European Union Reference Laboratory for monitoring bacteriological and viral contamination of bivalve molluscs

The Centre for Environment, Fisheries & Aquaculture Science
Weymouth Laboratory,
Barrack Road,
The Nothe,
Weymouth,
Dorset DT4 8UB UK
Tel: +44 (0) 1305 206600, Fax +44 (0) 1305 206601
Email: fsq@cefas.co.uk http://www.crlcefas.org

Guidance for National Reference Laboratories on performance assessment follow-up activities in proficiency testing and for official control laboratories Version 2. October 2011

Introduction

Article 33 of 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 sets out the remit of European National Reference laboratories (NRLs) (Anon 2004). This article specifies that where appropriate, NRLs should organise comparative tests, also known as proficiency testing (PT), between official laboratories and ensure an appropriate follow-up of such comparative testing.

All laboratories undertaking official controls on live bivalve molluscs should participate in a relevant PT scheme organised by their NRL or another designated programme (e.g. those organised by the EURL). Proficiency testing enables both an independent assessment of laboratory performance and comparative performance assessments with other participants. The frequency of such participation should be at least biannual to enable identification of poor performance over a realistic timescale. Laboratory performance should be monitored by the NRL on a regular basis. Poor performance should be investigated and reasons for failures identified. Laboratories that continually or persistently fail in proficiency tests may be suspended from official control testing by the relevant authorities.

Frequently PT schemes utilise statistical approaches to assess participant's performance and assign acceptability criteria. The following document describes an approach to assessing performance in comparative testing based upon allocation of numerical scores. Examples of follow-up procedures and suggested courses of action in the event of continual or persistence poor performance are provided.

The use of scoring

Allocation of scores in PT schemes enables measurement of performance based on empirical data. The advantages of the use of scoring in proficiency testing are listed below.

- Scoring systems are used to help assess participants' results in PT schemes. Allocation of scores helps participants', and other entities (e.g. EURL, NRL, accreditation bodies, Competent Authorities) assess their performance.
- Scores can be used to assess performance in a single distribution (or sample) and to monitor ongoing performance over time with assessments on cumulative scores over a specified timeframe or number of distributions.
- Scores help scheme organisers recognise those participants' who are experiencing problems and thus enable provision of additional help, advice and support.
- Scores are usually allocated following statistical analysis of participants' results. It is important that scoring procedures are reviewed frequently to ensure continued fitness for purpose.

European Union Reference Laboratory for monitoring bacteriological and viral contamination of bivalve molluscs

The Centre for Environment, Fisheries & Aquaculture Science
Weymouth Laboratory,
Barrack Road,
The Nothe,
Weymouth,
Dorset DT4 8UB UK
Tel: +44 (0) 1305 206600, Fax +44 (0) 1305 206601
Email: fsq@cefas.co.uk http://www.crlcefas.org

Monitoring of laboratory performance

Laboratory performance should be monitored frequently and according to a defined schedule. Where poor performance is noted certain procedures should be instigated. When scoring systems are utilised failures may be identified by participants' scores that fall outside of defined performance criteria.

Such occurrences should trigger follow-up activities by NRLs all PT failures should be examined by the NRL. Follow-up procedures should be fit for purpose and regularly reviewed.

In the first instance it is recommended that the laboratory experiencing a failure in a proficiency test should be contacted and reasons for failure identified. This will enable the laboratory to conduct an investigation under their quality procedures into the nature of the failure and if available repeat the test.

The NRL should undertake proactive checks covering official control laboratory (OCL) performance in PT on at least an annual basis

Example follow-up procedures

Follow-up procedures can include:

- Examination of methodology in use, through for example, scrutiny of the laboratories standard operating procedures and result interpretation/reporting protocols.

- For culture based methods in microbiology e.g. ISO TS 16649-3 and EN/ISO 6579, quality control information of media should be scrutinized to ensure that media are performing adequately.

- Equipment records for equipment used in the procedures (e.g. incubators, measuring instruments, refrigerators) should be checked to ensure appropriate calibration, maintenance and performance.
- Staff training records should be examined to ensure that staff are adequately trained; familiar with procedures and that ongoing checks of staff competence are in place.

- Clerical procedures should be scrutinized to ensure that sample receipt, sample labeling, laboratory numbering and supporting clerical procedures are in place. It is worthy of note that frequently failures in proficiency testing can stem from failure to return results within a specified time frame. Laboratory systems should be in place to ensure that results are reported accurately and on time.

- Accreditation records should be checked to ensure that staff adhere the laboratory quality policy at all times.

- The use of, type and relevance of internal quality controls should be examined.

European Union Reference Laboratory for monitoring bacteriological and viral contamination of bivalve molluscs

The Centre for Environment, Fisheries & Aquaculture Science
Weymouth Laboratory,
Barrack Road,
The Nothe,
Weymouth,
Dorset DT4 8UB UK
Tel: +44 (0) 1305 206600, Fax +44 (0) 1305 206601
Email: fsq@cefas.co.uk http://www.crlcefas.org

- Laboratory quality procedures for reacting to internal/external quality control failures.
- Onsite observation of practices in the poorly performing laboratories.

Corrective Actions

If a laboratory continues to fail in a proficiency test (or series of tests), or fails to provide adequate justification for the responsible authorities should be notified.

Continued failure in PT may result in the formal removal of the laboratory from official control testing.

References

Anon (2004). European Communities 2004. Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. Off. J. Eur. Communities L 165, 30.4.04 : 1-141.