

MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD





EUROPEAN UNION REFERENCE LABORATORY FOR MARINE BIOTOXINS

EURLMB 2014 PROFICIENCY TESTING SCHEMES FOR MARINE BIOTOXINS

PROGRAMME

Coordination:

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1. INTRODUCTION

In compliance with the duties of the European Union Reference Laboratories for feed and food described in Article 32(1b) of 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, the European Union Reference Laboratory for Marine Biotoxins (EURLMB) provides a programme of comparative testing trials on marine biotoxins determination. These Proficiency Testing schemes (PTs) are addressed to the National Reference Laboratories (NRLs) in each EU Member State and to the Spanish network of official control laboratories.

2. OBJECTIVES

The aim of the PTs organised by the EURLMB is to evaluate the ability of participant laboratories to satisfactorily apply the recognised methods for marine biotoxins analysis, for the purposes of Regulations (EC) Nos. 853/2004 and 854/2004, stated in Annex III of Commission Regulation (EC) N° 2074/2005. At the same time, the equivalence of the different methods applied will be assessed.

3. EURLMB PROFICIENCY TESTING SCHEMES

The EURLMB will conduct in 2014 one trial for each marine biotoxins group legislated in the EU:

- 3.1. EURLMB 2014 Proficiency Testing for ASP toxins determination (EURLMB-2014-PT-ASP).
- 3.2. EURLMB 2014 Proficiency Testing for LIPOPHILIC toxins determination (EURLMB-2014-PT-LIPO).
- 3.3. EURLMB 2014 Proficiency Testing for PSP toxins determination (EURLMB-2014-PT-PSP).

4. PARTICIPANTS

EU National Reference Laboratories and Spanish official control laboratories contact points are informed by electronic mail about the EURLMB-2014-Proficiency Testing Schemes Programme. They are invited to participate in the trials and requested to submit the provided Registration Form (EURLMB-2014-PTs_REGISTRATION FORM) by electronic email (<u>eurlmb@msssi.es</u>) within the announced deadline.

As a result of the agreements of the XVI Meeting of EU-RL/NRLs for Marine Biotoxins (Split, October 2013), additional non-NRL laboratories from UK and Croatia (1 laboratory per country) are invited to participate in the 2014 programme.

5. TEST MATERIALS

Materials for the Proficiency Testing Schemes will include <u>whole shellfish tissue</u> <u>homogenates</u> prepared at the EURLMB from non-contaminated and/or naturally contaminated shellfish samples.

Test materials will be dispatched frozen and dry ice conditioned (if permitted by transport rules in each country).

Homogeneity and stability studies for test materials are conducted at the EURLMB by recognised testing methods, in accordance with internationally accepted protocols (ISO/IEC 17043, ISO 13528 and "The International Harmonized Protocol for the Proficiency Testing of Analytical Chemistry Laboratories, IUPAC Technical Report, 2006").

6. METHODS

Laboratories will only be accepted for participation if they participate with methods established in the EU legislation (Regulation (EC) No 2074/2005 and its amendments) and/ or methods internationally validated through collaborative trials.

The <u>methods</u> used for the different Proficiency Testing Schemes must be <u>those</u> <u>usually applied by participant laboratories for official control</u>. Participation with

alternative methods will be also acceptable, as long as these methods are in agreement with the requirements indicated above.

7. INSTRUCTIONS

The PTs coordinators (see timetable) will contact the participants in each trial by email to confirm the date for materials to be dispatched.

As soon as samples are dispatched, participants will receive (by email) dispatch details, Protocol for the study, Arrival Form and Reporting File. The PT Protocol will include all the instructions related to materials reception and storage, methods to be used for analysis and reporting of the results.

Test materials will be accompanied by a letter stating the identity code for each participant. This code must be recorded in all the documents exchanged related to the study. (Note: usually this letter is located at the bottom of the materials box, below the dry ice, except for third countries that it is sent by email).

NOTE for <u>laboratories participating in the PSP PT with AOAC 2005.06 OMA</u>: A EURLMB example of the analysis of a sample with *Gymnodinium catenatum* toxic profile, (chromatograms and calculations), that can serve as a guide will be sent to the registered participants. They will also receive calculations case study together with the PT documents.

8. EVALUATION OF RESULTS

Statistical evaluation of results will be carried out according to internationally accepted protocols (ISO/IEC 17043 and ISO 13528).

Only quantitative results will be statistically evaluated. When a chemical method is used to determine total toxicity by quantification of different individual toxins, results where toxins not present in the sample are quantified or results where not all the toxins from a given toxic profile are quantified will be rejected prior calculation of the assigned total toxicity.

In the <u>EURLMB-2014-PT-PSP</u> special attention will be given to the possibility of distinguishing two different results groups during the evaluation. If this is the case a separate evaluation of MBA and HPLC results will be conducted. As

agreed in the Fourth Working Group on the determination of PSP toxins (Brussels, 16- 17 January 2014) laboratories participating with AOAC 2005.06 OMA will have to report both results corrected for recovery and not corrected.

The determination of the assigned value will be done according to ISO 13528:2005 Guide. Therefore the assigned value of a test material will be the robust average of the results reported by all the participants in the PT round, and will be calculated using Algorithm A. The standard deviation for proficiency assessment used for z-score evaluation will be calculated using the Horwitz curve modified by Thompson.

9. REPORT

Each participant will receive a detailed report for each Proficiency Testing trial.

Participants' confidentiality will be assured by using identity codes in the report. However, the report and the EU-NRLs participants codes list will be provided to DG SANCO as part of the EURLMB Annual Technical Report, as requested in Commission Regulation (EC) N^o 926/2011 and DG SANCO "Protocol for the management of underperformance in comparative testing an/or lack of collaboration of NRLs with CRLs activities".

10.TIMETABLE

PROFICIENCY TESTING TRIAL	Participants registration deadline	Materials dispatch (tentative date)	Results submission	Report available	Study Coordinator (email)
EURLMB- 2014-PT-LIPO	9 th April 2014	Second week May 2014	Second week July 2014	September 2014	Ana Braña (abrana@externos.msssi.es)
EURLMB- 2014-PT-ASP	9 th April 2014	Second week May 2014	Second week July 2014	September 2014	Begoña Ben (bbeng@msssi.es)
EURLMB- 2014-PT-PSP	9 th April 2014	Second week May 2014	Last week August 2014	October 2014	Begoña Ben (bbeng@msssi.es)