
EURL-MP-background doc_002 (version 1)
Follow-up protocol - Protocol for management of underperformance in proficiency testing or lack of collaboration of NRLs

Modifications compared to previous version:

Not applicable.

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Notices:

This document has been drafted for EU National Reference Laboratories as background document on proficiency tests organised by the EURL-MP. It has been produced with the utmost care. However, WFSR does not accept liability for any claims based on the contents of this document.

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Table of Contents

1	Introduction	3
2	Underperformance in proficiency tests	3
2.1	Results of the proficiency test.....	3
2.2	Follow-up protocol - Underperformance in proficiency tests	3
2.2.1	Phase 1.....	3
2.2.2	Phase 2.....	4
3	Lack of collaboration (e.g. no participation to a workshop)	4
3.1	Phase 1.....	4
3.2	Phase 2.....	4
	References.....	5

1 Introduction

National Reference Laboratories (NRLs) are committed to collaborate in their area of competence with the EURL in proficiency test (PTs) provided by the EURL and in activities organised by the EURL, such as the annual workshop or training courses [1, 2].

The organisation of comparative testing or proficiency testing (PTs) among National Reference Laboratories (NRLs) is a key responsibility for European Union Reference Laboratories [1]. The EURL mycotoxins & plant toxins (EURL-MP) organises PTs in the area of mycotoxins and plant toxins in food and feed on a yearly base. Participation to the PTs is obligatory for the NRLs and participation is open to Official Laboratories (OLs) on invitation of their respective NRL. In case of underperformance of the NRL, it is the task of the EURL to initiate a follow up action according to the Commission protocol [3].

This document describes how the results of a PT are presented and communicated with the Commission. Furthermore, it describes the protocol for the management of underperformance in proficiency testing or lack of collaboration of NRLs

2 Underperformance in proficiency tests

2.1 Results of the proficiency test

The performance of the participants in the PT is evaluated according to the EURL-MP PT performance assessment procedure [4] and described in the corresponding PT report, which is are both accessible on the webpage of the EURL-MP. In this report, the participating NRLs and OLs are listed in alphabetic order of the Member or Affiliated State and the results of each participant are presented anonymously. The EURL-MP provides the Commission with the coding of the NRL laboratories.

In case of underperformance of NRLs, the next two-step procedure for EURL-MP actions will be applied. Follow up on underperformance of OLs is the responsibility of the applicable NRL.

2.2 Follow-up protocol - Underperformance in proficiency tests

2.2.1 Phase 1

1. The EURL-MP informs the NRLs of the publication of the PT report. In case of underperformance, the EURL will ask the NRL for feedback on the possible causes for the observed deviations and follow up action for improvement if applicable.

Underperformance includes:

- Unable to participate in the PT
 - Incompleteness of scope (determination of only part of the toxins requested)
 - Questionable or unsatisfactory z-score(s)
 - False positive result(s)
 - False negative result(s)
2. The feedback from the NRL must include at least a detailed analysis of the cause of the deviation and the proposes corrective actions, means of verification and including a

proposed timeline.

3. The NRL response to the report shall be transmitted by email to the EURL-MP within one month after the request for information.
4. Upon acknowledgment of reception of the explanation, the EURL-MP shall decide if the case can be closed or if further corrective actions need to be taken. The decision will be notified to the NRL.

During step 1-4, strict confidentiality will be kept between EURL-MP and NRL.

5. In case further action is needed (i.e. repetition of test, on-site visit or training), the EURL-MP shall inform the NRL which action will be decided. After corrective actions, a re-assessment of the NRL shall be realised and notified to the NRL.
6. In case of on-site remediation, a dedicated mission report shall be written by the EURL-MP including, when needed, a “to do” list as well as a timeline for the “to do” items. The NRL shall inform the EURL-MP on the achievements of the “to do” items according to the timeline.

The mission report shall be transmitted to the NRL as well as to the Commission for information.

In case of repeated underperformance, or if corrective actions from Phase 1 still result in an underperforming situation, or if the NRL does not fully collaborate to solve the Phase 1 requirements, Phase 2 will be initiated.

2.2.2 Phase 2

7. The EURL-MP will officially inform the Commission and will transmit the dossier to DG SANTÉ. The Commission shall inform the competent authority of the Member State of the NRL and require that appropriate actions be taken.

3 Lack of collaboration (e.g. no participation to a workshop)

3.1 Phase 1

1. The EURL-MP shall contact the NRL asking to report on the lack of collaboration.
2. The NRL response shall be transmitted by email to the EURL-MP within one month after request for information.
3. Upon acknowledgment of reception of NRL response, the EURL-MP shall decide if the delivered explanation is justifying the lack of collaboration. The justification of the NRL shall be transmitted to Commission for information.

In case of repetitiveness of lack of collaboration, or in case of absence of response by the NRL, Phase 2 will be initiated.

3.2 Phase 2

4. The EURL-MP will officially inform the Commission and will transmit the dossier to DG SANTÉ. The Commission shall inform the competent authority of the Member State of the NRL and require that appropriate actions be taken.

References

1. EU, Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 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). EURLEX 02017R0625: OJ L95, pp. 163.
2. EURL residues of pesticides, 2017, Protocol for management of underperformance in comparative testings or lack of collaboration of NRLs, pp. 2. <http://www.eurl-pesticides.eu/userfiles/file/ProtocolForFollowUpUnderperformance.pdf>.
3. European Commission, Protocol for management of underperformance in comparative testing and/or lack of collaboration of National Reference Laboratories (NRLs) with Community Reference Laboratories (CRLs) activities. pp. 2. https://eur1cefas.org/media/4149/protocol_for_management_of_underperformance_in_comparative_testing_and_or_lack_of_collaboration_of_national_reference_laboratories.pdf.
4. EURL mycotoxins & plant toxins, 2019, EURL-MP-background doc_001 v1, Performance assessment in proficiency tests organised by the EURL mycotoxins & plant toxins in food and feed. pp. 8. https://www.wur.nl/en/Research-Results/Research-Institutes/food-safety-research/Reference-laboratory/European-Union-Reference-Laboratory-1/EURL-mycotoxins-plant-toxins/Library-EURL-MP.htm#eurl_mp_background_documents.