12th Edition: Released on

GENERAL PROTOCOL

for EU Proficiency Testings on Pesticide Residues in Food and Feed

Introduction

This protocol contains general procedures valid for all European Union Proficiency Testings (EUPTs) organised on behalf of the European Commission, DG-SANTE[1] by the four European Union Reference Laboratories (EURLs) responsible for the area of pesticide residues analysis in food and feed. These EUPTs are organised for 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[2]:

- 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 EUPTs allow the individual laboratory to evaluate if its performance is satisfactory. Additionally, the aim 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[3]. Participating laboratories will be provided with an assessment of their analytical performance that they can use to demonstrate their (ongoing) analytical proficiency and compare themselves with other participating laboratories.

[1] DG-SANTE = European Commission, Health and Food Safety Directorate-General

[2] 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.

[3] https://food.ec.europa.eu/plants/pesticides/maximum-residue-levels/enforcement/eu-multi-annual-control-programmes_en

Table of Content

Significant changes in new edition to previous edition

Some parts of the old version have been removed, so this edition includes only the information necessary for the participants. There have been no changes to the evaluation process. Apart from that, only editorial changes have been made.

EUPT- Organisers and Scientific Committee

EUPTs are organised either by single EURLs, or collaboratively by more than one EURL.

An **organising team** (in the following named **organisers**[4]) is appointed by the EURL(s) in charge of a given PT. The organisers are in charge of all administrative and technical PT activities of a proficiency testing (PT) round, which include e.g., the PT-announcement, the production of the proficiency testing item (PT-item), the undertaking of homogeneity and stability assessments, the packing and shipment of the PT-Items, 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 the 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)[5] has been established in agreement with DG-SANTE. The EUPT-SC consists of expert scientists with many years of experience in PTs and/or pesticide residue analysis. The latest **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's role is to assist the organisers during the planning and the data evaluation phase of a PT-round. Input from the EUPT-SC is for example requested, when it comes to selecting the commodity, selecting the analytes to be included in the Target Pesticides List (p. 6), establishing the Minimum Required Reporting Levels (MRRLs) for each of the analytes, statistically evaluating the participants' results (in anonymous form), as well as for 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 PT item and the approximate concentrations at which they should be present.

[4] The term organisers are to be considered equivalent to the term PT-provider in ISO 17043:2023-10

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

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 preliminary evaluation of the EUPT-results, especially where case-by-case decisions are needed. PT plans for the next EUPT season are also discussed during these meetings.

EUPT Participants – Eligibility and Obligation for Participation

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[6]
- 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[7]), and
- Art. 101 (1)(a) of Regulation (EU) No. 2017/625[2] (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 to 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 obliged laboratories with their current 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.

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

EUPTs are furthermore open to the following laboratories as long as sufficient material is available:

a) any other OfLs from EU countries that are not covered by the above obligations to participate

b) NRLs and OfLs from EFTA countries

[6] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities. https://eur-lex.europa.eu/eli/reg/2017/625/oj

[7] 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).

c) NRLs and OfLs from EU-candidate countries and

d) other laboratories from EU or EFTA countries analysing official organic samples within the frame of Reg. 889/2008/EC

e) governmental laboratories from Third Countries (countries outside EU)

f) other laboratories from Third Countries as long as they are involved in controls of products destined for export to the EU.

Laboratories of groups d) and f) will be requested to provide a proof of their function (e.g. scan copy of a document stating official appointment).

In exceptional justified cases (e.g. where the number of OfLs/NRLs analysing a specific compound is small) additional commercial labs from the EU and beyond may be invited to participate in an EUPT). In a given EUPT, each laboratory/institution is allowed to submit only one single set of results. Any subcontracting of analyses to another institution must be communicated to the organisers, preferably prior to the start of the EUPT.

Participation fee and Invoicing

By completing the registration for participation in a given EUPT, the laboratory agrees to proceed with a timely payment of the participation fee. The invoice fee covers the costs of production, handling and delivery of the PT Test Items. The organisers will issue digital invoices in PDF format only, and without any electronic signature. The EURLs retain the right to decline any request for supplementary forms or additional paperwork in connection with the payment. The laboratories should note that additional costs will incur if such extra services are requested, depending on the incurring extra workload. Extra costs may also be incurred if a new modified invoice is requested, e.g. because of missing or erroneous information caused by errors or omissions by the registered laboratory during registration. OfLs not paying the EUPT participation fee will be initially reminded, and then warned that information concerning their lab may be blacked out in the final report of the concerned EUPT, that the certificate of participation may not be issued to them, and that their participation in subsequent EUPTs could be denied. In case of a repetitive non-payment, the EUPT organisers may inform the corresponding NRL and/or the competent authority responsible for the OfL.

Confidentiality and Communication

The owner of all EUPT data is DG-SANTE and as such they have access to all information.

For each EUPT, the laboratories are given a unique code (lab code), initially only known to themselves and the organisers. Furthermore, the EURLs reserve the right to share EUPT results and codes among 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[2], 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 of 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 PT items to the participants 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 for preparing the PT item, as well as links to the EUPT-Target Pesticides List and the EUPT-Calendar.

