

# GENERAL PROTOCOL

## for EU Proficiency Tests on Pesticide Residues in Food and Feed

### Introduction

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

The following four EURLs for pesticide residues were appointed by DG-SANTE based on the official controls Regulation (EU) No. 2017/625<sup>3</sup>:

- EURL for Fruits and Vegetables (EURL-FV),
- EURL for Cereals and Feedingstuff (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).

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 EU multiannual co-ordinated control programme<sup>4</sup>. 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.

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<sup>1</sup> DG-SANTE = European Commission, Health and Food Safety Directorate-General

<sup>2</sup> For more information about the EURL/NRL/OfL-Network please refer to the EURL-Web-portal under:  
"<http://www.eurl-pesticides.eu>"

<sup>3</sup> Regulation (EU) 2017/625 of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products.. Published at OJ of the EU L95 of 07.04.2017

<sup>4</sup> European Commission Proficiency Tests for Pesticide Residues in Fruits and Vegetables, Trends in Analytical Chemistry, 2010, 29 (1), 70 – 83.

## EUPT-organisers and Scientific Committee

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

An **Organising Team** (in the following named organisers) is appointed by the EURL(s) in charge. This team is responsible for all administrative and technical matters concerning the organisation of the Proficiency Test (PT), e.g. the PT-announcement, the production of the PT-material (Test Item), the undertaking of homogeneity and stability tests, the packing and shipment of the PT-materials, the handling and evaluation of the results and method information submitted by the participants, the drafting of the preliminary and final reports as well as generation and distribution of EUPT-participation certificates.

To complement the internal expertise of the EURLs, a group of external consultants forming the **EUPT-Scientific Committee** (EUPT-SC)<sup>5</sup> has been established and approved by DG-SANTE. The EUPT-SC consists of expert scientists with many years of experience in PTs and/or pesticide residue analysis. The actual [composition of the EUPT-SC](#) and the affiliation of each of its members is shown on the EURL-Website. The members of the EUPT-SC are also 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).

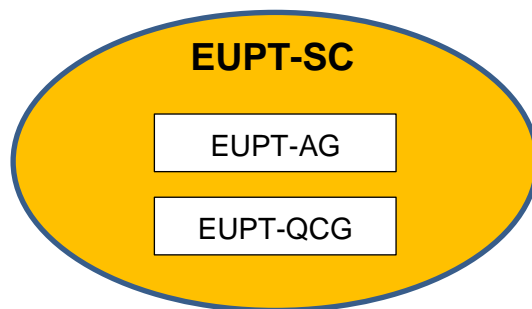
The EUPT-SC's role is to help the organisers make decisions regarding the EUPT design: the selection of the commodity, the selection of the analytes to be included in the Target Pesticide List (see below), the establishment of the Minimum Required Reporting Levels (MRRLs), the statistical treatment and evaluation of the participants' results (in anonymous form), and the drafting and updating 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 analytes to be present in the Test Item and the approximate concentrations at which they should be present.

The EUPT-SC typically meets once a year, after all EUPTs of the season have been conducted and preliminarily evaluated by the four pesticide EURLs. The aim of these meetings is to discuss the EUPT-results, especially where case-by-case decisions are needed. PT plans for the next EUPT season and, if needed, possible changes in the EUPT-General Protocol are also discussed during these meetings. The main topics and decisions on these meetings are documented.

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<sup>5</sup> Link to the List of current members of the EUPT Scientific Committee:  
<http://www.eurl-pesticides.eu/library/docs/allcrl/EUPT-SC.pdf>



*Figure 1: Composition of EUPT-Scientific Committee*

The present EUPT General Protocol (EUPT-GP) was drafted by the EURLs and reviewed by the EUPT-SC. Follow the link to access a website giving an [overview of the GP-versions](#).

