PERFORMANCE EVALUATION CRITERIA

Confirmatory and screening analyses:

In confirmatory analysis, the compounds are separated by chromatographic techniques (GC, HPLC, UPLC, LC...); afterwards they are detected by MS, FLD, DAD, etc...
In screening analysis, participants use techniques as ELISA, RIA, lateral flow, microbiological assay, etc...

Elaboration of laboratory data

In the statistical data processing, all the data submitted by the participants are elaborated considering two decimal places. In case there are not declared decimal places, they are considered as corresponding to "zero" (E.g. 25=25,00 - 25,3=25,30 - 25,32=25,32).
Concerning the use of decimal places, we advise you to consult document EA4/16, point 7.6.

The Assigned Value x_{pt}:

The Assigned Value x_{pt}, is the value attributed to a particular property of proficiency test items (definition from ISO 13528).
In the routine, the results from the confirmatory analysis (chromatographic techniques) are considered a reference; they are used with legal purpose (as regulatory requirement). Instead, screening methods have the purpose to analyse in a short time a wide quantity of samples; in case of "positive" results, the data will be verified through the use of chromatographic techniques.
Because of above described, the Assigned Value x_{pt} derives just from participants' quantitative results obtained with confirmatory analysis. The screening results are compared to the Assigned Value x_{pt} obtained from the confirmatory data.
The procedure for determining the Assigned Value x_{pt} is described below.
After excluding results that are identified as invalid the data population is checked for normality and for the presence of outliers by applying appropriate statistics and visual presentations. For both spiked and incurred test materials, x_{pt} represents the value of concentration obtained from Algorithm A (ISO 13528) or from the median. The chosen value will be reported in the Final Report.
The value is not assigned when $p < 8$, where “p” is the number of data after invalid results rejection.

In case of “blank” test materials, the threshold above which the analyte should not be present is based on the capability of participants to determine the analyte. The statistical “mode” is chosen as the estimator, if there are several modes, the greater one is chosen as the estimator.

The standard uncertainty of the assigned value $u(x_{pt})$

The standard uncertainty $u(x_{pt})$ is calculated as:

$$u(x_{pt}) = s^* / \sqrt{p}$$

where:

- s^* is the robust estimate of the participant standard deviation;
- p is the number of participants.

In case of not negligible effects of inhomogeneity and instability, if $0.1 < [u(x_{pt})]^2/\sigma_{pt}^2 \leq 0.5$, the standard uncertainty is expanded by the factor 1,25

$$u(x_{pt}) = 1{,}25\ [s^* / \sqrt{p}]$$

In case of median as estimator, the standard deviation is calculated as s* = MADe (where MADe is the Median Absolute Deviation).

When the standard uncertainty is too high, the assigned value could be inaccurate. Therefore:

- In case $[u(x_{pt})]^2/\sigma_{pt}^2 > 0.5$, the consensus value is not determined and individual laboratory performance scores are not reported. Summary statistics are provided only for information.
- In case $0.1 < [u(x_{pt})]^2/\sigma_{pt}^2 \leq 0.5$, the uncertainty is not negligible. The effects of uncertainty are introduced in the calculation of the z-score (that will be calculated as z'-score). The standard uncertainty $u(x_{pt})$ is expanded by factor 1.25 only in case inhomogeneity and instability effects are not negligible.

It may happen that only few participants confirm the presence of some analytes in the test materials. In such cases, the presence of an analyte is considered:
- "unconfirmed", when less than 25 % of participants detect the compound;
- "confirmed", when 25% of participants, or more, detect the compound (the minimum number of positive results is anyway three).

z-score, z'-score and σ_{pt} (standard deviation for proficiency assessment):
When the number of confirmatory quantitative data is $p \geq 8$, the participant's result (confirmatory and screening) are converted into a z-score according to the equation:

$$\text{z-score} = (x_i - x_{pt}) / \sigma_{pt}$$

where:
- x_i is the analyte concentration value reported by the laboratory;
- x_{pt} is the assigned value (obtained with confirmatory methods);
- σ_{pt} is the standard deviation for proficiency assessment calculated from b x_{pt}.
- b = %RSD / 100, (RSD = Relative Standard Deviation)
- the %RSD value comes from the Horwitz equation (Horwitz, W., 1988, Pure Appl. Chem. 60, 855-864)

$$\%RSD = 2^{(1-0.5 \log Xpt)}$$

where x_{pt} is expressed as a dimensionless concentration.

