FOOD CONTACT CENTER

Dear Customers,

Food Contact Center clarifies in the supply conditions the policy relating to the formulation of conformity statements and the interpretation of measurement uncertainty associated with analytical data:

Conformity assessments are provided upon request by the Customer. The conformity assessment refers to current legislation (or to limits provided by the Customer in the case of specifications). In formulating the assessment, measurement uncertainty is not applied to the result when a tolerance is also associated with the reference limits (e.g., overall migration).
As a general rule regarding measurement uncertainty, the Laboratory operates a comparison between pure numbers.

Further details on measurement uncertainty are reported in the Test Reports:
For chemical parameters, the values of expanded uncertainty refer to a confidence interval of 95%, with a coverage factor k=2.

The Laboratory Quality Manual states:
The Test Report describes the measurement uncertainty indicated for the various tests, upon request by the Customer, expressed as expanded uncertainty in the same units of measure as the test result, with a declaration of the confidence level and coverage factor used. Uncertainty is always included if the result is close to the legal limit or is relevant to the validity or use of the test reports.
(The result, as required by the Italian National Institute of Health, is expressed with the same number of significant figures as the legal limit).

In formulating the assessment, measurement uncertainty is not applied to the result when a tolerance is also associated with the reference limits (e.g., overall migration).

In the Test Reports, the Laboratory clearly indicates conformity in such a way that it clearly identifies:

- to which results the conformity refers;
- which specifications, standards, or parts thereof are met or not met;
- the decision rule applied (unless it is already contained in the requested standard or specification).

As of today, the Laboratory issues a Declaration of Conformity/Non-Conformity only upon request of the customer, following the specifications below:

- if specific decision rules are included in the relevant standard, these will be used for the evaluation of conformity of the result;
- if the Customer requests a declaration of conformity with a decision rule that describes how measurement uncertainty is taken into account when declaring conformity to a specific requirement, this will be defined during the contractual phase;
- in the absence of standards or specific requests from the Customer, the Laboratory may issue conformity assessments, if requested by the Customer, based on the test result without taking uncertainty into account, directly comparing the result with the reference value. In this case, based on risk analysis and assuming that the estimate of the measurand has a normal probability distribution, the risk of false acceptance or false rejection is up to 50%.

The Laboratory is aware of the different interpretations on this matter, and of what is suggested in document ILAC G8:09/2019 *Guidelines on Decision Rules and Statements of Conformity*, in the subsequent Accredia DT-10, and in ISPRA guideline 52/2009.

The latter document, consistent with the criteria reported in the later ILAC and Accredia documents, states:

Measurement uncertainty, calculated in accordance with the general principles of UNI-13005:2000, represents the interval, determined with a confidence level of about 95%, within which the "true value" of the characteristic of interest lies, while the measurement result constitutes the best estimate of this value. It can therefore be stated that, beyond any reasonable doubt, the "true value" of the characteristic of interest is included within the interval defined by the uncertainty associated with the measurement result.

When reference standards or measurement users do not indicate decision rules, a probabilistic criterion must be used for conformity assessment, which considers the Measurement Result (R) non-conforming when it exceeds the Limit Value (VL) with a probability greater than 95%. In other words, the sample is non-conforming to the VL when the measurement result exceeds the VL beyond any reasonable doubt, i.e., taking into account the measurement uncertainty (U), estimated at a 95% confidence level.

