

**Proposal for management of
underperformance
National Reference Laboratories
and Official Laboratories**



Protocol for management of underperformance in comparative testing and/or lack of collaboration of National Reference Laboratories (NRLs) with Community reference laboratories (CRLs) activities

According to article 32 of Regulation (EC) 882/2004¹, Community reference laboratories (CRLs) shall be responsible for coordinating application by the NRLs of analytical methods, in particular by organising comparative testing and by ensuring an appropriate follow-up of such comparative testing.

Article 33 of the Regulation establishes that NRLs shall collaborate with the CRLs in their area of competence.

The NRLs are a key tool for the proper implementation of official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, therefore their performance is of outmost importance.

Appropriate actions must be taken if the results of comparative tests reveal underperformance or if NRLs fail to collaborate properly with the corresponding designated CRL.

The following two-step protocol is suggested in case of

- (a) underperformance (i.e. failure in proficiency test)
- (b) lack of collaboration by the NRLs with the CRL

¹ OJ L 165, 30.4.2004, p. 1, corrected by OJ L 191, 28.5.2004, p. 1. Regulation as last amended by Commission Regulation (EC) No 776/2006 (OJ L 136, 24.5.2006, p. 3)

Phase 1

(a) Underperformance (i.e. failure in proficiency test)

- CRL should contact the NRL and provide assistance trying to identify the origin of the bad result. On the spot visits and training could be foreseen if necessary.
- Repetition of the comparative test if feasible (e.g. within 3 months) and close assessment of the results by the CRL

Confidentiality should be kept during this phase in order to ensure good co-operation from the NRL. The results of the proficiency test and the codes of the laboratories are included in the report transmitted to the Commission. Apart from that there is no need to further involvement of the Commission until the results of the following comparative test are available and re-assessed.

(b) Lack of collaboration by the NRLs with the CRL:

- CRL should contact the NRL if lack of collaboration with CRL activities. CRL should ask the NRL for the reasons of no participation to a proficiency test or a workshop. The justification provided by the NRL should be included in the report submitted to the Commission

Phase 2

(c) Underperformance (i.e. fail in proficiency test)

- If the results of the following comparative test still reveal underperformance of the NRL or the collaboration of the NRL is not adequate, the Commission shall be informed officially by the CRL including a report of the main findings and corrective actions to improve the situation.
- The Commission shall inform the competent authority and require that appropriate actions are taken.

(d) Continuous lack of collaboration by the NRLs with the CRL:

- In case of repetitiveness of the lack of response of the NRL, the Commission shall be informed officially by the CRL and the Commission shall inform the competent authority and require that appropriate actions are taken.

Two step protocol is suggested when Underperformance of NRL is detected

Phase 1:

Identifying the origin of the bad results (failure in PTs)

Actions:

- i. On the spot visits and training if necessary*
- ii. Repetition of the comparative Test if feasible and close the assessment of results by the EURL*

Phase 2:

If the results still reveal underperformance

Actions:

- i. The Commission shall be informed officially by the EURL including a report of the main findings and corrective actions*
- ii. The Commission shall inform the Competent Authority and require that appropriate actions are taken*

PROPOSAL of criteria for:

Underperformance for NRLs in MRMs and SRMs

Scope: Two consecutive years in the last four EUPTs, with no participation or less than 90% of the compulsory compounds being targeted/detected (80% for SRM-compounds)

Accuracy: Two consecutive years, in the last four EUPTs, with AZ^2 higher than 3 (MRM)

for EU Proficiency Tests on Pesticide Residues

Follow-up activities in Food and Feed

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. Even results within $|z| \leq 2.0$ may have to be checked if there is indications of a significant positive or negative bias.

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 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-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 two EUPTs of the last four EUPTs falling within their responsibility area if they: a) haven't participated, or b) targeted less than 90% of the compulsory pesticides 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).

for EU Proficiency Tests on Pesticide Residues
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Additionally, NRLs that obtained AZ^2 higher than 3 in two consecutive EUPTs of the last four EUPTs, will be considered as **underperforming in accuracy**. A two-step protocol established by DG-SANTE will be applied as soon as underperformance of an NRL is detected¹⁵:

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.

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.

PROPOSAL of criteria for:

Underperformance for OfLs in MRMs and SRMs

Scope: Two consecutive years in the last four EUPTs, with no participation or less than 90% of the compounds being targeted/ detected (80% for SRM-compounds)

Accuracy: 10% of the reported, in the last four EUPTs, Z scores >3

Actions: Inform the NRLs about the situation