GENERAL PROTOCOL for EU Proficiency Tests on Pesticide Residues in Food and Feed (General EUPT-Protocol)

Introduction

This protocol contains general procedures valid for all European Union Proficiency Tests (EUPTs) organised on behalf of the European Commission, DG-SANCO\(^1\) by the four European Union Reference Laboratories (EURLs) responsible for pesticide residues in food and feed. These EUPTs are directed at laboratories belonging to the Network\(^2\) of National Reference Laboratories (NRLs) and Official Laboratories (OfLs) of the EU Member States. Official labs from EFTA countries and EU-Candidate countries are also welcome to participate in the EUPTs. Laboratories from Third countries may be permitted to participate on a case-by-case basis after consultation with DG-SANCO.

The following four EURLs for pesticide residues were appointed by DG-SANCO based on regulation 882/2004/EC\(^3\):

- EURL for Fruits and Vegetables (EURL-FV),
- EURL for Cereals and Feedingstuffs (EURL-CF),
- EURL for Food of Animal Origin and Commodities with High Fat Content (EURL-AO) and
- EURL for pesticides requiring Single Residue Methods (EURL-SRM)

NRLs are appointed at Member State level, based on the provisions of Regulation 882/2004/EC, whereas OfLs are laboratories that are actively involved in official control of pesticide residues in food or feed in the sense of Regulation 882/2004/EC or Regulation 396/2005/EC. This includes labs involved in control within the framework of national and/or EU-controlled programmes as well as labs involved in import controls according to Regulation 669/2009/EC.

\(^1\) DG-SANCO = European Commission, Health and Consumer Protection Directorate-General

\(^2\) For more information about the EURL/NRL/OfL-Network please refer to the EURL-Web-portal under: http://www.eurl-pesticides.eu

\(^3\) Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. Published at OJ of the EU L191 of 28.05.2004
According to Article 28 (3) of Regulation 396/2005/EC⁴, all laboratories analysing samples for the official control of pesticide residues are obliged to participate in Proficiency Test(s) organised by the European Union.

The aim of these EUPTs is to obtain information regarding the quality, accuracy and comparability of pesticide residue data in food and feed reported to the European Union within the framework of the national control programmes and the co-ordinated multiannual community control programme⁵. Participating laboratories will be provided with an assessment of their analytical performance that they can use to demonstrate their analytical performance and compare themselves with other participating laboratories.

**EUPT-Organizers and External Consultants**

EUPTs are organised by individual EURLs or by more than one EURL in joint collaboration.

An **Organising Team** is appointed from the EURL(s) in charge. This team is responsible for all administrative and technical matters concerning the organisation of the PT, e.g. PT-announcement; production of Test Item and Blank Item; undertaking of homogeneity and stability tests; packing and shipment of the Test Item, handling and evaluation of the results and method information submitted by the participants and the drafting of the preliminary and general reports.

To complement the internal expertise of the EURLs a group of external consultants named **EUPT-Scientific Committee** (EUPT-SC)⁶ has been established and approved by DG SANCO. The EUPT-SC consists of expert scientists with long-term experience in PTs and/or pesticide residue analysis. The actual composition of the EUPT-SC, the affiliation of each member and the topics each member is consulted are listed in the EURL-Website. They will also be listed in the Specific Protocol and the Final Report of each EUPT.

The EUPT-SC is made up of the following two subgroups:

a) **An independent Quality Control Group** (EUPT-QCG) and

b) **An Advisory Group** (EUPT-AG),

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⁶ Link to the List of current members of the EUPT Scientific Committee:
The EUPT-SC’s role is to help the organisers make decisions regarding the EUPT design: the selection of the commodity; the selection of pesticides to be included in the Target Pesticide List (see below); the establishment of the Minimum Required Reporting Levels (MRRLs); the evaluation and statistical treatment of the results (in anonymous form); and the drafting of documents such as the General and Specific PT Protocols and the Final EUPT-Reports.

The EUPT-QCG has the additional function of supervising the quality of EUPTs and of assisting the EURLs in confidential aspects such as the choice of the pesticides to be present in the Test Item and the concentrations at which they should be present in the Test Item.

The EUPT-SC typically meets once a year, after the EUPTs of all four pesticide EURLs have been conducted, to discuss the evaluation of the EUPT-results and consult the EURLs in their decisions. Upcoming EUPTs are also planned during these meetings.

The EUPT-Organising Team and the EUPT-SC together form the EUPT-Panel.

