



# PROFICIENCY TESTS

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## PROTOCOL

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This booklet gives information about the design of proficiency tests offered by BIPEA. For any further information, please feel free to contact us: +33140052630 / [contact@bipea.org](mailto:contact@bipea.org) / [www.bipea.org](http://www.bipea.org)

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## BIPEA PRESENTATION

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Created in 1970, BIPEA is a non-profit organization that provides proficiency testing programs in different fields including grains, food, the environment, cosmetics, hygiene, and the pharmaceutical industry.

## GENERAL INFORMATION ABOUT PROFICIENCY TESTING PROGRAMS

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### Proficiency test definition (EN ISO/CEI 17043)

Evaluation of a participant's performance against pre-established criteria through interlaboratory comparisons.

### Interlaboratory comparisons definition (EN ISO/CEI 17043)

Organization, execution and evaluation of measurements or tests on the same or similar entities by two or more laboratories under predetermined conditions.

### Proficiency testing's benefits

By taking part in a proficiency test, the laboratory gets an assessment of its performance that contributes to improve customer's confidence and identify problems within the laboratory.

It may also allow the determination of test / measurement methods' effectiveness and comparability, the uncertainties validation, staff training...

### Standards

EN ISO/CEI 17043 « Conformity assessment – General requirements for proficiency testing »

EN ISO 9001 « Quality system management – Requirements »

ISO 13528 « Statistical methods for use in proficiency testing by interlaboratory comparisons »

EN ISO 5725 « Accuracy (trueness and precision) of measurement methods and results »

### Proficiency testing program

BIPEA offers proficiency testing programs that are annual programs composed by several rounds including a wide range of matrices.

These annual programs allow:

- Laboratories to get an evaluation of their performances in order to monitor themselves on the long run and highlight bias or drifts.
- BIPEA to enhance quality control performances through a range of three to thirty rounds depending on the program chosen

Proficiency testing schemes' schedules are available on BIPEA.

Laboratories can follow the delivery dates, analyses to be conducted, deadlines of data transmission and publication of interlaboratories testing reports.

## ORGANIZATION OF A PROFICIENCY TESTING

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### Proficiency testing scheme

A proficiency test is determined by the following steps:

- Laboratories' registration,
- Shipment of the samples,
- Homogeneity and stability control of the samples,
- Dispatching of test materials,
- Report results and information,
- Statistical analysis of results with and estimation of assigned value,
- Evaluation of laboratory performance,
- Publication of the report for all participants.

### Coordination and responsibility

#### Coordinator

For each proficiency testing scheme, a technical advisor (from BIPEA staff) is in charge of the coordination of the tests. He especially assists the chairperson and guarantees the compliance with the requirements of ISO / IEC 17043 standard.

#### Chairperson (of commission)

For each proficiency testing scheme, a chairperson is elected by the participants. He/She provides a specific technical competence the proficiency testing's program.

The missions of the chairperson are:

- bringing his/her technical expertise in the proficiency testing scheme
- approving the results of the statistical analysis before publication of the report
- approving the minutes and the annual report of the scheme which are prepared by BIPEA

The chairperson is the privileged discussion partner between BIPEA and the participants. He/She remains responsible for collecting potential new requests and needs.

#### Technical groups

President can rely on a technical group composed of some participants to help him/her in his mission.

#### Technical management board

The Technical Management Board is composed of technical experts:

- Chairpersons of each proficiency testing scheme,
- Scientific advisors,
- Members appointed for their expertise in specific areas.

The Technical Management Board is the advisory body of BIPEA (technical) Management. It is consulted for:

- The creation of a new proficiency testing scheme,
- The design of the general statistical model,
- Technical issues,
- New market development,
- Strategic focus.

The Technical Management Board meets at least once a year.

### Subcontracting

BIPEA uses subcontractors for carrying out homogeneity and stability control. These analysis are performed by laboratories accredited according to ISO/IEC 17025 standard (when possible). If a subcontractor participate in a proficiency testing scheme, it will be treated the same way as the other participants.

By performing all other steps of the proficiency test, BIPEA ensure a continuous improvement of its proficiency testing schemes.

## COMMUNICATION WITH PARTICIPANTS

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### Registration

All laboratories performing physical, chemical, microbiological or sensory analyses can be interested in BIPEA interlaboratory proficiency tests.

