VALIDATION OF METHODS

In the absence of analytical methods in the legal texts CEN and/or ISO should be used.

If other methods are used, methods should be validated (EN ISO 16140).

VALIDATION OF METHODS

The laboratory shall validate:

- **non-standard methods**
- **laboratory-developed methods**
- **standard methods used outside their intended scope or otherwise modified**

The validation shall be as extensive as necessary to meet the needs of the given application or field of application.

Validation can include procedures for sampling, handling and transportation of tests or calibration items using reference standards, methods, or materials.

The techniques used for method validation can be one or a combination of:

- **calibration or evaluation of bias and precision**
- **systematic assessment of the factors influencing the result**
- **testing method robustness through variation of controlled parameters**
- **comparison of results achieved with other validated methods**
- **interlaboratory comparisons**
- **evaluation of measurement uncertainty of the results**

This publication was funded by the European Union. Its contents are the sole responsibility of the NSF Euro Consultants Consortium and do not necessarily reflect the views of the European Union.

EU FOOD SAFETY
AB GIDA GÜVENLİĞİ

RECORDS OF VALIDATION

- the validation procedure used
- specification of the requirements
- determination of the performance characteristics of the method
- a statement on the validity of the method, detailing its fitness for the intended use

QUALITATIVE MICROBIOLOGICAL METHODS

(detected/not detected and confirmation and identification procedures)

- Specificity
- Sensitivity
- Relative trueness
- Positive deviation
- Negative deviation
- Repeatability
- Reproducibility
- Limit of detection
- Matrix effect

QUANTITATIVE MICROBIOLOGICAL METHODS

- Specificity
- Sensitivity
- Relative trueness
- Positive deviation
- Negative deviation
- Repeatability
- Reproducibility
- Limit of quantification