The decisions of the EUPT-Panel will be documented.

The present EUPT General Protocol was jointly drafted by the EUPT-SC and the EURLs and was approved by DG-SANCO.

**EUPT Participants**

Within the European Union all NRLs operating in the same area as the organising EURL as well as all OfLs whose scope overlaps with that of the EUPT are legally obliged to participate in EUPTs. The four EURLs will annually issue and distribute via the EURL-website a joint list of all OfLs that must participate in each of the EUPTs to be conducted within a given year. This “List of Obliged Labs” is to be considered as tentative as it is based only on information submitted by OfLs concerning their commodity scope and status. The legal obligation of NRLs and OfLs to participate in EUPTs arises from:
- Art. 28 of Reg. 396/2005/EC (for all OfLs analyzing for pesticide residues within the framework of official controls in food or feed)

- Art. 33 of Reg. 882/2004/EC (for all NRLs)

If necessary, the “list of obliged labs” can be updated within the same year to take account of any changes in the lab profiles.

NRLs are responsible for checking whether all relevant OfLs within their network are included in the list of obligated laboratories and whether the contact information and commodity-scope is correct.

OfLs are furthermore urged to keep their own profiles within the EURL-DataPool up-to-date, especially their commodity and pesticide scopes and their contact information.

Labs that are obliged to participate in a given EUPT, and that are not intending to participate, must provide the reasons for their non-participation without prejudice of any legal action taken against them for not participating. This also applies to initially participating laboratories that fail to report results.

Confidentiality and Communication

The proprietor of all EUPT data is DG-SANCO and as such has access to all information.

For each EUPT, the laboratories are given a unique code, initially only known to themselves and the Organisers. In the final EUPT-Report, the list of participating laboratories will not be linked to their laboratory codes. It should be noted, however, that the Organisers, at the request of DG-SANCO, may present the EUPT-results on a country-by-country basis. It is therefore possible that a link between codes and laboratories could be made, especially for those countries where only one laboratory has participated. Furthermore, the EURs reserve the right to share EUPT results and codes amongst themselves: for example, for the purpose of evaluating overall lab or country performance as requested by DG-SANCO.

As laid down in Regulation 882/2004, NRLs are responsible for evaluating and improving their own OfL-Network. On request from the NRLs the EURs will provide them with the PT-codes of the participating OfLs belonging to their OfL-Network. This will allow NRLs to follow the participation and performance of the laboratories within their network.

Communication between participating laboratories during the test on matters concerning a PT exercise is not permitted from the start of the PT exercise until the distribution of the preliminary EUPT-report.
For each EUPT the organizing EURL prepares a specific EUPT-Website where all relevant documents in their latest version are linked. The official language used in all EUPTs is English.

Announcement / Invitation Letter

At least 3 months before the Test Item of a given EUPT is distributed to the laboratories the EURLs publish an Announcement/Invitation letter on the EURL-web-portal and distribute it via e-mail to the NRL/OFL mailing list available to the EURLs. This letter contains the commodity to be used as the Test Item, as well as links to the tentative EUPT-Target Pesticide List and the tentative EUPT-Calendar.

Target Pesticide List

This list contains all analytes (pesticides and metabolites) to be sought, along with the Minimum Required Reporting Levels (MRRLs) valid for the specific EUPT. The MRRLs are typically based upon the lowest MRLs found either in Regulation 396/2005/EC or Commission Directive 2006/125/EC (Baby Food Directive).

In some cases, that will be clearly marked, residue definitions in the Target Pesticide List may differ from the legal ones. Labs must express their results as stated in the Target Pesticides List.

Specific Protocol

For each EUPT the organizing EURL will publish a Specific Protocol at least 2 weeks before the Test Item is distributed to the laboratories. The Specific Protocol contains all the information previously included in the Invitation Letter but in its final version, information on payment and delivery, instructions on how to handle the Test Item upon receipt and on how to submit results, as well as other relevant information.

Homogeneity of the Test Item

In order for the Test Item to be suitable for the proficiency test the pesticides contained in it must be uniformly distributed within the bulk Test Item. The variation of the pesticide concentration between the different sub-sample test portions should not significantly impact the performance of the participating labs. To check for homogeneity, two analytical portions, taken from at least ten randomly
chosen units of treated Test Item, are analysed in duplicate. Both, sample preparation and measurements should be conducted in random order.

The homogeneity test data are statistically evaluated according to the International Harmonized Protocols published by ISO and IUPAC.

