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EUROPEAN REFERENCE LABORATORY FOR MARINE BIOTOXINS

**WORK PROGRAMME FOR THE EUROPEAN REFERENCE LABORATORY FOR
MARINE BIOTOXINS**

January-December 2015

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Work Programme for the EU Reference Laboratory for Marine Biotoxins

Objectives and work plan for the period January-December 2015

The legal functions and duties of the Community Reference Laboratories for feed and food are described in Article 32(1) 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.

According to the functions and duties above mentioned the EURLMB presents this Work Programme compiling all the activities required with the aim of accomplishing the responsibility as European Reference Laboratory.

In addition to the activities that have been usually carried out this year the EURLMB includes two new activities as a request of DGSANCO.

One of these activities is focused on the evaluation of specific issues affecting the phytoplankton control with the aim of potentially establishing the adequate guidelines destined to the Competent Authorities in the Member States.

The second extra activity included this year deals with the evaluation of the applicability of the EU Reference Method for Lipophilic toxins (LC-MS/MS) for the analysis of processed (canned) samples. This activity has been the result of a request of DGSANCO as a result of a question presented by the Spanish Competent Authority.

The activities of the EURLMB for 2015 are therefore described as follows:

1. Coordination of activities of NRL network and provision of technical assistance and training

1.1. Organization of the XVIII Workshop of the European NRL network of marine Biotoxins

Date: to be determined (Oct. - Nov. 2015)

Place: to be agreed during the XVII meeting

Duration: 1,5-2 days

The EURLMB will organise and coordinate the workshop and will edit the minutes that will be distributed to the participants and published on the EURLMB website. The participation of invited experts in this workshop could be contemplated.

1.2. Supply information to EU MS and third countries on analytical methods for marine biotoxins

Duration: ongoing

In addition to on-going assistance, the EURLMB website is available at:

<http://www.aesan.msssi.gob.es/en/CRLMB/web/home.shtml>.

Issues related with marine toxins legislation, methodologies, standard operating procedures, validation reports, seminars, meetings, minutes, conclusions and recommendations, as well as the activities of the EURLMB will continue to be published and updated at the EURLMB Website.

Additional information might be also supplied by email or any other possible source when requested.

1.3. Assist NRLs on the implementation, validation, accreditation of EU Reference methods for the analysis of marine biotoxins

Support on issues related with analytical methods (Standard Operation Procedures, etc.) for marine biotoxins and their application will be provided. This support could be provided electronically, although visits of staff from NRLs to the EURLMB and vice versa when necessary could be also contemplated.

Duration: ongoing.

EURLMB will also assist NRLs on the implementation and validation of alternative analytical methods of interest, by providing them with technical information, standards if available, contaminated materials, etc., at their request. Moreover, protocols for the analysis of the different groups of marine biotoxins regulated in the EU will be published in the EURLMB website, although any specific information or support related with the application of these protocols will be also directly provided to the NRLs when necessary.

1.4. Technical assistance to Third Countries on analytical methods

EURLMB will assist Third countries with technical support on analytical methodologies or any other useful information about the analysis and control of marine biotoxins (analytical methods, legislation, etc.), also by providing them with samples from EURLMB Proficiency Testing trials for own testing on their methods performance. This will be useful for the validation and accreditation of their methods for marine biotoxins detection. The provision of samples will depend on availability. Participation on Proficiency Testing could be also contemplated upon request and according to availability. The inclusion of these Third countries in the activities of the EURLMB could imply certain fees.

The technical assistance Chile, on analytical methods, particularly LC-MS/MS for Lipophilic toxins is included in the activities of the EURLMB for 2015 as a particular request from DGSANCO of participating on STM activities under BTSF (Better Training for Safer Food) Program.

1.5. Training activities for the staff of NRL MS and Third countries

Trainings on methodological advances on Marine Toxins will be organised according to the NRLs needs. These needs will be discussed and identified at the 2014 annual NRLs Workshop that will take place in Lisbon, kindly hosted by the Portuguese NRL in October 2014 (tentatively 23-24). (Maximum two trainings)

Participants from Third Countries or from other non EU-NRLs laboratories interested in these trainings, could be admitted, upon request and according to availability (maximum 4 countries), as it was above mentioned, the inclusion of these additional participants will imply extra fees as it was mentioned above **(1.4)**

As a request from DGSANCO specific training on LC-MS/MS will be provided to experts from Chile on instrumental methods, in particular LC-MS/MS for Lipophilic toxins as an STM activity under BTSF (Better Training for Safer Food) Program.

Training activities will be supported by the research group at the Analytical Chemistry and Food Department at the University of Vigo.

The participation of external experts could be also contemplated depending on the training activity.