σ_{pt} is related to the concentration of the analyte: it comes from Horwitz equation (unless otherwise specified); in case of contamination less than 10 ppb the Thompson equation modified Horwitz equation (Thompson, M., 2000, Analyst 125, 385-386). In particular circumstance σ_{pt} is chosen from Proficiency Test provider's (PTp) experience, derived from previous rounds. The adopted criteria is reported in the Final Report.

If $0.1 < [u(x_{pt})]^2/\sigma_{pt}^2 \leq 0.5$, participant's result are converted into a z'-score according to the equation:

$$\text{z'-score} = (x_i - x_{pt}) / \sqrt{\sigma^2_{pt} + u^2(x_{pt})}$$

where:
- x_i is the analyte concentration value reported by the laboratory;
- x_{pt} is the assigned value (obtained with confirmatory methods);
- σ_{pt} is the standard deviation for proficiency assessment calculated from b x_{pt}
- $u(x_{pt})$ is the standard uncertainty as previously described.

In case of z'-score, the assigned value will be given in *italics* when the uncertainty is not negligible, with underlined font where inhomogeneity and instability effects are not negligible.

The laboratory performance evaluation was established taking into account the following criteria for z-score and z'-score:

- when $|z| \leq 2$ acceptable (satisfactory)
- when $2 < |z| \leq 3$ warning signal (questionable)
- when $|z| > 3$ action signal (unsatisfactory)

Screening assessment

Participants who use screening methods, have to provide qualitative answer (detected/not detected). If they are able, they have to indicate in addition "less than..." or "greater than...".
The results are classified as "satisfactory" in the following cases:

- The laboratory detects the analyte or the group of analytes that are effectively present in the test material.
- The laboratory does not detect the analyte or the group of analytes that are not effectively present in the sample.

The results are classified as "unsatisfactory" in the following case:

- The laboratory does not detect the analyte or the group of analytes that is/are effectively present in the sample, but according to the method specifications the analyte/analytes is/are detectable. It means that a false negative has been reported.

The results are classified as "questionable" in the following case:

- The laboratory detects an analyte or a group of analytes that were not effectively present in the sample. It means that false positive has been detected. The false positive results are not considered unsuitable, because routine screening positive results should be confirmed by chromatographic methods.

The results are classified as "congruent" in the following case:

- The laboratory does not detect the analyte that is effectively present, as its method does not allow it. This is an information concerning the capability of the method. The participant should take into consideration if his method has the appropriate capability in respect of his requirement.

The results are not classified, therefore "not applicable" in the following case:

- The laboratory detects the analyte or a group of analytes that were not effectively present in the sample, but the level detected is lower than declared value. In this case it is not possible to evaluate its results.
- The laboratory does not detect the analyte that is effectively present, but his capability corresponds exactly to the assigned value.

Because of the different country legislations, the regulatory limits are not considered in the results evaluation.

When no assigned value is provided because the statistical analysis does not allow to reach the consensus, but the presence of the molecule is confirmed, there will be a note informing screening laboratories that has to be considered a good performance when the laboratory detects a present molecule.

Because of the different country legislations, the regulatory limits are not considered in the results evaluation.

Example of evaluation.

TEST MATERIAL CONTAMINATION	RESULT (PROVIDED BY PARTICIPANT)	EVALUATION	Z-SCORE
Contamined material (the analyte is present above or below the regulatory limit) Assigned Value X_{pt} = 6 ppb (from confirmatory methods)	detected	satisfactory	not provided
	detected = 5 ppb or detected = 7 ppb	satisfactory	provided
	detected > 5 ppb or detected > 7 ppb	satisfactory	not provided
	not detected	unsatisfactory	not provided
	not detected < 5 ppb	unsatisfactory	not provided
	not detected < 7 ppb	congruent	not provided
	not detected < 6 ppb	not applicable	not provided
Blank material Value < 6 ppb (from confirmatory methods)	not detected	satisfactory	not provided
	not detected < 7ppb or not detected < 5ppb	satisfactory	not provided
	detected	questionable	not provided
	detected > 5 ppb or detected > 7 ppb	questionable	not provided
	detected = 6 ppb or detected = 7 ppb	questionable	not provided
	detected = 5 ppb	not applicable	not provided