Target Pesticides List and PT-Residue Definitions

The Target Pesticides 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 set at 50% of the lowest MRLs found either in Regulation (EC) No. 2005/396 or in Regulation (EU) No. 2016/128 (Baby Food Directive).

The residue definition in an EUPT may differ from the legal one if this is deemed necessary by the organisers for ensuring a better evaluation of the results. Participants must express their results as defined in the Target Pesticides List of the respective EUPT. Separately quantifiable analytes are typically listed separately unless stated otherwise.

Specific Protocol

The organising EURL will publish a Specific Protocol at least 2 weeks before the PT testing item is shipped to the participants. 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 PT item upon receipt and on how to submit results, as well as other relevant information.

Homogeneity of the PT Item

The Homogeneity of the PT test Item evaluated according to ISO 13528:2022, Annex B[8].

Stability of the Analytes Contained in the PT Item

The PT item will be tested for stability according to ISO 13528:2022, Annex B[8].

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. This can be done via the EURL data submission tool (in the following named Webtool) by answering the question whether the concerned analyte is included within the routine scope of the laboratory and the question about the analytical experience with the compound.

General Procedures for Reporting Results

Participating laboratories are responsible for reporting their own quantitative results to the organisers within the stipulated deadline. Each laboratory will be able to report only one result for each analyte detected in the PT item. The concentrations of the analytes detected should be expressed in ‘mg/kg’ unless indicated otherwise in the specific protocol of the respective EUPT.

[8] ISO 13528:2022: ‘Statistical methods for use in proficiency testing by interlaboratory comparisons”, International Organization for Standardization.

When reporting, the following number of significant figures should be given:

Concentration values ≤ 0.01 mg/kg - two significant figures (e.g. 0.0078; 0.010)
Concentration values > 0.01 mg/kg to three significant figures (e.g. 0.0123; 0.123; 1.23; 12.3 mg/kg).

No penalties will apply where a laboratory reports deviating numbers of significant figures. For the calculation of z scores, the values will be used as reported.

Laboratories should not report results below their own reporting limits (RLs). Any reported numerical result that is lower than the RL will be marked as a 'False Reporting' (FR), see False Reporting on page 9.

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 the method used inherently accounts for method bias (see cases a-c below), laboratories are required to report the recovery (in percent), and whether their results was corrected mathematically using a recovery factor reflecting the reported recovery.

Results with bias above 20% (apparent recovery not within the range of 80-120%), for which no correction for bias was undertaken, might 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 Webtool. 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 obliged to provide information on the analytical method(s) they have used. This must be done via the Webtool, which serves for submitting analytical results.

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"[9] by the organiser, and/or (ii) "not detected" by the overwhelming majority (e.g. > 95 %) of the participating laboratories that had targeted the specific analytes.

Any results reported lower than the MRRL will not be considered as false positives, even though these results should not have been reported. If these results are additionally lower than the lab's reporting limit, they will be attributed with FR ('False Reporting').

- ***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 organisers to treat the PT item and b) detected by the organisers as well as the majority of the participants that had targeted these specific analytes at or above the respective MRRLs. Such results will also be regarded as "not correctly found" when it comes to categorization in A and B based on scope.

Where for a compound present in the PT item a laboratory reports "not detected" and a RL exceeding the assigned value, the result will still be judged as a false negative, despite this practice being consistent and adequate within a routine working environment. The FN judgement should in this case penalize the laboratory for not being able to achieve sufficient sensitivity for the analyte in question.

- ***False reporting (FR)***

A result reported below the laboratories own reporting limit (RL) will be evaluated as a 'False Reporting' (FR). If the analytes concerned are present in the test material, z scores will be calculated as for any other numerical results. Furthermore, these results will be included in the population of results for the determination of the assigned value, unless they are excluded for other reasons (e.g. reported by laboratories of non-EU or EFTA countries, generated using biased methods, etc.).

[9] The term "not detected" is also used in the Webtool. In this context this term entails also cases where no numerical result was reported (e.g. because the level determined was < MRRL and/or < RL)

- ***Estimation of the Assigned Value (x_{pt})***

The Assigned Values (consensus concentration) will typically be estimated using the robust mean estimate of the participant results (x^*) as described in ISO 13528:2022[10], taking into account the results reported by EU and EFTA countries laboratories only.

In reports, assigned values will be rounded to 3 significant figures if ≥0.01 mg/kg and to 2 significant figures if <0.01 mg/kg (i.e. 0.0078; 0.123; 1.23; 12.3 mg/kg). For the calculation of z scores, the organisers may opt to use assigned values rounded to more significant figures than those stated above.

- ***Omission or Exclusion of Results***

Results reported by laboratories from non-EU/EFTA member states are excluded from the population used to derive the assigned value.

Despite the use of robust statistics, all results 10 times higher than the assigned values will be omitted and the assigned values will be recalculated.

