.

- the measurement result is **non-compliant** if the measured value exceeds the tolerance limit.

The **risk** of false reject is **up to 50%** for results close to the tolerance limit.

RULE ACC. TO SANTE/12682/2019 (binary rule):

- the measurement result is **compliant** if the measured value, considering measurement uncertainty (at the confidence level of 95%), does not exceed the tolerance limit.

The risk of false accept is **up to 50%** for results (measured values) close to the acceptance limit or **over 50%** for measured values above the tolerance limit.

- the measurement result is **non-compliant** if the measured value, considering measurement uncertainty (at the confidence level of 95%), exceeds the tolerance limit.

RULE ACC. TO ILAC G8:03/2009 (non-binary rule):

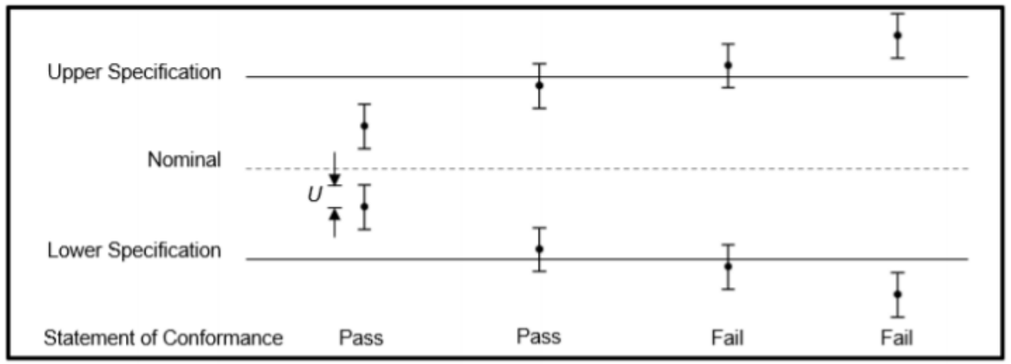
- the measurement result is **compliant** if the measured value increased by expanded uncertainty (at the confidence level of 95%) does not exceed the tolerance limit. **The risk** of false accept is **up to 2.5%** for results close to the tolerance limit.
- the measurement result is **indeterminate** if the result of measurement increased/decreased by expanded uncertainty (at the confidence level of 95%) is within the tolerance limit.
- the measurement result is **non-compliant** if the measured value reduced by expanded uncertainty (at the confidence level of 95%) exceeds the tolerance limit. The **risk** of false reject is **up to 2.5%** for results close to the tolerance limit.

Where the decision rule is prescribed by the customer or is described in regulations (e.g. by a regulator) or in relevant normative documents, it is not necessary for the laboratory to consider the level of risk. In such cases, the laboratory follows the specified decision rule and refers to it when making conformity statements in the test report.

BINARY DECISION RULES

1. Simple acceptance rule acc. to ILAC G8:09/2019

A decision rule where the acceptance limit is the same as the tolerance/specification limit (i.e. AL.=TL.).



U = 95% expanded measurement uncertainty

Fig. 1. Graphical representation of a binary statement - Simple Acceptance – acc. to ILAC-G8:09/2019
„Guidelines on decision rules and statements of conformity."

CONFORMITY STATEMENT ISSUED AS:

PASS (compliant) - the test result is below the acceptance/tolerance limit, AL.=TL.
The risk of false accept is up to 50% for results close to the tolerance limit.
FAIL (non-compliant) – the test result is above the acceptance/tolerance limit, AL.=TL.
The risk of false reject is up to 50% for results close to the tolerance limit.

APPLICATION:
The decision rule applied when deciding on compliance/non-compliance of **the results of all tests** with specified requirements/specifications.

2. Decision rule acc. to SANTE/12682/2019

A decision rule where the acceptance limit is the same as the tolerance/specification limit (i.e. AL.=TL.).

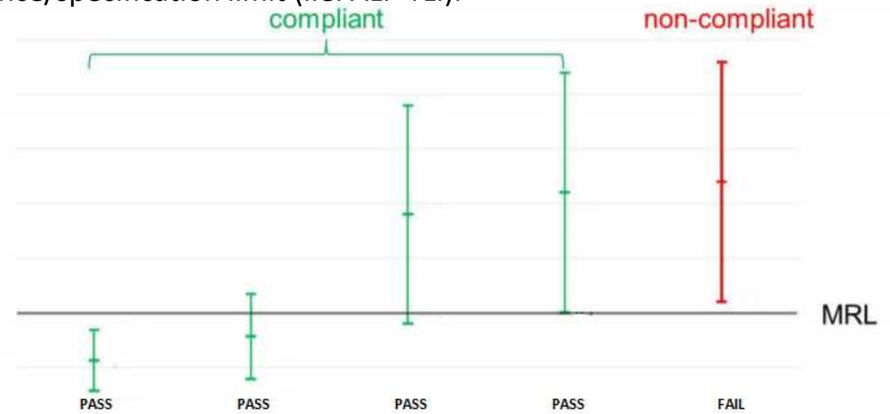


Fig. 2. Graphical representation of a binary decision rule – acc. to SANTE/12682/2019
„Analytical quality control and method validation procedures for pesticide residues analysis in food and feed"