The acceptance criterion for the Test Items to be sufficiently homogenous for the Proficiency Test is that $s_{sam}^2$ is less than $c$ with $s_{sam}$ being the between-bottle sampling standard deviation and $c = F_1 \times \sigma_{all}^2 + F_2 \times s_{an}^2$. $F_1$ and $F_2$ are constants, with values of 1.88 and 1.01, respectively, if 10 samples are used. $\sigma_{all}^2 = 0.3 \times \text{FFP-RSD (25\%)} \times$ the analytical sampling mean for all pesticides, and $s_{an}$ is the estimate of the analytical standard deviation.

The results of all homogeneity tests are presented to the EUPT-SC. In special cases where the above homogeneity test criteria are not met, the EUPT-SC considering all relevant aspects (e.g. the homogeneity results of other pesticides spiked at the same time, the overall distribution the participants’ results, the analytical difficulties faced during the test, knowledge of the analytical behavior of the pesticide question) may decide to overrule the test. The reasons of this overruling have to be transparently explained in the Final EUPT-Report.

**Stability of the analytes contained in the Test Item**

To make sure that any pesticide losses occurring during the PT at the recommended storage conditions will not significantly impact the performance of the labs a stability test according to ISO 13528, Annex B is conducted by the Organizers. The time delay between the first and the last stability test must exceed the period of the EUPT-exercise. Typically the first analysis is carried out shortly before the shipment of the test Items and the second one shortly after the deadline for submission of results. To better recognize trends and gain additional certainty one or more additional tests may be conducted by the Organizers. At least 6 sub-samples (analytical portions) should be analyzed on each test day (e.g. 2 analytical portions withdrawn from three randomly chosen containers OR 6 portions withdrawn from one container). In principle all pesticides contained in the Test Item should be checked for stability. However, in individual cases where sufficient knowledge exists that the stability of a certain analyte (e.g. inorganic bromide) is very unlikely to be significantly affected during storage (e.g. based on past stability tests or based on knowledge of its physicochemical properties) the Organizers, after consultation with the EUPT-QCG, may decide to omit a specific stability test. The final decision on whether analytes for which the stability test was not undertaken must be included in the final evaluation after consideration of the distribution of results (Qn-RSD) and following consultation with EUPT-SC.
A pesticide is considered to be adequately stable if \(|x_1 - y_i| \leq 0.3 \times \sigma\), where \(x_1\) is the mean value of the first stability test, \(y_i\) the mean value of the last stability test and \(\sigma\) the standard deviation used for proficiency assessment (typically 25% of the assigned value).

The results of all stability tests are presented to the EUPT-SC. In special cases where the above stability test criteria are not met, the EUPT-SC considering all relevant aspects (e.g. the past experience with the stability of the compound, the overall distribution the participants’ results, the analytical difficulties faced during the test, knowledge about the analytical behavior of the pesticide question) may decide to overrule the test. The reasons of this overruling will be transparently explained in the Final EUPT-Report.

The Organizers may also decide to conduct additional stability tests at different storage conditions than those recommended to the participants e.g. at ambient temperature.

Considering knowledge about the expected susceptibility of pesticides in the Test Item to possible losses, the organizers will chose the shipment conditions to be such that pesticide losses are minimized (e.g. shipment of frozen samples, addition of dry ice). As shipment time can differ between labs/countries it is recommended that the organizers conduct additional stability tests at conditions simulating shipment. Should critical losses be detected for certain pesticides EUPT-SC should be informed (or the EUPT-QCG before or during the test). Case-by-case decisions may be taken considering all relevant aspects including the shipment time of the samples to each laboratory.

**Methodologies to be used by the participants**

Participating laboratories are instructed to use the analytical procedure(s) that they would routinely employ in official control activities (monitoring etc.). Where an analytical procedure has not yet been established routinely this should be stated.

**General procedures for reporting results**

Participating laboratories are responsible for reporting their quantitative results to the Organiser within the stipulated deadline. Any pesticide that was targeted by a participating laboratory should be reported as “analysed”. Each laboratory will be able to report only one result for each analyte detected in the Test Item. The concentrations of the pesticides detected should be expressed in ‘mg/kg’ and in some cases in ‘µg/kg fat’ for products of animal origin.

The Test Item is intentionally treated with pesticides whereas the Blank Item is analysed to ensure that it does not contain any of the pesticides in the Target Pesticides List at or above the specified
MRRLs. Both the Test Item and Blank Item have to be analysed by the participating laboratories and any pesticide detected in them must be reported.