Our policy is based on the analysis of the performance of the laboratories over time. The laboratories register at the beginning of the series to all the scheduled rounds. When the registration is made during the year, the laboratory is registered for all the remaining rounds of the annual series.

### Participation fees

The participation fees include:

- Annual fee, including membership fees for new members. Our non-profit status leads us to solicit a financial participation from the members to support administrative charges.
- Price of the proficiency testing program.

The terms and conditions are available on BIPEA's website ([link](#)).

### Confidentiality

A coding system allows BIPEA to ensure the confidentiality of the information provided by the participants and the anonymity of participants. A commitment of confidentiality is signed by all of BIPEA's staff and by external partners (technical experts).

All information concerning members remains confidential, both in terms of content and source, except for relevant legal requirements.

Where BIPEA is required by law, or authorized by contractual provisions, to disclose confidential information, the member or customer concerned is notified of the information provided, unless prohibited by law.

#### Confidentiality of participants

A "laboratory number" is assigned to each laboratory upon enrolment. This code is permanent and allows rapid identification.

BIPEA does not publish any directory of its members, nor list of participants in its proficiency testing program.

#### Confidentiality of participants' data

Identification of the results published in the interlaboratory comparisons report is ensured by a 4-digit-code randomly allocated to each of the participants: this code is named "edition code". It is confidential and temporary: it is changed every year at the beginning of each annual series.

### Claims.

If participants have any concerns, please contact us by email at:

- [contact@bipea.org](mailto:contact@bipea.org)
- [statistiques@bipea.org](mailto:statistiques@bipea.org) requests related to interlaboratory comparison reports
- [scientifique@bipea.org](mailto:scientifique@bipea.org)
- [sales@bipea.org](mailto:sales@bipea.org).

Claims are treated according to an internal procedure. The principal steps are as follows:

1. Acknowledge and register the claim;
2. Evaluate the claim;
3. Provide feedback to the laboratory;
4. Open a nonconformity if the claim is substantiated.

Appropriate corrective actions are then implemented and communicated to the concerned laboratory.

### Contact

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## PROFICIENCY TEST DESIGN

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### Choice of raw material

The products used in the proficiency tests are selected to be as close as possible to real matrices analysed by laboratories on routine bases. Raw materials can be commercial products or not, used as they are or modified, spiked or processed.

### Samples' production

Samples' production is adapted and depends on:

- The nature of the concerned product (liquid, powder, grains and granulated product, meat, fish, etc.)
- The needed characteristics.

The characteristics can be naturally present, added or spiked to reach the levels required by the participants. For homogeneity and stability reasons, the samples can be synthetic matrices.

Equipment and process used are specific to each proficiency test. They enable to obtain:

- Samples produced according to industrialised, reproducible and robust process, with limited human intervention.
- Sufficient homogeneity Between-samples to meet the requirements of the test.
- Sufficient stability of the samples for the duration and the target of the test

The principle of the sample production used for each test is indicated in the interlaboratory comparisons report.

### Homogeneity and Stability control

Homogeneity and stability testing will be conducted according to the EN ISO 13528 standard. Once the homogeneity and stability are fulfilled to meet the requirements of the test, the samples are sent to the laboratories. For technical or logistical reasons, homogeneity checks can be carried out simultaneously or after sending the samples.

Homogeneity and stability checking's conclusion are indicated in the interlaboratory comparisons report.

Nature and frequency of these checking depend on the testing programs.

They are determined by the coordinator, according to:

- The knowledge (bibliography, experimental studies, experts' advises, etc.),
- Experimental studies during the implementation of new proficiency tests,
- The results of the previous tests,
- The annual frequency of the proficiency tests.

An assessment of the homogeneity and stability results is performed after each test, by the examination of the results distribution compared to the characteristics of the samples or according to the date of analysis given by the laboratory, and by the observed standard deviations.

### Packaging and shipping

The samples are packed to ensure their integrity, and so that their characteristics do not evolve regarding the aim of the test. Some samples are shipped at monitored temperature (refrigerated or frozen parcels).

All shipments are made by express carrier. For laboratories outside Europe, shipments can be anticipated so that expected times of samples' delivery are the same as European laboratories.