CONFORMITY STATEMENT ISSUED AS:

PASS (compliant) - the test result does not exceed the maximum residue levels indicated in the requirement, or exceeds the MRL by a value lower than or equal to expanded uncertainty.
The risk of false accept is up to 50% for results (measured values) close to the acceptance limit or over 50% for measured values above the tolerance limit.
FAIL (non-compliant) - the test result exceeds the MRL, indicated in the requirement, by more than by the value of expanded uncertainty.

APPLICATION:
The decision rule applied when deciding on compliance/non-compliance of **pesticide residues results** with specified requirements/specifications.

NON-BINARY DECISION RULES

3. Decision rule acc. to ILAC G8:03/2009

comparison of the result, taking the determined measurement uncertainty into account, with the specified requirements.

CONFORMITY STATEMENT ISSUED AS:

PASS (compliant) - the measurement result increased/decreased by 95% expanded measurement uncertainty does not exceed the specification limit.

Indeterminate - the measurement result increased/decreased by 95% expanded measurement uncertainty falls within the limit. Neither compliance nor non-compliance can be stated.

FAIL (non-compliant) - the measurement result reduced by 95% expanded measurement uncertainty exceeds the specification limit.

APPLICATION:

The decision rule used when deciding on compliance/non-compliance of **the results of all tests** with specified requirements/specifications.

