1. PURPOSE AND SCOPE

This instruction is intended to specify how measurement uncertainties for the results are generated and validated for a particular method, ensuring that identified critical influencing factors are under control and indicating how they should be reported.

2. RESPONSIBLES

Activities	Responsibles	Info
Creating the Decision Rule	-Quality Management Unit -Laboratory Unit Supervisor -Technical Staff	Laboratory Manager
Evaluation of the Decision Rule	-Laboratory Unit Supervisor -Technical Staff	Laboratory Manager

3. DEFINITIONS AND ABBREVIATIONS

Decision Rule: A rule that describes how measurement uncertainty is to be taken into account when stating compliance with a specified requirement.

4. APPLICATIONS

In our laboratory, the decision rule is applied in quantitative analyses where measurement uncertainty is calculated. When a customer requests a compliance statement for the analysis based on a specification or standard (such as pass/fail, within tolerance/ out of tolerance), the specification or standard and decision rule must be clearly defined. In the implementation of the decision rule, regulations and official documents for work conducted with official authorities are taken into consideration. If there are legal regulations regarding the application in special requests from the customer, information on this should be provided.

If the selected decision rule is not already included in the requested specification or standard, the customer should be notified, and an agreement should be reached with the customer on this matter. When a compliance statement is provided according to the specification or standard, the report specifies on which results the applied decision rule is based and which specification/standards were applied. If a compliance statement is included in the report, it explicitly states which coverage probability for extended uncertainty is used, for example, stating, "The compliance statement is based on a 95% coverage probability for extended uncertainty."

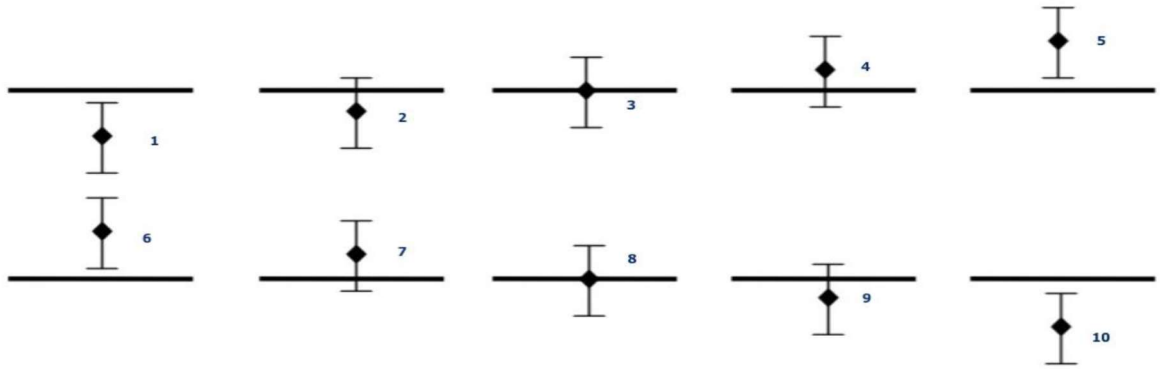
The decision rule is agreed upon with the customer when it is established, and the customer is informed. Deviations requested by the customer should not compromise the integrity of the laboratory or the validity of the results. Evaluation according to the decision rule is carried out by the Laboratory Unit Manager and Analyst under the knowledge of the Laboratory Manager.

When a compliance statement is provided according to a specification or standard based on customer requests, the applied decision rule and the risk level of the relevant rule (such as false acceptance, false rejection, and statistical assumptions) should be considered according to the **P805 Risk and Opportunity Management Procedure**.

4.1. Decision Rule Application

When analysis is performed according to a specified requirement, and the customer or requirement mandates a declaration of conformity, an explanation is given in the report content indicating whether the analysis results comply with this specified requirement. It is stated in the laboratory report content that the results to which the declaration of conformity is applied, according to which requirement a conformity assessment is made, and what the decision rule is if it is not included in the specification or standard. There are several possible situations in which uncertainty affects the declaration of compliance, and these are set out below:

Figure 1. Situations Related to the Decision Rule



Measurement result by the agreed upon method

Uncertainty range by agreed upon method

Case 1: The measured result is below the upper limit even when extended upward by half the uncertainty range. The product complies with the specification.

Case 2: The measured result is below the upper limit by less than half of the uncertainty range; therefore, it is not possible to state availability. However, if a level of confidence below 95% is acceptable, it may be possible to indicate compliance.

Case 3: The measured result is just above the limit; therefore, it is not possible to indicate compliance or non-compliance at any significant confidence level. However, if it is necessary to make a decision regardless of the level of confidence: If the requirement is that the measured value ≤ the upper limit, it may be possible to state a conformity. If the required measured value < upper limit, it may be possible to indicate a non-compliance.

Case 4: The measured result is above the upper limit by less than half of the uncertainty range; Therefore, it is not possible to state non-compliance. However, if a confidence level below 95% is acceptable, it may be possible to indicate non-compliance.