### Analyses and methods

Once the shipment is done, participants can consult on BIPEA's website, in their member area, the instructions explaining how to manage the samples.

The analyses to be performed are also available. The laboratories choose analyses and methods for which they want to check their proficiency. The samples must be analysed according to the usual procedures applied in the laboratory.

#### Laboratories result's transmission

The laboratories enter their results on BIPEA's secured member area within results' submission deadline frame. Specific passwords are given to the laboratories upon registration, to be used either to enter the results, or to validate them. "INPUT" password can be communicated to all operators. "VALID" password must only be used by authorized staff to validate laboratory's results.

Even when results are already transmitted to BIPEA, they can be modified before the deadline: in order to do so you have to repeat the whole result transmission procedure. To confirm the safe submission of the results, a transmission code is sent to the laboratory, if any doubt this code prevails. The progress of result submission can be checked at any time on the member area, they will appear either as "free", "in progress" or "transmitted".

If the results are not transmitted, one or two alerts are sent to the laboratory two to five days before the deadline of results submission.

Beyond the deadline, the results cannot be entered into the member area anymore.

## DATA ANALYSIS AND PERFORMANCE ASSESSMENT

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The aim of BIPEA's interlaboratory comparisons is to enable the laboratory to control the trueness of its analysis results. This control is carried out through the comparison with an assigned value.

The statistical treatment is performed according to ISO 13528 standard "Statistical methods for use in proficiency testing by interlaboratory comparisons".

The way to estimate the assigned value and the tolerance is defined and validated by the technical group of each proficiency testing scheme.

### Assigned value

The assigned value or "conventionally true value" (X) corresponds to the value assigned to an analytical parameter for the proficiency test. This value is either:

- determined before the test,
  - using values which come from the formulation
  - using a value which comes from measurements on national standard device for which metrological traceability is established
- estimated at the end of the test, using consensus values which come,
  - either from the results of a group of well-known and controlled participating laboratories (the selection criteria are determined by the specialized Commission),
  - either from the results of all the participating laboratories

The selected estimator is the mean value coming from the application of the robust algorithm A of ISO 13528 standard. This assigned value is provided with its standard uncertainty which allows to quantify the confidence that can be granted to this assigned value. If another estimator is used, it is then indicated in the corresponding interlaboratory comparison report.

In any case, the robust mean value is compared with other estimators such as median or mode.

If less than eight results are used to estimate the assigned value, this one is provided for indicative purpose only. The assessment of the trueness must therefore be carefully taken into account due the low number of values.

If the number of results is less than four, no assigned value is estimated.

For quantitative results in microbiology, a logarithmic transformation (log10) of the analytical results is carried out and all the statistical calculations are performed with transformed data.

### Performance criteria

#### Tolerance value determination

The assessment of the trueness of a result is carried out through the use of a tolerance value (VT):

- determined before the test. It could be:
  - a prescription value or a regulatory value,
  - a performance aim of the participants,
  - a value from the reproducibility standard deviation of the standardized analytical method,
  - a value from the standard deviation of the results of the participants during a round of a proficiency test.
- estimated at the end of the test, using the observed dispersion:
  - either from the results of a group of well-known and controlled participating laboratories (the selection criteria are determined by the specialized Commission),
  - either from the results of all the participating laboratories.

In general, the selected tolerance value is a performance objective defined before the test by the technical group and known by the participants before the test. It is often coming from the standard deviations of the results of the participants observed during previous cycles of proficiency tests. By default, the tolerance value is twice the standard deviation of the results of the considered test.

Half of the tolerance value chosen by the technical Commission gives the standard deviation for proficiency assessment according to ISO 13528 standard.

$$\sigma_{pt} = \frac{VT}{2}$$

For each analytical parameter, the defined tolerance value is written in the interlaboratory comparisons report.

### Statistical assessment

The performance assessment is performed by positioning the participants' results in relation to numerical limits. It is preferably expressed in the unit of the measurand in order to link the performance evaluation directly to the measurement error.

The cases below are applied to quantitative variables.

To assess the proficiency of the laboratories, the tolerance value is used to define an interval around the assigned value. Inside this interval [assigned value  $\pm$  tolerance value], by convention, a measurement or test result ( $x$ ) is considered as true and laboratories proficiency as acceptable.