1.6. Meetings

Meetings dealing with the above mentioned methodological advances on Marine Toxins could be also organised after the identification of the needs which will be also discussed at the 2014 annual NRLs Workshop. These meetings will be organised and the participation of experts worldwide will be considered when appropriate.

The training activities, as well as the meetings will be mainly focused on implemented methods, currently used for the analysis of PSP, LPTs and also Emerging Toxins, which are becoming of concern in the EU (particularly Ciguatoxins and Palytoxins).

Big priority is going to be given to collaborations with other groups of experts in this field, including potential visits of experts to the EURL (to attend seminars or meetings), or even visits from EURL staff to expert laboratories to be helped in method set up and implementations.

The possibility of organizing trainings and meetings on methods of interest for marine biotoxins could be also contemplated if required.

1.6.1. Working groups

a) LC-MS: In addition to issues related with the applicability of this methodology for the analysis of Lipophilic toxins (as reference method in the EU) the activities of this WG during 2015 will be particularly focused in two issues:

a.1) Setting up of an International validation of an extension of LC-MS/MS method for Lipophilic toxins under implemented conditions. The extension includes Domoic Acid, Cyclic Imines and Brevetoxins.

The aim of this validation is the worldwide harmonization of an LC-MS/MS method which includes the most relevant toxins with a common lipophilic characteristic on their structure. It is also an aim of this study to try to work on the direction of a future AOAC validation. The EURLMB will coordinate the study and consequently all the related WGs.

Several Laboratories with expertise in the use of LC-MS/MS (from EU and outside Europe) have been selected to participate in this validation. After a previous meeting of the LC-MS/MS WG, the basis for this validation has been discussed. A second WG will be organized to set up the validation, establish criteria etc. An electronic WG will be also created as a convenient tool for continuous discussions about the development of the validation. Depending on the development of the study and the advances during the period of this Work Programme, the possibility of an additional WG could be also contemplated.

a.2) As a request from DGSANCO and additional meeting of the Working Group on LC-MS will be included in this Work Program to evaluate a report presented by the Spanish Competent Authority, regarding to potential drawbacks encountered on the application of the reference method (LC-MS/MS) for the analysis of Lipophilic toxins, in processed samples (canned mussels). The Working Group will meet to evaluate and discussed the report presented and according to the conclusions of this meeting, further studies on these particular samples might be conducted.

b) Working Group on Phytoplankton control

After a request of DGSANCO of including in the EURLMB Work Programme an activity related with the Phytoplankton control in production areas in order to clarify specific issues. The EURLMB will create a new Working Group among the NRLs to discuss these issues.

The activities of this Working Group will be focused in:

- Monitoring of the presence of toxin-producing plankton
- Elaboration of sampling plans
- Sampling frequency
- Representativeness of water columns (detection of toxic species, algae population trends)

These activities might lead to the elaboration of specific guidelines destined to the Competent Authorities in the member States.

The participation of external experts in these WGs could be also contemplated.

1.7. Collaboration with the University of Vigo (Department of Analytical and Food Chemistry) in the organization of symposiums, seminars or activities related with the Analysis of Marine Biotoxins

The International AOAC Joint Symposium on Marine and freshwater toxins will be organised by the research group of the Department of Analytical and Food Chemistry of the University of Vigo. Some EURLMB staff will be also involved in the organization of this International event that will be held in Baiona, Pontevedra, in the Spring-Summer 2015.

2. Scientific advice and support

2.1. Provide scientific assistance to DGSANCO

The EURLMB will assist DGSANCO and FVO if it is required on issues related with the control of marine biotoxins in molluscs.

Any other scientific assistance of interest for DGSANCO could be also provided when requested.

2.1.1. Provide technical assistance in cases where the results of analysis are contested between Member States and/or Member States and Third Countries (when requested).

2.1.2. Technical assistance for CODEX Alimentarius, (participation in Working Groups etc.) will be provided. Any other technical support requested by DGSANCO will be also provided.

3. Interlaboratory Proficiency Testing

The interlaboratory Proficiency Testing trails organised by the EURLMB for the NRLs are aimed at evaluating the ability of the NRLs to apply efficiently the recognised testing methods for marine biotoxins, for the purpose 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 methods applied for the different toxin groups included in the EU Regulation is also evaluated. The EURLMB will organise one trial for each of the regulated marine biotoxins group:

- 3.1.** EURLMB 2015 Proficiency Testing for PSP toxins determination (EURLMB-2015-PT-PSP)
- 3.2.** EURLMB 2015 Proficiency Testing for LPTs determination (EURLMB-2015-PT-LIPO)
- 3.3.** EURLMB 2015 Proficiency Testing for ASP toxins determination (EURLMB-2015-PT-ASP)

The schedule for the Proficiency Testing (registration form , samples dispatch, results submission and PT report) will be agreed by the EU-NRLs network and published at the “EU EURLMB/NRLs timetable of activities for 2015”, which will be circulated to the network in the first quarter of 2015.