Case 5: The measured result is beyond the upper limit, even if the uncertainty range is extended downwards by half. Therefore, the product does not conform to specification.

Case 6: The measured result is above the lower limit even when extended downward by half the uncertainty interval. Therefore, the product complies with the specification.

Case 7: The measured result is above the lower limit by less than half of the uncertainty range; therefore, it is not possible to state availability. However, if a level of confidence below 95% is acceptable, it may be possible to indicate compliance.

Case 8: The measured result is just above the limit; therefore, it is not possible to indicate compliance or non-compliance at any significant confidence level. However, if it is necessary to make a decision regardless of the level of confidence: If the requirement is that the measured value ≥ the lower limit, it may be possible to state a conformity. If the requirement is the measured value > upper limit, it may be possible to indicate a mismatch.

Case 9: The measured result is below the lower limit by less than half of the uncertainty range; Therefore, it is not possible to state non-compliance. However, if a confidence level below 95% is acceptable, it may be possible to indicate non-compliance.

Case 10: The measured result is beyond the lower limit, even if the uncertainty range is extended upward by half the uncertainty range. Therefore, the product does not conform to specification.

When applying the decision rule, evaluation is made according to the following groups.

- If there is a definition in the legal legislation regarding the application of the decision rule,
- Situations where there is a limit regarding the parameter in the legislation or product standards, but the application of the decision rule cannot be defined,

- The Laboratory Unit Supervisor monitors the implementation of the legal legislation. Among these;
- In nitrate analysis; After correcting the measurement result with recovery, the result obtained by subtracting the measurement uncertainty (k=2 95%) can be compared with the limit value.
- In pesticide analysis; The result obtained by subtracting the measurement uncertainty from the measurement result can be compared with the limit value.
- If there is information about the decision limit (CCα) and the interpretation of the analytical result in the legislation, the decision limit (CCα) is calculated according to the formula below and the measurement result is evaluated according to the decision limit.
  $CC\alpha = MRL + 1{,}64 \times s_R$ (%95 *In the Confidence Interval*)
- In cases where a limit exists but there is no instruction regarding the application of the decision rule, and a special request customer requests a declaration of conformity, the measurement uncertainty (k=2 95%) is compared with the limit by adding or subtracting the measurement result, depending on whether the limit is minimum or maximum.
- If conformity notification is required in the relevant legislation or standard, but no information is given about the effects of measurement uncertainty in the conformity assessment, the limit is compared with the result obtained without taking into account the measurement uncertainty in the conformity assessment.
- If the legal requirements require a decision regarding rejection or acceptance, the situation in Figure 1 can be stated as compliance with specification limit 2 (with a lower level of confidence calculated and reported). Case 4 in Figure 1 non-conformity to specification can be indicated (with a lower calculated and reported confidence level).
- If the product or test standard requires a declaration of conformity in the laboratory report. However, if the relevant standards do not provide any information regarding the effects of confidence level and measurement uncertainty in the assessment of conformity, the laboratory may evaluate conformity or non-compliance based solely on whether the test result obtained is within the specified limits, without taking into account the confidence level and measurement uncertainty.
- If legal requirements require notification of an assessment of conformity or non-compliance, regardless of the level of confidence, the notification must be made according to the limit specified by the legislation:
- If the limit is defined as "<" or ">" and the test result is equal to the limit, non-compliance is indicated,
- If the limit is defined as "≤" or "≥" and the test result is equal to the limit, compliance is indicated.

4.2. Decision Rule Application in Official Samples

Evaluations of import and export samples are made in accordance with the regulations published by the Turkish Ministry of Agriculture and Forestry. If a declaration of conformity according to another standard or specification specified by the customer is not requested, the evaluation is made by using the measurement uncertainty, if any, in favor of the food business operator, as specified in the Sampling Procedure of the General Directorate of Food and Control.

5. RELATED DOCUMENTS

- General Conditions for TS EN ISO / IEC 17025 Testing and Calibration Laboratory
- TÜRKAK Food Laboratories Decision Rule Information Guide
- Guidance on ILAC-G8 Declaration of Conformity to Specification
- P701 Request, Offer and Contracts Review Procedure
- F02-P701.EN ANALYSIS CONTRACT FORM

6. REVISIONS

Revision Number	Date	Revisioned Article	Reason for Revision
01	03.02.2025	-	Laboratuvarımızın Adı ANTALYA VELTIA ÖZEL GIDA KONTROL LABORATUVARI, ticari unvanı VELTIA LABORATUVAR VE DANIŞMANLIK HİZMETLERI A. Ş.- ANTALYA ŞUBESİ ve Şirket Logosu değiştirilerek revize edildi.

Prepared by	Controlling by	Approved by
Tayfun ÇAYLAK Quality Management Unit Responsible	**Tayfun ÇAYLAK Quality Management Unit Responsible**	**Ersin Göksel YELBOĞA Laboratory Manager**