#### z-score

The z-score is calculated using the assigned value ( $x_{pt}$ ) and half of the tolerance value ( $VT/2$ ). A z-score with an absolute value above 2.0 is considered as a warning signal; a z-score with an absolute value above 3.0 is considered as an action signal.

$$z = \frac{(x - x_{pt})}{(\frac{VT}{2})}$$

The z-score expresses the result of the laboratory ( $x$ ) as a number without unit.

#### zeta-score

The  $\zeta$ -score is calculated using the assigned value, the standard uncertainty of the assigned value and the standard uncertainty of the laboratory. The  $\zeta$ -score can be used in the same way as the z-score with the limit values of 2.0 and 3.0.

$$\zeta = \frac{x - x_{pt}}{\sqrt{u_x^2 + u_{x_{pt}}^2}}$$

The  $\zeta$ -score is calculated only if the following conditions are fully satisfied:

- the assigned value is estimated independently from the results of the proficiency test,
- the uncertainty of the result provided by the participant is properly mastered by the laboratories.

#### z'-score

The z' score is calculated using the assigned value, the standard uncertainty of the assigned value and the standard deviation for proficiency assessment. The z' score can be interpreted using the same critical values 2.0 and 3.0 as for the z-score.

$$z' = \frac{x - x_{pt}}{\sqrt{\sigma_{pt}^2 + u_{x_{pt}}^2}}$$

The z' score is applied after verification of the condition for limiting the standard uncertainty on the assigned value and its consequences and is transposed in the Bipea proficiency tests in the form of an enlargement of the tolerance value ( $VT'$ ).

### Qualitative data

In the case of qualitative data, the evaluation of performance is carried out in the form of comments or recommendations available in RCIL. For some cases of binary qualitative variables for which several series of samples of different levels are sent, the evaluation is carried out by comparing the individual

relative specificity ( $r_{SP}$ ), relative sensitivity ( $r_{SE}$ ) and relative accuracy ( $r_{AC}$ ) to the limits set by the Technical Commission.

### Uncertainty evaluation

In a proficiency testing scheme, the uncertainty claimed by the laboratories can be asked for a specific proficiency test. Two informative indicators, calculated from the expanded uncertainty of the assigned value ( $U_{xpt}$ ) and the standard deviation of the results of the participants ( $s^*$ ), allow each participant to place its uncertainties in regards of:

- a minimum value,  $\text{Min } U_x = U_{xpt} (k = 2)$
- a maximum value,  $\text{Max } U_x = 3 \times s^* (k = 2)$ .

If the uncertainty of the laboratory is outside the borders defined above, the laboratory is invited to check the value or the estimation of its uncertainty. However, an uncertainty below the minimum or above the maximum can remain correct.

## REPORTS

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### Interlaboratory comparisons report

The interlaboratory comparisons report is published, as soon as possible, after the results' transmission deadline. However a certain time period is needed as different steps must be carried out to produce the report:

- Studying of the data to remove obvious errors,
- Performing a statistical treatment,
- Checking of the proficiency tests by the coordinator
- Approval by the by the technical group which is represented by the chairman of the proficiency testing scheme,
- Authorization of publication by the statistical department.

Additional information related to the set-up of the tests as well as the results and the comments provided by the participants are mentioned in the reports:

- histograms, for quantitative continuous variables
- sector diagrams for qualitative variables,
- other graphs if needed.

The interlaboratory comparisons report is sent by email to all the participants as an Adobe PDF file. It can be sent to two different email addresses for each participant

### Customized report

A customized report, with the results of the concerned laboratory and the main statistical data of the test can be downloaded from the member area, using the passwords « input » or « valid ». This report is available as soon as the interlaboratory comparisons report is published.

With this report, the laboratory can view quickly, in one or two pages, all its results and the corresponding assessments for the concerned test.

### Data downloads

At the end of the proficiency test, all laboratory's data is available in the member area and can be downloaded in a .csv file. This download can be done for a customized selection of tests (with several years backup) and analytical parameters.

This downloads include the results of the laboratory and the main statistical data

### Annual report

Every year, for a considered proficiency testing scheme, an annual report is carried out by the coordinator after consultation of the technical group. This report provides an overview of the tests over several years.

The report is approved by the chairman of the proficiency testing scheme and sent to all the participants.■