- ***Uncertainty of the Assigned Value u(x_{pt})***

The uncertainty of the robust mean values $u(x_{pt})$ will be calculated according to ISO 13528:2022 as:

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

where s^* is the robust standard deviation and p is the number of results.

- ***Standard Deviation of the Assigned Value (target standard deviation)***

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

Based on experience from previous EUPTs[11], a percentage FFP-RSD of 25 % is currently used for all analyte-matrix combination, with the target standard deviation being calculated as follows:

[10] 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).

[11] 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

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

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 from participant results").

- ***z scores***

This parameter is calculated using the following formula:

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

where x_i is the value reported by the laboratory, x_{pt} is the assigned value, and $\text{FFP-}\sigma_{pt}$ is the standard deviation using the FFP approach. Z scores shown in the preliminary and Final EUPT-Report 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.

Following ISO 17043:2010[12], z scores will be classified as follows:

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

Z scores higher than 5 will be reported as >5 in the reports and in certificates.

All false negatives will be assigned a z score of -4.

- ***Collection of Measurement Uncertainty (MU) Figures***

For each EUPT the participating labs are asked to voluntarily report the MU figure they would report in routine analyses.

- ***Categorization of Laboratories***

A scope-based classification into Category A and Category B will be employed. Laboratories that

a) have analysed at least 90% of the compulsory analytes in the target pesticides list
b) have correctly detected and quantified at least 90 % of the analytes present in the PT item
c) reported no false positives

[12] ISO/IEC 17043:2010. Conformity assessment – General requirements for proficiency testing

will be considered to have demonstrated 'sufficient scope' and will therefore be classified into Category A. The criterion of analytes present in the PT item, will be calculated as 90 % of the number of analytes needed to be correctly detected and quantified (no obtained FN for any of the compounds) rounding down to the nearest full number (see Table 1).

Table 1: Number of analytes from the Target Pesticides List needed to be targeted or analytes present in the PT item that need to be correctly detected and quantified to have sufficient scope.

No. of compulsory analytes present in the PT 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	N - 1
6	5.4	5	
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	
15	13.5	13	N - 2
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	N - 3
26	23.4	23	

- ***Overall Performance of Laboratories - Combined z Scores***

For evaluation of the overall performance of laboratories the average of the squared z scores (AZ^2)[13] are calculated. To minimize the influence of outlying results, the calculation of AZ^2 will not be conducted in the case of < 6 results. Z scores higher than 5 will be set as 5 and false negative z scores (-4.0) will be included. Combined z scores will only be calculated for laboratories within Category A and considering results of compulsory analytes only.

[13] 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. DOI:10.1007/s00216-010-3877-3

Considering the cut-off of high z scores at 5, 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.

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

Laboratories within Category B will be typically ranked according to the total number of analytes they correctly reported to be present in the PT item. The number of acceptable z scores achieved may be presented, too.

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 being too low.

Where only a few results per lab are available (mostly the case in EUPT-SRMs), 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 combined z score calculations.

Publication of Results

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

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 included in all tables or figures in the Final EUPT-Report.

Certificates of Participation

The EUPT organisers will deliver a Certificate of Participation to each participating laboratory showing the z scores achieved for each individual analyte, and if available the classification into Categories, and AZ^2 scores. The certificates will be sent by email and in some cases also be uploaded onto the EURL-DataPool and thereby be accessible to the concerned laboratories only.

Feedback and Complaints

Complaints and appeals on aspect concerning the PT are welcome. Complaints about a non-arrival of a PT item or about the bad condition of the PT item upon arrival should be done through the Webtool shortly as indicated in the specific protocols. The EURLs will track complaints about the evaluation of the participants results and follow up within due time. After the publication of the final EUPT report, the organizers reserve the right not to consider any complaints arriving more than two months after its publication.

Appeals and complaints concerning the principles of organisation and statistical analysis of the results according to the General Protocol should be made prior to the start of a PT. By signing up to an EUPT, the participant agrees with the provisions of the General Protocol valid for the PT-season in question.

At any time before, during or after the PT participants have the possibility to contact the organisers and make improvement suggestions or indicate general errors. After the distribution of the Final EUPT-Report, participating laboratories may be given the opportunity to give their feedback to the organisers and make suggestions for future improvements through a survey.

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 and carefully study the latest version of these documents.**

If substantial errors are discovered in the Preliminary EUPT-Report the organisers will distribute a new corrected version, therein it will be stated that the previous version is no longer valid. The online version on the PT website will be replaced.

Where substantial errors are discovered in the Final EUPT-Report 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 revised certificates will be issued.

Follow-up Activities on Behalf of Participants

According to ISO 17025, 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.

Upon request, the laboratory's corresponding NRL and/or EURL is to be informed about the outcome of any investigative activities for false positives, false negatives and for results with |z| ≥ 3.0.

Follow-up Activities on Behalf of Organizers and Underperformance Rules

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 PT 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[14]:

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 appropriate actions to be taken.

Disclaimer

The EURLs retain 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.

[14] Article 101 of Regulation (EU) 2017/625