### **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 legal obligation of NRLs and OfLs to participate in EUPTs arises from:

- Art 38 (2) of Regulation (EU) No. 2017/625<sup>3</sup> Art. 28 (3) of Reg. (EC) No. 2005/396 (for all OfLs analysing for pesticide residues within the framework of official controls of food or feed<sup>6</sup>)
- Art. 101 (1)(a) of Regulation (EU) No. 2017/625<sup>3</sup> (for all NRLs)

Every year, shortly before launching the registration period of the first of the four EUPTs in a given EUPT-Season, all OfLs and NRLs are asked to update their routine scope of commodities as well their contact information within the EURL-DataPool. Based on this information the OfLs are classified into those that are obliged and those that are eligible participate in each of the EUPTs to be conducted within a given year..

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

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.

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<sup>6</sup> Official controls in the sense of Regulation (EU) 2017/625. This includes labs involved in controls within the framework of national and/or EU programs, as well as labs involved in import controls according to Regulation (EU) 2019/1793 (which repealed Regulation (EC) No. 2009/669).

Labs that are obliged to participate in a given EUPT, and that are not able to participate, must provide the reasons for their non-participation. This also applies to any participating laboratories that fail to report results.

OfLs not paying the EUPT sample delivery fee will be initially warned that their participation in subsequent EUPTs could be denied. In case of a repetitive non-payment, the EUPT organisers will inform the corresponding NRL to take action.

### **Confidentiality and Communication**

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

For each EUPT, the laboratories are given a unique code (lab code), initially only known to themselves and the organisers. In the final EUPT-Report, the names of participating laboratories will not be linked to their laboratory codes. It should be noted, however, that the organisers, at the request by DG-SANTE, may present the EUPT-results on a country-by-country basis. It may therefore be possible that a link between codes and laboratories could be made, especially for those countries where only one laboratory has participated. Furthermore, the EURLs 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-SANTE.

As laid down in Regulation (EU) No. 2017/625<sup>3</sup>, NRLs are responsible for evaluating and improving their own OfL-Network. On request from the NRLs, the EURLs 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 preliminary report distribution.

For each EUPT the organising EURL prepares a specific EUPT-Website where all PT-relevant documents in their latest version are linked. In case of important modifications on any of these documents, the participating laboratories will be informed via e-mail. In any case, as soon as the PT-period starts the participants are encouraged to visit the particular EUPT-Website, to make sure that they are using the latest versions of all PT-relevant documents.

The official language used in all EUPTs is English.

### **Announcement / Invitation Letter**

Approximately 3 months before the distribution of the Test Item the EURLs will 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 will inform about the commodity to be used as 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 for, 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 (EC) No. 2005/396 and Regulation (EU) No. 2016/128 (Baby Food Directive). Labs must express their results as stated in the Target Pesticides List.

## Specific Protocol

For each EUPT the organising EURL will publish a Specific Protocol at least 2 weeks before the Test Item is distributed to the participating laboratories. The Specific Protocol will contain 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 any other relevant information.

## Homogeneity of the Test Item

The Test Item will be tested for homogeneity typically before distribution to participants. The homogeneity tests usually involve analysis of two replicate analytical portions, taken from at least ten randomly chosen units of treated Test Item. Measurements should be conducted in random order. The homogeneity test data are statistically evaluated according to ISO 13528:2022, Annex B<sup>7</sup> or to the International Harmonized Protocols jointly published by ISO, AOAC and IUPAC<sup>8</sup>. 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 analytes spiked at the same time, the overall distribution of the participants' results (CV\*), the analytical difficulties faced during the test, knowledge of the analytical behaviour of the compound in question), may decide to overrule the test. The reasons of this overruling have to be transparently explained in the Final EUPT-Report. For certain analytes with comparable properties, an equivalent distribution within the sample can be expected if they were spiked/used at simultaneously. The homogeneity test, of one or more of these analytes, may thus be skipped or simplified. If, however, the distribution of participants' results for an analyte that was not or not fully tested for homogeneity, is found to be atypically broad, compared to the tested analytes, the EUPT-SC may decide that a homogeneity test should be performed a posteriori.

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<sup>7</sup> ISO 13528:2022: 'Statistical methods for use in proficiency testing by interlaboratory comparisons', International Organization for Standardization.