**Correction of results for recovery**

According to the Method Validation and Quality Control Procedures for Pesticide Residues Analysis in Food and Feed\(^7\), it is common practice that pesticide analysis results are not corrected for recovery, but may be corrected if the average recovery is significantly different from 100 % (typically if outside the 70 – 120 % range but with good precision). Other approaches for recovery correction explicitly allowed in the SANCO document are the use of isotope labelled analogues of the target analytes as Internal Standards (ISTDs) as well as the approach of ‘standard addition’ with additions of analyte(s) being made to analytical portions. Where reported residue data have been adjusted for recovery, this must be indicated on the specific field of the ‘Result Submission Form’. Laboratories are required to report whether their results were adjusted for recovery and, if a recovery factor was used, the recovery (in percentage) must also be reported. No recovery data are required where correction for recovery results automatically from using the ‘standard addition(s)’ approach, or isotopically-labelled internal standards (in both cases with spiking of the Test Item at the beginning of the extraction procedures). In these cases, the laboratories should report the recovery adjustment approach that was followed.

**Methodology information**

All laboratories are requested to provide information on the analytical method(s) they have used. A compilation of the methodology information submitted by all participants is presented in an Annex of the final report. Where necessary the methods are evaluated and discussed, especially in those cases where the result distribution is not unimodal or very broad (e.g. Qn-RSD>35%). If no sufficient information on the methodology used is provided, the Organiser reserves the right not to accept the analytical results reported by the participants concerned.

**Results evaluation**

The procedures used for the treatment and assessment of results are described below.

\(^7\) Document N° SANCO/12495/2011
- **False Positive results**

These are results of pesticides from the Target Pesticides List, that are reported at or above their respective MRRL although they were: (i) not detected by the Organiser, even after repeated analyses, and/or (ii) not detected by the overwhelming majority (e.g. >95 %) of the participating laboratories that had targeted the specific pesticides. In certain instances, case-by-case decisions by the EUPT-Panel may be necessary.

Any results reported lower than the MRRL will not be considered as false positives, even though these results should not have been reported.

- **False Negative results**

These are results for pesticides reported by the laboratories as 'analysed' but without reporting numerical values although they were a) used by the Organiser to treat the Test Item and b) detected by the Organiser as well as the majority of the participants that had targeted these specific pesticides at or above the respective MRRLs. Results reported as <RL (RL= Reporting Limit of the laboratory) will be considered as not detected and will be judged as false negatives. In certain instances, case-by-case decisions by the EUPT-Panel may be necessary.

In cases of the assigned value being less than a factor of 4 times the MRRL, false negatives will typically not be assigned. The EUPT-Panel may decide to take case-by-case decisions in this respect after considering all relevant factors such as the result distribution and the reporting limits of the affected labs.

- **Estimation of the assigned value (μ)**

The assigned value (= consensus concentration or 'true' concentration) will be typically estimated using the median of all the results after excluding outliers. In special justifiable cases, the EUPT-Panel may decide to eliminate certain results traceably associated with gross errors (see “Omission or Exclusion of results” below) or to use only the results of a subgroup consisting of laboratories that have repeatedly demonstrated good performance for the specific compound in the past.
– **Omission or Exclusion of results**

Before estimating the assigned value, outliers\(^8\) and other results associated with obvious errors have to be removed from the population.

Where the Organizers (e.g. after the publication of the preliminary report) receive information that indicates gross errors, which have a strong impact on the generated result, such as:

a) incorrect recording (e.g. due to transcription errors by the participant, decimal point faults or transposed digits),

b) calculation errors (e.g. missing factors),

c) analysis of a wrong sample,

d) use of wrong concentrations of standard solutions,

e) incorrect data processing (e.g. integration of wrong peak),

f) major deviation from the analytical procedure

g) inappropriate storage or transport conditions (in case of susceptible compounds),

h) use of inappropriate procedures that demonstrably lead to significantly biased results (e.g. due to degradation or incomplete extraction).

Particular results will be examined on a case-by-case basis to decide whether or not they should be excluded from the population used to determine the assigned value. Even results that cannot be specifically identified as outliers might be excluded. All decisions to omit/exclude results will be discussed with the EUPT-SC and the reasoning for the omission of each result clearly stated in the final EUPT-Report. An omission of a result from the calculation of the assigned value does, however, **not** necessarily mean that z-scores will not be calculated.

