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EUROPEAN REFERENCE LABORATORY FOR MARINE BIOTOXINS

WORK PROGRAMME FOR THE EUROPEAN REFERENCE LABORATORY FOR MARINE BIOTOXINS

January-December 2014

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Work Programme for the EU Reference Laboratory for Marine Biotoxins

Objectives and work plan for the period January-December 2014

LEGAL FUNCTIONS AND DUTIES

The 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.

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

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

Date: to be determined (Oct. - Nov. 2014)

Place: to be agreed during the XVI 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.

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.

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

Support on issues related with the EURLMB Standard Operation Procedures (SOPs) and their application will be provided.

Duration: ongoing.

EURLMB will assist NRLs on the implementation and validation of alternative analytical methods of interest, by providing them with technical information, standards when 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.

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.

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 2013 annual NRLs Workshop that will take place in Split, Croatia in the last week of October (tentatively 24-25). (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).

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

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 2013 annual NRLs Workshop. These meetings will be organised with the participation of experts worldwide.

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).

Extensions and implementations on the applicability of LC-MS/MS to other groups of toxins of interest in the EU, will be emphasized with the aim of having LC-MS/MS as a confirmatory tool for an extended number of marine toxins, particularly now, that the era of the Mouse Bioassay is reaching its end.

Evaluation of the applicability of alternative screening methods such as Cytotoxicity based assays will be carried out. The method set up will be contemplated and additional efforts will be devoted to apply these methods to new and emerging toxins such as Ciguatoxins.

Big priority if 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 alternative methods of interest could be also contemplated if required.

1.6.1. Working groups

1.6.1.1. LC-MS: The activities of this WG will be focused in evaluating implementations on the applicability of this technique, nevertheless the main focus of this group will be the attempt of looking for a worldwide harmonized protocol for multitoxin analysis (LPTs, DA) and to validate this approach internationally, including selected and limited number of experts labs worldwide (Canada, Japan, New Zealand, etc.) on the basis of the one implemented at the EURLMB and UVIGO which has been recently validated in house.

1.6.1.2. PSP: This working group could meet if appropriate (after evaluating needs at the Annual meeting in October 2013). The activities could be focused on the evaluation of potential alternative methodologies such as Receptor Binding Assay (RBA), or LC-MS/MS. Also evaluating the situation with MBA for this particular toxin group could be discussed among the Working Group if appropriate.

1.6.1.3. Emerging Toxins: The possibility of a Working Group meeting to evaluate the situation in Europe regarding the presence of new and Emerging toxins could be evaluated in the Annual meeting in Croatia. Discussions and meetings to evaluate the possibility of joint efforts (participation in projects, collaborations, etc.) to face the problem of emerging toxins in Europe (methodologies, toxicological and epidemiological studies, development of standards and reference materials) will be emphasized by the EURLMB.

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

International Symposiums, Meetings (AOAC Task Force, etc.) to discuss advances in the field of Marine Biotoxins might be organised in the Spring-Summer 2014.

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. Provide technical assistance in the preparation of the project of equivalence of bivalve molluscs EU/US, Discussions are still ongoing and an evaluation of the situation in the EU is being revised at present but further meetings to discuss this particular issue are expected during the period of this work programme.

2.1.3. Technical assistance for CODEX Alimentarius, (participation in Working Groups etc.) will be provided, and 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 different methods applied is evaluated. The EURLMB will organise one trial for each marine biotoxins group legislated in the EU:

3.1. EURLMB 2014 Proficiency Testing for PSP toxins determination (EURLMB-2014-PT-PSP)

3.2. EURLMB 2014 Proficiency Testing for LPTs determination (EURLMB-2014-PT-LIPO)

3.3. EURLMB 2014 Proficiency Testing for ASP toxins determination (EURLMB-2014-PT-ASP)

The schedule for the Proficiency Testing (participants registration, 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 2014”, which will be circulated to the network in the first quarter of 2014.

NRLs will receive the Programme and the Application Forms to register on the PT trials. Information about the foreseen dates for samples dispatch and results submission will be also provided. The samples for PT trials will be accompanied with a letter including the identity Code of each laboratory participant in the study. Participants will also receive by email the protocol for the Testings.

The Sample arrival Form, should be sent to the EURLMB after the reception of the materials and a Reporting Sheet will be also sent for results submission.

The results on EURLMB-2014-Proficiency Testings will be presented by the EURLMB during the XVII 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.

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 2013 (planned for March 2014).

4. Missions

- 4.1.** 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)
- 4.2.** Participate if necessary 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)
- 4.3.** Ongoing participation in the Codex Alimentarius working groups and meetings related to marine biotoxins.
- 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 Marine Biotoxins and their Analysis.
- 4.6.** Visits of EURL staff to expert Labs to implement methodologies for marine toxins (if required).

5. Development of analytical and detection methods

- 5.1.** Setting up of an International Worldwide Validation of an implemented LC-MS/MS methodology for multitoxin analysis with harmonization purposes.
- 5.2.** 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.
- 5.3.** Continuation with tasks 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)
- 5.4.** Evaluation of the applicability of LC-MS/MS for PSP Toxins.
- 5.5.** Development of Citotoxicity-based assays for Ciguatoxins.

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 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 CRLs 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-2013 Proficiency Testing for PSP, lipophilic and ASP toxins determination in order to identify the origin of the bad results.

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

According to DG SANCO protocol, the EURLMB will contact those NRLs for which a lack of collaboration with the EURL is detected.