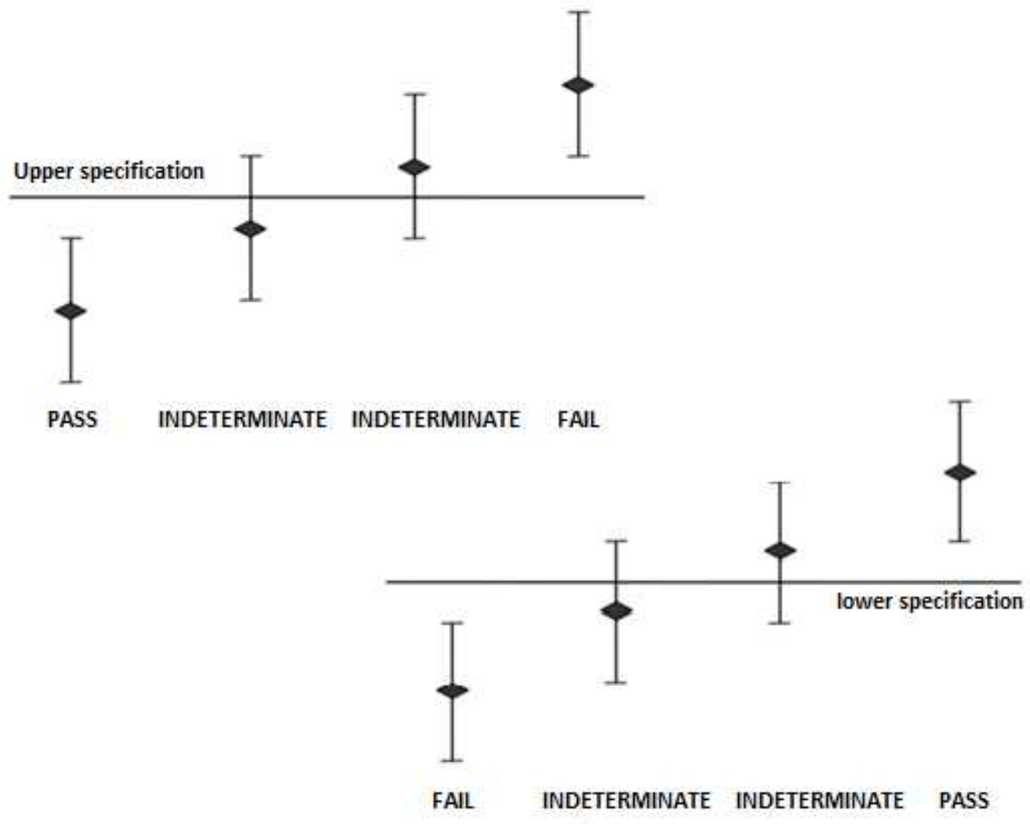


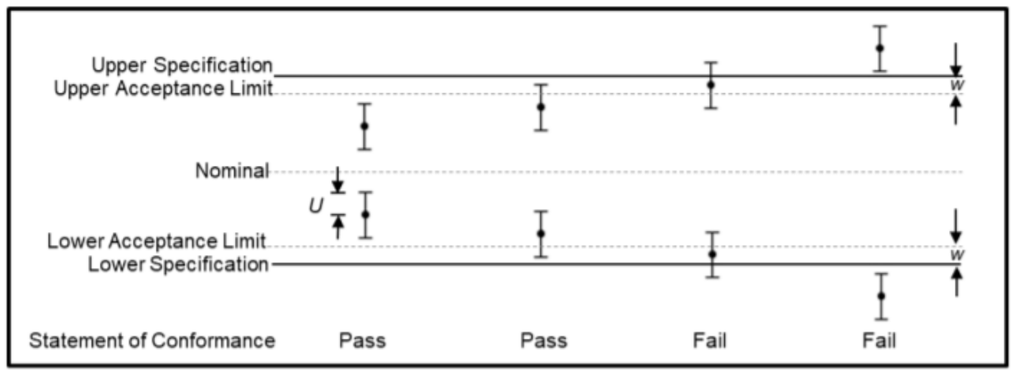
Fig. 3. Graphical representation of a decision rule acc. to ILAC-G8:03/2009 „Guidelines on the Reporting of Compliance with Specification"

other rules propositions:

DECISION RULES WITH GUARD BANDS

These rules use the so-called guard band to determine the acceptance interval and the rejection interval.
The guard band (w) (w≠0) is the tolerance/specification limit (TL) minus the acceptance limit (AL) i.e. w = TL - AL .

Binary rule with guard bands acc. to ILAC G8:09/2019



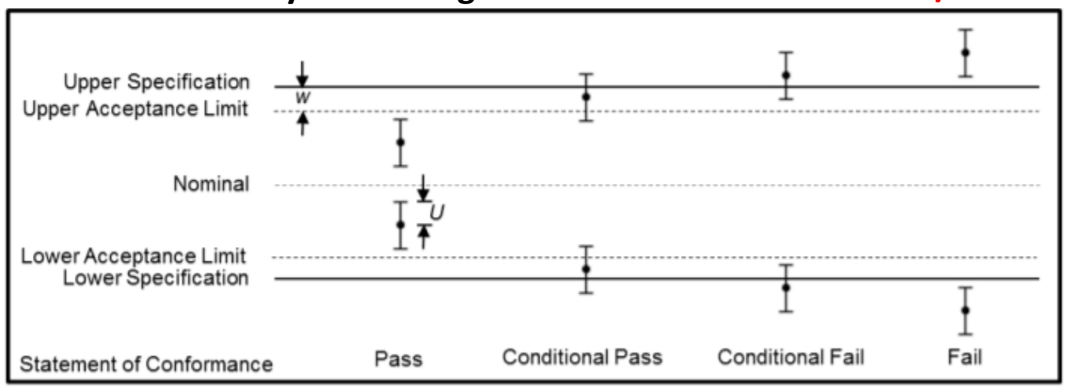
U = 95% expanded measurement uncertainty

Fig.4. Graphical representation of a binary statement with guard bands – acc. to ILAC-G8:09/2019 „Guidelines on decision rules and statements of conformity."

CONFORMITY STATEMENT ISSUED AS:

PASS (compliant) - acceptance based on the guard band; if the measurement result is below the acceptance limit, AL=TL - w. The risk of false accept is less than 2.5%.
FAIL (non-compliant) - rejection based on the guard band; if the measurement result exceeds the acceptance limit, AL = TL - w. The risk of false reject is less than 2.5%.

Non-binary rule with guard bands acc. to ILAC G8:09/2019



U = 95% expanded measurement uncertainty

Fig. 5. Graphical representation of a non-binary statement with guard bands – acc. to ILAC-G8:09/2019 „Guidelines on decision rules and statements of conformity."

CONFORMITY STATEMENT ISSUED AS:

PASS (compliant) - the measured result is below the acceptance limit, AL = TL - w. The risk of false accept is 2.5%.
Conditional pass - the measured result is within the guard band and below the tolerance limit, within the range (TL - w, TL). The risk of false accept is up to 50%.
Conditional fail - the measured result exceeds the tolerance limit but is below the tolerance limit added to the guard band, within the range (TL, TL + w). The risk of false reject is up to 50%.
FAIL (non-compliant) - the measured result is above the tolerance limit added to the guard band (TL + w). The risk of false reject is 2.5%.

APPLICATION OF BOTH RULES:
The decision rule used when deciding on compliance/non-compliance of **the results of all tests** with specified requirements/specification.