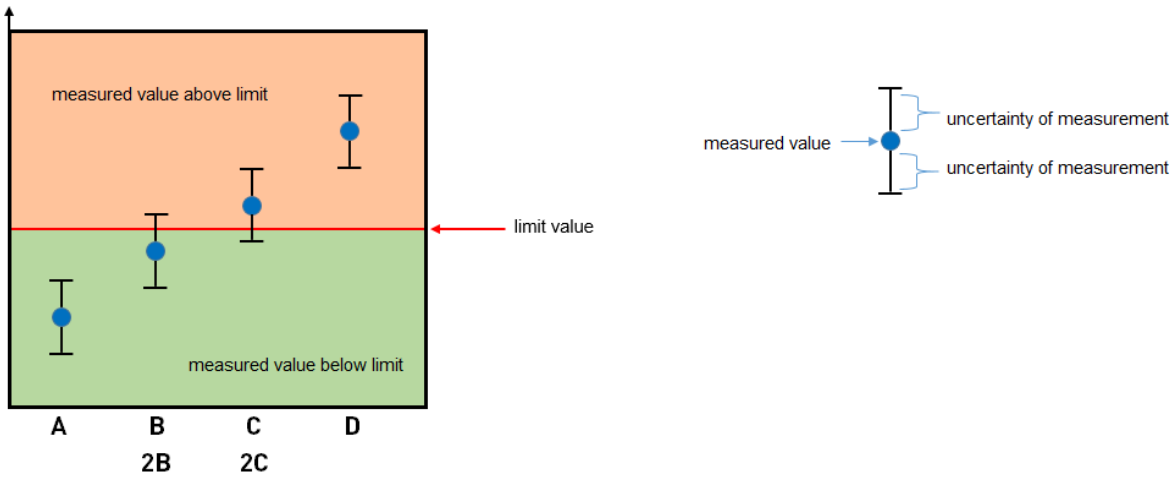
Information for customers on the decision rule for food and cosmetics.

Dear customer,

If you have agreed on the assessment of results obtained in the tests to verify conformity with specified requirements, due account will be taken of the specifications set out in DIN EN ISO 17025:2018 (*Allgemeine Anforderungen an die Kompetenz von Prüf- und Kalibrierlaboratorien - General requirements for the competence of testing and calibration laboratories*).

A distinction is made between 4 different cases:



1. Decision rule <u>excluding</u> measurement uncertainty:

If a regulation or specification stipulates that the measurement uncertainty is not to be taken into account, or that the measurement uncertainty has already been factored in when calculating the requirement (threshold), then the relevant procedure is to apply the decision rule without taking the measurement uncertainty into account. The only process which takes place is to compare the threshold limits with the result of the analysis or the mean value of the results of the analysis. The risk of a wrong assessment in cases B and C is approximately the same as the measurement uncertainty.

This results in the following evaluations:

Cases A and B: compliant. The threshold is observed.

Cases C and D: non-compliant. The threshold is not observed.

2. Decision rule <u>including</u> measurement uncertainty:

Unless specified or agreed otherwise, the expanded measurement uncertainty of k=2 and a confidence level of approximately 95% will be taken as a basis. The risk of a wrong assessment in cases B and C will then be about 5%.

According to the decision rule, this will result in the following evaluations:

Case A: compliant.
The threshold is observed. The measurement result is below the threshold even when the measurement uncertainty is taken into account.

Case 2B: not reliably compliant.
The measurement result is below the threshold and, from a statistical point of view, it can also be above the threshold after addition of the expanded measurement uncertainty (confidence interval 95%).

Note: When applying this risk-based decision rule, the result is classified as not reliably compliant because the result including the measurement uncertainty tends to be below the threshold from a statistical point of view. A residual risk of an incorrect compliant evaluation is accepted.

Case 2C: not reliably compliant.
The measurement result is above the threshold but, from a statistical point of view, it can also be below the threshold after subtraction of the expanded measurement uncertainty (confidence interval 95%).

Note: When applying this risk-based decision rule, the result is classified as not reliably compliant because the result including the measurement uncertainty can also be below the threshold from a statistical point of view. The risk of an incorrect compliant evaluation is only accepted if the relevant regulatory authority also applies this rule, for example, or an agreement has been made with the customer to this effect.

Case D: non-compliant.
The threshold is not observed. The measurement result is above the threshold even when the measurement uncertainty is taken into account.

Notwithstanding the cases outlined above, decision rules can also be based on customer requirements as specified in writing. Please contact us.

We will only issue an assessment of the results or a statement on conformity in our test reports if instructed to do so in writing.