NRLs will receive the Programme and the application form to register on the PT trials. Information about the foreseen dates for samples dispatch and results submission and all the required documentation for the studies will be also provided.

Laboratories will follow the EURLMB Instructions and recommendations for the Tests and will confirm the reception of all the documentation. Results of the Proficiency Tests will be submitted to the EURLMB on the Reporting Files taking into account the established deadline.

The results on EURLMB-2015-Proficiency Testings will be presented by the EURLMB during the XVIII Workshop of the European NRL network of marine biotoxins and discussed by the group of participants. A final and detailed report including all the information about participants, aim of the study, schedule and instructions, materials preparation, methods used, evaluation of the results, etc. will be elaborated and edited by the EURLMB for each PT, and after circulation to the participants in the study, for comments and revision, this report will be published at the EURLMB website.

Follow-up actions will be taken with the aim of analysing the reasons for Laboratories underperformance when required. These follow-up actions will also help Laboratories to solve the problems encountered.

A follow-up report on the management, in cases of underperformance in the Proficiency Testing by NRLs, will be submitted to DG SANCO together with the EURLMB technical report for 2014 (planned for March 2015).

4. Missions

- 4.1.** Assist DGSANCO on working groups and meetings related to marine biotoxins. (ongoing participation in the Codex Alimentarius, FVO, etc)

- 4.2. Visit NRLs when necessary, in order to solve problems related with the application and performance of methodologies for marine toxins, or other related issues of interest (results after PT trials, **validation studies**, etc.) (see points 3 and 5). These visits could be also related with Phytoplankton control issues
- 4.3. Participate when requested in activities related to the involvement on the Working Group 5 ('Biotoxins') of CEN/TC 275 Technical Committee "Food Analysis–Horizontal methods" (European Committee for Standardization).The present activity of this Working Group is focused on two HPLC methods (one for ASP toxins and one for PSP toxins) which have been recently proposed to be considered as active work items. This Working Group is expected to meet again in 2015.
- 4.4. Assist Third countries on technical issues upon request.
- 4.5. Participation in International Forums of discussion and scientific events (conferences, seminars, meetings, etc.) related with the advances on the field of Phytoplankton, Marine Biotoxins and their Analysis.
- 4.6. Visits of EURL staff to expert labs to implement methodologies for marine toxins (if required). In this particular point a mission to Chile will be conducted as a request from DGSANCO to participate on an STM activity under the BTSF (Better Training for Safer Food) Program.

5. Research activities on the development of analytical and detection methods

- 5.1. Setting up the Pre-trial for the International Validation of the extension of the LC-MS/MS methodology for multitoxin analysis and further work for the International validation set-up.
- 5.2. Development and optimization of alternative sample pretreatment protocols for the analysis of different groups of marine biotoxins in complex matrices.
- 5.3. Ongoing activities on the setting up, implementation and application of alternative assays (biochemical, biological, etc.) of particular interest for the analysis of Emerging toxins (Ciguatoxins, Palytoxins), work carried out in collaboration with USA and other EU laboratories.
- 5.4. Ongoing activities related with the implementation of methodologies based on LC tandem mass spectrometry (LC-MS/MS) for the determination of Emerging toxins in the EU (Cyclic Imines, Ciguatoxins, Palytoxins)
- 5.5. Development of LC-MS/MS for PSP Toxins.
- 5.6. Implementation of the HPLC-FLD post-column method (AOAC 2011.02 OMA) for the determination of PSP toxins. This implementation will be mainly focused on the improvement of the chromatography, by using alternative chromatographic columns and the extension to additional PSP toxins will be also investigated

Note: All the activities related with Research and Development at the EURLMB will be carried out with the direct support of the research group of the Analytical Chemistry and Food Department of the University of Vigo. Collaboration in these research activities will be emphasized.

6. Implementation of DG SANCO “Protocol for the management of underperformance in comparative testing and/or lack of collaboration of National Reference Laboratories (NRLs) with EURLs activities”

6.1. Underperformance (i.e. failure in proficiency test). See Point 3. The EURLMB will carry out a follow-up of those NRLs that fails in the EURLMB-2014 Proficiency Testing for PSP, lipophilic and ASP toxins determination in order to identify the origin of this underperformance.

6.2. Re-enforcement of the collaboration between NRLs and EURLMB.

According to DG SANCO protocol, the EURLMB will emphasize the contact with NRLs by requesting information about NRLS activities also emphasizing their communication with their own Competent Authorities in particular about EURLMB discussions and activities.

The EURLMB will take special follow-up actions with those NRLs for which a lack of collaboration is detected.

DG SANCO will be informed about all the issues and follow up actions taken as a result of the lack of performance or lack of collaboration of NRLs.