<sup>8</sup> Thompson M., Ellison S.L.R., Wood R., "The International Harmonized Protocol for the proficiency testing of analytical chemistry laboratories" (IUPAC Technical Report). Pure Appl. Chem. 2006, 78, 145 – 196

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

The Test Items will also be tested for stability - according to ISO 13528:2022, Annex B<sup>7</sup>. 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 last one shortly after the deadline for submission of results. To better recognise trends and gain additional certainty one or more additional tests may be conducted by the organisers. At least 6 sub-samples (analytical portions) should be analysed on each test day (e.g. 2 analytical portions withdrawn from three randomly chosen containers OR 6 portions withdrawn from a single container). In principle, all analytes 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 is very unlikely to be significantly affected during storage (e.g. based on experience from past stability tests or knowledge of its physicochemical properties), the organisers, after consultation with the EUPT-QCG, may decide to omit a specific stability test. The EUPT-SC will finally decide whether analytes for which the stability test was not undertaken will be included in the Final EUPT-Report, considering all relevant aspects such as the distribution of the participant's results (CV\*).

An analyte is considered to be adequately stable if  $|y_i - y| \leq 0.3 \times \sigma_{pt}$ , with  $y_i$  being the mean value of the results of the last phase of the stability test,  $y$  being the mean value of the results of the first phase of the stability test and  $\sigma_{pt}$  being 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 measurement variability, analytical difficulties faced during the test and knowledge about the analytical behaviour of the compound in question) may decide to overrule the test. The reasons of this overruling will be transparently explained in the Final EUPT-Report.

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

**Stability during shipment:** Considering knowledge about the expected susceptibility of analytes in the Test Item to possible losses, the organisers will choose the shipment conditions to be such that analyte losses are minimised (e.g. shipment of frozen samples, addition of dry ice). As shipment-duration can differ between labs/countries it is recommended that the organisers keep track of the shipment duration and then decide whether it is reasonable to conduct additional stability tests at conditions simulating shipment. Should critical losses be detected for certain analytes, the EUPT-SC will be informed (or the EUPT-QCG before or during the test). Case-by-case decisions may be

taken by the EUPT-SC considering all relevant aspects including the duration and conditions of the shipment to the laboratory as well as the feedback by the 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 method has not yet been established routinely this should be stated.

### **General procedures for reporting results**

Participating laboratories are responsible for reporting their own quantitative results to the organiser within the stipulated deadline. Any analyte 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 analytes detected should be expressed in ‘mg/kg’ unless indicated otherwise in the specific protocol. Laboratories should not report results below their reporting limits.

### **Correction of results for bias**

According to the DG-SANTE Guidelines, the result of an analyte needs to be adjusted for method bias if the bias exceeds 20%. Unless a method is used that inherently accounts for method bias (see cases a-c below), laboratories are required to report the recovery (in percent), and whether their results were corrected mathematically using a recovery factor reflecting the reported recovery.

The EUPT-Panel will examine whether results, for which no correction for recovery was undertaken, should be omitted from the population used for calculating the assigned value.

When the laboratory uses any of the following approaches inherently accounting for method bias, this needs to be indicated in the appropriate fields within the Web-Tool. In such cases, reporting of the recovery rate is not mandatory.

- a) use of stable isotope labelled analogues of the target analytes as Internal Standard (ILISs), added to the analytical portion at an early stage of the procedure
- b) ‘procedural calibration’ approach
- c) ‘standard addition’ approach with additions of analyte(s) to the analytical portions before extraction.

## Methodology information

All laboratories are requested to provide information on the analytical method(s) they have used. The Web-Tool, which also serves for submitting analytical results, is typically used for collecting method information.

The collection of method information is considered very important by the EUPT-SC, as it facilitates the interpretation of results and the identification of analytical patterns associated with systematically biased results. A compilation of the methodology information submitted by all participants may be presented in an Annex of the Final EUPT-Report or in a separate report. Where the initial method information provided by the participating laboratories is not sufficient for evaluating methodology-related errors, or where additional information critical for results evaluation is needed, the EURLs and/or the EUPT-Panel may decide to conduct specific follow-up surveys among the concerned laboratories. If no sufficient information on the methodology used is provided, the organisers reserve the right not to accept the analytical results reported by the participants concerned or even refuse participation in the following PT.

