

## WORK PROGRAMME of EURL for **MARINE BIOTOXINS**

**PERIOD:** 2019-2020

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## INTRODUCTION

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.

From 29 April 2018, Regulation (EU) 625/2017 Art 94(2):

European Union reference laboratories designated in accordance with Article 93(1) shall be responsible for the following tasks insofar as they are included in the reference laboratories' annual or multiannual work programmes that have been established in conformity with the objectives and priorities of the relevant work programmes adopted by the Commission in accordance with Article 36 of Regulation (EU) No 652/2014.

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 2019-2020 work programme 28 Member States and 2 EFTA Member States (Iceland and Norway) are considered eligible for EURL assistance and invited to participate in EURL organised training programmes, comparative testing, etc. Third country laboratories are also invited to participate as appropriate in comparative testing and training activities on a cost recovery basis.

As a result of the reorganization of the tasks covered by the EURL for viral and bacteriological contamination of bivalve molluscs after BREXIT. The EU Commission assigned a new task to the EURLMB related with the classification and monitoring of production areas for bivalve molluscs. According to this new activity, The EURLMB Network will be expanded to include at least 7 Member States with Production areas as well as the 2 EFTA member States (Iceland and Norway) as well as the Three EURLs involved in the activities related to microbiological contamination of BM (E. coli, Salmonella, Virus). Additional Member States with minor production areas could be also included among this Network upon request.

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## TO ENSURE AVAILABILITY AND USE OF HIGH QUALITY METHODS AND TO ENSURE HIGH QUALITY PERFORMANCE BY NRLs.

Please, provided activities related to Regulation (EU) 2017/625:

(Number of Sub-activity boxes can be adjusted by EURL)

- Art. 94.2.a *Providing national reference laboratories with details and guidance on the methods of laboratory analysis, testing or diagnosis, including reference methods.*
- Art. 94.2.b *Providing reference materials to national reference laboratories*
- Art. 94.2.c *Coordinating the application by the national reference laboratories and, if necessary, by other official laboratories of the methods referred to in point (a), in particular, by organising regular inter-laboratory comparative testing or proficiency tests and by ensuring appropriate follow-up of such comparative testing or proficiency tests in accordance, where available, with internationally accepted protocols, and informing the Commission and the Member States of the results and follow-up to the inter-laboratory comparative testing or proficiency tests.*
- Art. 94.2.l *Where relevant for their area of competence, cooperate among themselves and with the Commission, as appropriate, to develop methods of analysis, testing or diagnosis of high standards.*

**Sub-activity 1.1:** Supply information to EU NRLs on analytical methods for marine biotoxins

**Objectives:** *To contribute to the improvements in the performance of the EU harmonised methods*

### **Description:**

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. All the private information of the Network will be published in a restricted area of the EURLMB Website to which, only NRLs can access using a specific code. Additional information might be also supplied by email or any other possible source when requested.

### **Expected Output: improved performance and standardisation across laboratories**

**Duration:** January- December 2019-2020 (ongoing)

EURLMB website is available at: <http://www.eurlmb.org>

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## Sub-activity 1.2: Provide reference materials to EU NRLs

### **Objectives:**

*To help laboratories to implement methodologies and to validate them to reach or maintain accreditation*

### **Description:**

The EURLMB provides reference materials to NRLs when requested and depending on availability, with the aim of helping NRLs with the implementation of their own methodologies in their laboratories.

The reference materials that the EURLMB is currently providing to the NRLs is a new certified reference material for Lipophilic and Amnesic shellfish poisoning toxins. These materials were provided to the EURLMB by the former IRMM. The materials were made through the joint efforts of the (JRC, EU Commission) and the NRC, CNRC (Canada) in the development of reference materials for marine biotoxins, and in particular for Lipophilic toxins, the mentioned reference material consists on a fried dried material (FDMT) with certified value, for Lipophilic toxins together with Amnesic shellfish toxins. The IRMM provided vials containing these materials to the EURLMB, some of which have been already distributed among the EU NRLs to help them with method development for accreditation purposes and also for method implementations. Further distribution of the materials is being considered to NRLs upon request. Some third countries have been also supported on method development and implementation, these materials have been also provided with this aim.

The FDMT is currently commercially available

**Other reference** materials, in particular contaminated samples of different bivalves with different biotoxins profiles and with an assigned value are being also distributed among NRLs when requested and depending on the availability. The homogeneity and stability of these materials are guaranteed.

NRLs are also informed about all the different sources of certified reference materials commercially available.