It may be useful to review and discuss the figure below, which is constructed in an analogy to Fig. 1 of ILAC G8:03/2009 (8).
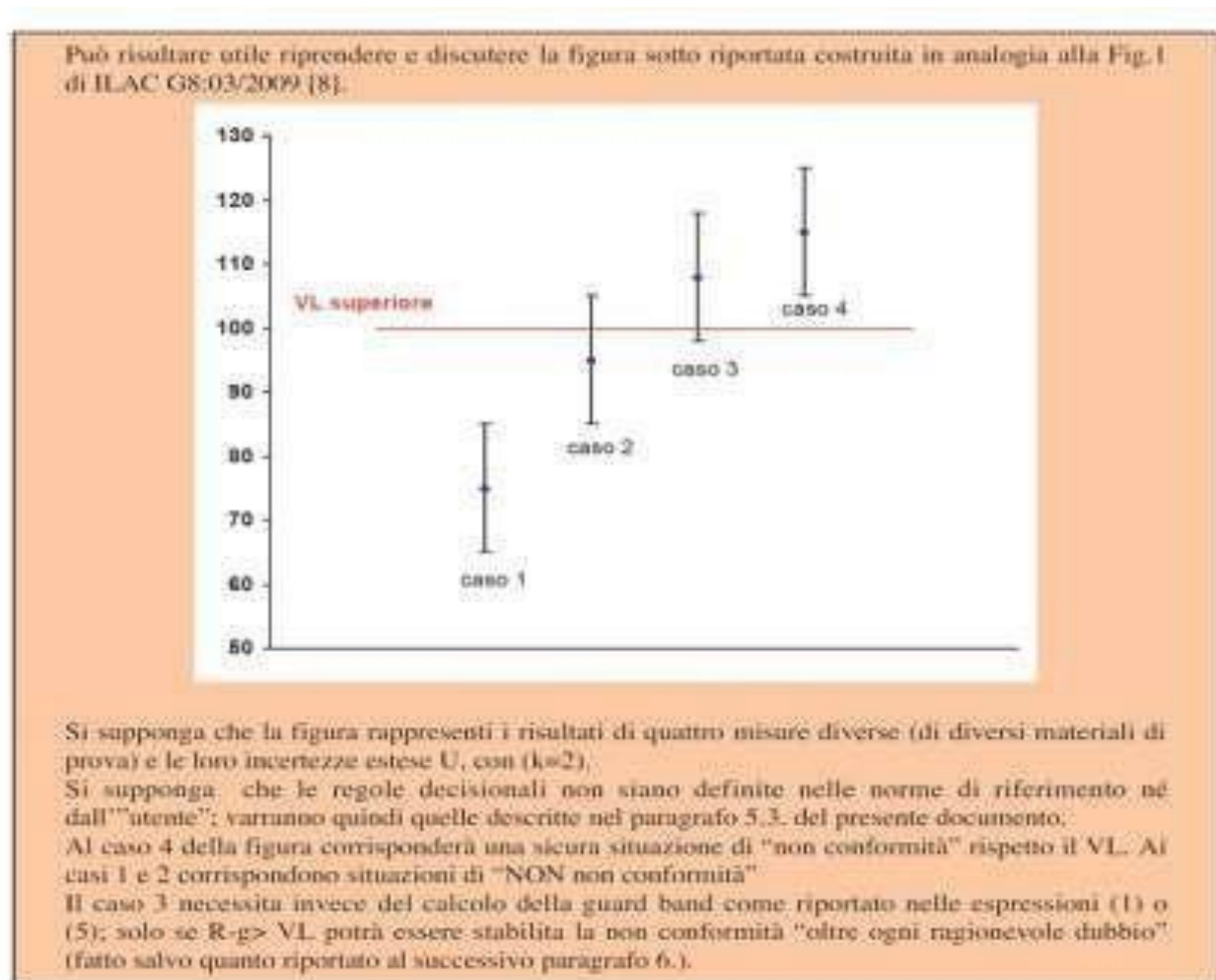
Assume that the figure represents the results of four different measurements (of different test materials) and their expanded uncertainties U, with (k=2). Assume that the decision rules are not defined in the reference standards or by the user: therefore, those described in paragraph 5.3. of this document will apply. Case 4 in the figure will correspond to a certain situation of "non-conformity" with respect to the VL (limit value). Cases 1 and 2 correspond to situations of "NOT non-conformity". Case 3, on the other hand, requires the calculation of the guard band as reported in expressions (1) or (5); only if R-g > VL can non-conformity be established "beyond any reasonable doubt" (subject to what is reported in the subsequent paragraph 6.).

As shown in the example in the image, only case 4 constitutes a NON-CONFORMITY.

Technical Director