Where results are to be omitted/excluded based on the use of a biased methodology, the number of results associated with this type of methodology as well as the overall distribution of results (kernel-density histogram) will be taken into account. The Organizers may furthermore conduct experiments demonstrating that a certain methodology leads to significantly biased results.

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\(^8\) Reported results that are numerically so distant from the rest of the results within a dataset, that they are considered irreconcilable with them.
After eliminating obvious errors, all results with z-scores > 5 will be regarded as outliers and excluded from the assigned value calculation. After exclusion of these results, the assigned value of the remaining results and the corresponding z-scores will be recalculated.

Following the omission/exclusion of all values with z-scores > 5 an appropriate outlier test (e.g. the Grubbs' test) may be applied, if this is deemed necessary, to identify any statistical outliers within the remaining data-set. The Grubbs' test should be applied following the instructions in ISO 5725-2 and only where the distribution of the results appears to be Gaussian (no clear indications for bimodality). The significance level (α) for identifying statistical outliers using the Grubbs' test will be set at 0.01 (=99% confidence level). Omitted results might be interesting as they might give indications about possible source(s) of errors. The Organizers will thus ask the relevant lab(s) to provide feedback on possible sources of errors (see also “follow-up activities”).

**Uncertainty of the assigned value**

The uncertainty\(^9\) of the assigned values \(\mu_i\) is calculated as:

\[
\mu_i = 1.25 \times \frac{Q_n SD}{\sqrt{n}}
\]

Where \(Q_n SD\) is the robust standard deviation and \(n\) is the number of results.

In certain cases and considering all relevant factors (e.g. the result distribution, multimodality), the number of submitted results, information regarding analyte homogeneity/stability, information regarding the use of methodologies that might produce a bias by the participants), the EUPT-Panel may consider the assigned value of a specific analyte to be too uncertain and decide that the results should not be evaluated, or only evaluated for informative purposes. The provisions of ISO 13528:2005 concerning the uncertainty of the assigned value will be taken into account.

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**Standard deviation of the assigned value (target standard deviation)**

The target standard deviation (\(\delta\)) of the assigned value will be calculated using a Fit-For-Purpose Relative Standard Deviation (FFP-RSD) approach, as follows:

\[
\delta_i = b \times \mu_i \quad \text{with } b = 0.25 \: (25\% \: \text{FFP-RSD})
\]

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The percentage FFP-RSD is set at 25% based on experience from previous EUPTs\textsuperscript{10}. The EUPT-Panel reserves the right to also employ other approaches on a case-by-case basis considering analytical difficulties and experience gained from previous proficiency tests.

\textbf{z-scores}

This parameter is calculated using the following formula:

\[ z_i = \frac{(x_i - \mu_i)}{\delta_i} \]

Where \( x_i \) is the value reported by the laboratory, \( \mu_i \) the assigned value, and \( \delta_i \) the standard deviation for each pesticide (i).

Any \( z \)-scores > 5 will be reported as “> 5” and a value of “5” will be used to calculate combined \( z \)-scores (see below).

\( z \)-Scores will be interpreted in the following way:

\[
\begin{align*}
|z| & \leq 2 \quad \text{Acceptable} \\
2 < |z| \leq 3 \quad \text{Questionable} \\
|z| > 3 \quad \text{Unacceptable}
\end{align*}
\]

For results considered as false negatives, \( z \)-scores will be calculated using the MRRL or RL (the laboratory’s Reporting Limit) if the RL < MRRL. The EUPT-Panel will decide whether, or not, these values should appear in the \( z \)-score histograms.

\textbf{Category A and B classification}

The EUPT-Panel will decide how to classify the laboratories into two categories - A or B. Currently, laboratories that have detected and quantified a sufficiently high percentage of the pesticides present in the Test Item (e.g. at least 90\%) and reported no false positives will have demonstrated ‘sufficient scope’ and can therefore be classified into Category A. The 90\% criterion will be applied following Table 1.

Table 1. No. of pesticides needed to be detected to have sufficient scope.