Where necessary the methods are evaluated and discussed within the EUPT-SC, especially in those cases where the result distribution is not unimodal or very broad (e.g.  $CV^* > 35\%$ ).

## Results evaluation

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

### – **False Positive (FP) results**

These are results of analytes 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 analytes. In certain instances, case-by-case decisions by the EUPT-SC 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 (FN) results**

These are results for analytes 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 analytes 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-SC may be necessary.

In cases of the assigned value being less than a factor of 3 times the MRRL, false negatives will typically not be assigned. The EUPT-SC may decide to take case-by-case decisions in this respect after considering all relevant factors such as the result distribution and the RLs of the affected labs.

– **Estimation of the assigned value ( $x_{pt}$ )**

To minimise the influence of out-lying results on the statistical evaluation, the assigned value  $x_{pt}$  (= consensus concentration) will typically be estimated using the robust estimate of the participant's mean ( $x^*$ ) as described in ISO 13528:2022<sup>9</sup>, taking into account the results reported by EU and EFTA countries laboratories only. In special justifiable cases, the EUPT-Panel may decide including results submitted by laboratories not belonging to the EU-/EFTA-OfLs network or to even to only use the results of a subgroup of ('expert') laboratories that have previously repeatedly demonstrated good performance for the specific or similar compounds.

Furthermore, the EUPT-Panel may decide to eliminate certain results traceably associated with bias or gross errors for establishing the assigned value (see 'Omission or Exclusion of results' below).

Since the assigned values of the EUPT analytes are typically generated using robust mean concentrations of participant results ( $x_{pt}$ ), which are generated by a variety of analytical standards and methods, the assigned values of EUPTs are typically metrologically not traceable.

– **Omission or Exclusion of results**

Before estimating the assigned value, results associated with obvious mistakes have to be examined to decide whether they should be removed from the population. Such gross errors may include incorrect recording (e.g. due to transcription errors by the participant, decimal point faults or transposed digits, incorrect unit), calculation errors (e.g. missing factors), analysis of a wrong sample/extract (e.g. a spiked blank), use of wrong concentrations of standard solutions, incorrect data processing (e.g. integration of wrong peak), inappropriate storage or transport conditions (in case of susceptible compounds), and the use of inappropriate analytical steps or procedures that demonstrably lead to significantly biased results (e.g. employing inappropriate internal standards or analytical steps or conditions leading to considerable losses, due to degradations, adsorptions, incomplete extractions, partitioning etc.). Where the organisers (e.g. after the publication of the preliminary report) receive information of such gross errors, having a significant impact on a

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<sup>9</sup> ISO 13528:2022 'Statistical methods for use in proficiency testing by interlaboratory comparisons', International Organization for Standardization. Therein a specific robust method for determination of the consensus mean and standard deviation without the need for removal of deviating results is described (Algorithm A in Annex C).

generated result, the affected results will be examined on a case-by-case basis to decide whether, or not, they should be excluded from the population used for robust statistics. Results may also be omitted e.g. if an inappropriate method has been used even if they are not outliers. 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. However, z scores will be calculated for all results irrespective of the fact that they were omitted from the calculation of the assigned value.

Omitted results might be interesting as they might give indications about possible source(s) of errors. The organisers will thus ask the relevant lab(s) to provide feedback on possible sources of errors (see also “follow-up activities”).

Results reported by laboratories from non-EU member states are typically excluded from the population that is used to derive the assigned value (see also “Estimation of the assigned value”).

– ***Uncertainty of the assigned value***

The uncertainty of the assigned values  $u(x_{pt})$  is calculated according to ISO 13528:2022 as:

$$u(x_{pt}) = 1,25 \times \frac{s^*}{\sqrt{p}}$$

where  $s^*$  is the robust standard deviation and  $p$  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 that were used by the participants), the EUPT-SC 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 13528:2022 concerning the uncertainty of the assigned value will be taken into account.

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

The target standard deviation of the assigned value ( $FFP-\sigma_{pt}$ ) will be calculated using a Fit-For-Purpose approach with a fixed Relative Standard Deviation (FFP-RSD).

Based on experience from previous EUPTs<sup>10</sup>, a percentage FFP-RSD of 25 % is currently used for all analyte-matrix combination, with the target standard deviation being calculated as follows:

$$FFP-\sigma_{pt} = 0.25 \times x_{pt}$$

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<sup>10</sup> Comparative Study of the Main Top-down Approaches for the Estimation of Measurement Uncertainty in Multiresidue Analysis of Pesticides in Fruits and Vegetables. J. Agric. Food Chem., 2011, 59(14), 7609-7619. [DOI:10.1021/jf104060h](https://doi.org/10.1021/jf104060h)

The EUPT-SC reserves the right to also employ other FFP-RSDs or other approaches for setting the assigned value on a case-by-case basis, considering analytical difficulties and experience gained from previous proficiency tests.

For informative purposes the robust relative standard deviation (CV\*) of the participants results is calculated according to ISO 13528:2022; Chapter 7.7 following Algorithm A in Annex C (so called “consensus approach”).

– **z scores**

This parameter is calculated using the following formula:

$$z_i = \frac{(x_i - x_{pt})}{FFP-\sigma_{pt}}$$

where  $x_i$  is the value reported by the laboratory,  $x_{pt}$  is the assigned value, and  $FFP-\sigma_{pt}$  is the standard deviation using the FFP approach. Z scores will be rounded to one decimal place. For the calculation of combined z scores (see below) the original z scores will be used and the combined z scores will be rounded to one decimal place after calculation.

Any z scores > 5 will be typically reported as '> 5' and a value of '5' will be used to calculate combined z scores (see below).

Following ISO 17043:2010<sup>11</sup>, z scores will be classified as follows::

$ z  \leq 2.0$	Acceptable
$2.0 <  z  < 3.0$	Questionable
$ z  \geq 3.0$	Unacceptable

All false negatives will be assigned a z score of -4. These z scores will typically appear in the z score histograms and will be used in the calculation of combined z scores.

– **Collection of measurement uncertainty (MU) figures**

The participating labs will be asked to report the MU figure they would routinely report with each EUPT result. The EUPT-SC will decide whether and how to evaluate these figures and whether indications will be made to the laboratories in this respect.

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<sup>11</sup> ISO/IEC 17043:2010. Conformity assessment – General requirements for proficiency testing

– **Category classification**

The EUPT-SC will decide if and how to classify the laboratories into categories based on their scope and/or performance. Currently, a scope-based classification into Category A and Category B is employed. Laboratories that a) are able to analyse at least 90% of the compulsory analytes in the target pesticides list, b) have correctly detected and quantified a sufficiently high percentage of the analytes present in the Test Item (at least 90 %) and c) reported no false positives, will have demonstrated ‘sufficient scope’ and will be therefore classified into Category A. For the 90% criterion, the number of analytes needed to be correctly analysed to have sufficient scope will be calculated by multiplying the number of compulsory analytes from the Target Pesticides List by 0.9 and rounding to the nearest full number with 0.5 decimals being rounded downwards (see some examples in Table 1).

**Table 1. No. of analytes from the Target Pesticides List needed to be targeted or analytes present in the Test Item that need to be correctly detected and quantified to have sufficient scope.**

No. of compulsory analytes present in the Test Item / Target Pesticides List (N)	90 %	No. of analytes needed to be correctly detected and quantified / targeted to have sufficient scope (n)	n
3	2.7	3	N
4	3.6	4	
5	4.5	4	
6	5.4	5	N - 1
7	6.3	6	
8	7.2	7	
9	8.1	8	
10	9.0	9	
11	9.9	10	
12	10.8	11	
13	11.7	12	
14	12.6	13	N - 2
15	13.5	13	
16	14.4	14	
17	15.3	15	
18	16.2	16	
19	17.1	17	
20	18	18	
21	18.9	19	
22	19.8	20	
23	20.7	21	
24	21.6	22	
25	22.5	22	
26	23.4	23	

The EUPT-SC reserves the right to develop and apply alternative classification rules.