<table>
<thead>
<tr>
<th>No. of Pesticides Present in the Test Item (N)</th>
<th>90%</th>
<th>No. of Pesticides needed to be reported to have sufficient scope (n)</th>
<th>n</th>
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<tr>
<td>3</td>
<td>2.7</td>
<td>3</td>
<td>N</td>
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<tr>
<td>4</td>
<td>3.6</td>
<td>4</td>
<td>N - 1</td>
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<tr>
<td>5</td>
<td>4.5</td>
<td>4</td>
<td>N - 2</td>
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<tr>
<td>6</td>
<td>5.4</td>
<td>5</td>
<td>N - 3</td>
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<td>7</td>
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Overall performance of laboratories - combined z-scores

For evaluation of the overall performance of laboratories within Category A, the Average of the Squared z-Score \( (AZ^2) \)^11,12 (see below) will be used. The \( AZ^2 \) is calculated as follows:

\[
AZ^2 = \frac{\sum_{i=1}^{n} Z_i^2}{n}
\]

^11 Formerly named “Sum of squared z-scores (SZ^2)”

Where \( n \) is the number of z-scores to be considered in the calculation. In the calculation of the \( AZ^2 \), z-scores higher than 5 will be set at 5. Based on the \( AZ^2 \) achieved, the laboratories are classified as follows:

\[
\begin{align*}
AZ^2 \leq 2 & \quad \text{Good} \\
2 < AZ^2 \leq 3 & \quad \text{Satisfactory} \\
AZ^2 > 3 & \quad \text{Unsatisfactory}
\end{align*}
\]

Combined z-scores are considered to be of lesser importance than the individual z-scores. The EUPT-Panel retains the right not to calculate \( AZ^2 \) if it is considered as not being useful or if the number of results reported by any participant is considered to be too low.

In the case of EUPT-SRMs, where only a few results per lab may be available, the Average of the Absolute z-scores (AAZ) may be calculated for informative purposes, but only for labs with 5 or more z-scores available. For the calculation of the AAZ, z-scores higher than 5 will be set at 5.

Laboratories within Category B will be ranked according to the total number of pesticides that they correctly reported to be present in the test item. The number of acceptable z-scores achieved will be presented, too. The EURL-Panel retains the right to calculate combined z-scores (see above) also for labs within Category B, e.g. for informative purposes, provided that a minimum number of results (z-scores) are available.

**Publication of results**

The EURIs will publish a preliminary report, containing tentative medians and z-score values for all pesticides present in the Test Item, within 2 months from the deadline for result submission.

The Final EUPT Report will be published after the EUPT-Panel has discussed the results. Taking into account that the EUPT-Panel meets normally only once a year (typically in late summer or autumn) to discuss the results of all EUPTs organised annually by the EURIs in the following year, the final report may be published up to 10 months after the deadline for results submission.

**Certificates of participation**

Together with the Final EUPT-Report, the EURL Organiser will deliver a Certificate of Participation to each participating laboratory including the z-scores achieved for each pesticide and the combined z-scores calculated (if any) as well as the classification into Category A or B.
Feedback

At any time before, during or after the PT participants have the possibility to contact the Organizers and make suggestions or indicate errors. After the distribution of the Final EUPT-Report, participating laboratories will be given the opportunity to give their feedback to the Organisers and make suggestions for future improvements.

Correction of errors

Should errors be discovered in any of the documents issued prior to the EUPT (Calendar, Target Pesticides List, Specific Protocol) the corrected documents will be uploaded onto the website and in the case of substantial errors the participants will be informed. Before starting the exercise participants should make sure to download the latest version of these documents.

If substantial errors are discovered in the Preliminary EUPT-Report the Organizers will distribute a new corrected version, where it will be stated that the previous version is not valid. The existence of a new updated version will also appear on the EUPT-website.

Where substantial errors are discovered in the Final EUPT-Report the EUPT-Panel will decide whether a corrigendum will be issued and how this should look. The online version of the final report will be replaced by the new one and all affected labs will be contacted.

Where errors are discovered in EUPT-Certificates the relevant laboratories will be sent new corrected ones. Where necessary the laboratories will be asked to return the old ones.

Follow-up activities

Laboratories are expected to undertake follow-up activities to trace back the sources of erroneous or (strongly) deviating results - including all false positives and false negatives, along with results with $|z| > 2$.

Upon request, the laboratory’s corresponding NRL and EURL are to be informed of the outcome of any investigative activities for false positives, false negatives and for results with $|z| > 3$. Concerning z-scores between 2 and 3 the communication of the outcome of traceability activities is optional but highly encouraged where the source of deviation could be identified and could be of interest to other labs.
According to instructions from DG-SANCO, the “Protocol for management of underperformance in comparative testing and/or lack of collaboration of National Reference Laboratories (NRLs) with EU Reference Laboratories (EURLs) activities” is to be followed.

Disclaimer

The EUPT-Panel retains the right to change any parts of this EUPT – General Protocol based on new scientific or technical information. Any changes will be communicated in due course.