– **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 ( $AZ^2$ )<sup>12,13</sup> (see below) will be used. The  $AZ^2$  is calculated as follows:

$$AZ^2 = \frac{\sum_{i=1}^n z_i^2}{n}$$

Where n is the number of z scores to be considered in the calculation. In the calculation of  $AZ^2$ , z scores > 5 will be set as 5. Based on the  $AZ^2$  achieved, the laboratories are classified as follows:

$AZ^2 \leq 2.0$	Good
$2.0 < AZ^2 < 3.0$	Satisfactory
$AZ^2 \geq 3.0$	Unsatisfactory

Combined z scores are considered to be of lesser importance than individual z scores. The EUPT-SC 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 that have reported enough results to obtain 5 or more z scores. For the calculation of the AAZ, z scores higher than 5 will also be set as 5. The z scores appointed to false negatives will be also included in the calculation of the combined z scores.

Laboratories within Category B will be typically ranked according to the total number of analytes they correctly reported to be present in the Test Item. The number of acceptable z scores achieved will be presented, too. The EURL-SC 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) have been reported.

## Publication of results

The EURLs will publish a preliminary report, containing tentative assigned values and z score values for all analytes present in the Test Item, within 2 months of the deadline for result submission.

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<sup>12</sup> Formerly named "Sum of squared z scores ( $SZ^2$ )"

<sup>13</sup> Laboratory assessment by combined z score values in proficiency tests: experience gained through the EUPT for pesticide residues in fruits and vegetables. Anal. Bioanal. Chem., 2010, 397, 3061–3070.

The Final EUPT-Report will be published after the EUPT-SC has discussed the results. Taking into account that the EUPT-SC meets normally only once a year (typically in late summer or autumn) to discuss the results of all EUPTs organised by the EURLs earlier in the year, the Final EUPT-Report may be published up to 12 months after the deadline for results submission. Results submitted by non-EU/EFTA laboratories might not always be used in the tables or figures in the Final Report.

### Certificates of participation

Together with the Final EUPT-Report, the EUPT organiser will deliver a Certificate of Participation to each participating laboratory showing the z scores achieved for each individual analyte, the classification into Categories, and if deemed necessary also combined z scores. The certificates of participation will be uploaded onto the EURL-DataPool where they can be accessed by the concerned laboratories only.

### Feedback

At any time before, during or after the PT participants have the possibility to contact the organisers 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, General 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 organisers will distribute a new corrected version, where it will be stated that the previous version is no longer valid.

Where substantial errors are discovered in the Final EUPT-Report the EUPT-SC will decide whether a corrigendum will be issued and how this should look like. The online version of the Final EUPT 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 (typically those with  $|z| > 2.0$ ) - including all false positives. In exceptional cases, follow-up activities may even be indicated for results within  $|z| \leq 2.0$  (e.g. if two errors with opposed tendency cancel each other leading to acceptable results).

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  $|z| \geq 3.0$ . Concerning z scores between 2.0 and 3.0 the communication of the outcome of follow-up activities is optional but highly encouraged where the source of deviation could be identified and could be of interest to other labs.

In accordance with the instructions from DG-SANTE, 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.

NRLs will be considered as **underperforming in relation to scope** if in at least two of the last four EUPTs falling within their responsibility area they: a) haven't participated, or b) targeted less than 90% of the compulsory analytes in the target lists (80% for SRM-compounds), or c) detected less than 90% of the compulsory compounds present in the test items (80% for SRM-compounds). Additionally, NRLs that obtained  $AZ^2$  higher than 3 ( $AAZ$  higher than 1.3 for SRM-compounds) in two consecutive EUPTs of the last four EUPTs, will be considered as **underperforming in accuracy**. As soon as underperformance of an NRL is detected, a two-step protocol established by DG-SANTE will be applied<sup>14</sup>:

### Phase 1:

- Identifying the origin of the bad results (failure in EUPTs).
- Actions: On the spot visits and training if necessary and repetition of the comparative test if feasible and close the assessment of results by the EURL.

### Phase 2:

- If the results still reveal underperformance the Commission shall be informed officially by the EURL including a report of the main findings and corrective actions.
- The Commission shall inform the Competent Authority and require that appropriate actions are taken.

Underperformance rules for the OfLs will be established at a later stage.

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<sup>14</sup> Article 101 of Regulation (EU) 2017/625

**Disclaimer**

The EUPT-SC 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.