**Expected Output:** Improved analytical performance and increased harmonization across laboratories

**Duration:** January-December 2019-2020 (ongoing)

## Sub-activity 1.3: Proficiency Testing studies on PSP, ASP and LPTs

### **Objectives:**

*Proficiency Testings (PTs) are organised annually by the EURLMB for the three groups of marine biotoxins included in the EU legislation. PTs are aimed at evaluating the ability of the NRLs to apply the recognised testing methods for marine biotoxins, for the purpose of Regulations (EC) Nos. 853/2004 and 854/2004. The equivalence of the methods applied for the different toxin groups included in the EU Regulation is also evaluated through these tests.*

### **Description:**

The EURLMB organise trials for each of the regulated marine biotoxins group (PSP, ASP and LPTs) and the methodologies included in these PTs will be the ones officially included in the EU Legislation.

All the EU NRLs are requested to participate in these PTs. Two additional NRLs from Europe (Norway and Iceland) are also included in these tests and Official Laboratories from Third Countries of interests for the EU Commission might be also included upon request although these laboratories should cover the shipping costs

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Additional intercomparison exercises might be considered if it is needed, but priorities will be established according to the budget, in order to ensure the efficiency and applicability of the exercises.

The schedule for the Proficiency Testing (registration form, samples dispatch, results submission and PT report) has been agreed by the EU-NRLs network and published at the “EU EURLMB/NRLs timetable of activities for 2019 (the schedule for 2020 will be agreed on the 2019 Annual Workshop) This schedule will be circulated to the network in the first quarter of 2019 and 2020.

NRLs and additional participants will receive all the documentation required to participate on the PT trials. 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 2019 EURLMB—Proficiency Testing will be presented by the EURLMB during the Annual Workshop of the European NRL network of marine biotoxins, which will be scheduled in October 2019, and discussed by the group of participants. (The results for the 2020 EURLMB-PT will be similarly presented during the Annual Workshop (October 2020)

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 on the restricted area for NRLs. Follow-up actions will be taken with the aim of analysing the reasons for Laboratories underperformance when required.

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 Annual Technical report

- **Intercomparison study for the analysis of TTX by HILIC-LC-MS/MS**  
The continuity of this exercise during 2019-2020 will be agreed by the Technical Working Group depending on the needs, nevertheless the inclusion of an intercomparison as a follow up action to the previous exercise, is considered to be performed during 2019. The unavailability of naturally contaminated materials might imply having to continue with the approach of providing NRLs with uncontaminated bivalves matrices spiked with TTX standards. The materials will be distributed among the NRLs interested in participating in this study.  
Reports on the study will be discussed among the WG of technical experts from NRLs and available at the EURLMB website.  
Individual follow up will be also considered to help NRLs to implement the methodology. The results will be also presented to the EU Commission in the Annual Technical report.

## *Expected Output:*

*Comparative testing reports published on the EURLMB Website. Intercomparison study report published on the EURLMB website*

**Duration:** March-September 2019-2020 ( not yet scheduled for TTX)

## ***Sub-activity 1.4: Development of analytical methods for marine biotoxins control***

**Objectives:** *To develop new or implemented methods for the control of existing and emergent toxins in the EU*

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## **Description:**

The research activities focused on method development and considered of relevance in the control of marine biotoxins are summarised below. These activities are supported by the research team of the Analytical Chemistry and Food Department of the University of Vigo, lead by the EURLMB Director and directly involved in the work carried out by the EURLMB under the Contract signed between the AECOSAN and the University of Vigo. The financial support for the research carried out at the EURLMB is mainly provided by the research grants in which the UVIGO research team is involved. Four PhD students are currently involved in these research activities funded by the Xunta de Galicia, University of Vigo, EFSA. The research activity is therefore ensured by the UVIGO team lead by the EURLMB Director but not financial resources for research are taken from the EURLMB budget.

The research activities are prioritised in accord with the current challenges and needs in the control of marine biotoxins, which are also discussed and identified among the NRLs. The EURLMB also collaborates with NRLs on method development and implementation and this collaboration is also extended to experts worldwide through collaborative research projects in which the University of Vigo research team is involved as it was above mentioned.

## **According to this the R&D activities of the EURLMB during 2019-2010 will be focus on:**

- Continuation with activities focused on the development and optimization of alternative sample pretreatment protocols for the analysis of different groups of marine biotoxins in particular for their analysis in processed bivalve molluscs, with special emphasis on the implementation of the sample pretreatment protocols for the analysis of PSP toxins by AOAC 2005.06 (reference method for PSP since January 2019)
- Continuation with ongoing activities related with the implementation of methodologies based on LC tandem mass spectrometry (LC-MS/MS) for the determination of emerging toxins, in particular for Ciguatera poisoning. This research is becoming of particular relevance among FAO/WHO, CODEX, EFSA and the research team of the University of Vigo is directly involved in projects related with the development of methods for the characterization of Ciguatera poisoning by LC-MS/MS, screening of the toxicity by cell assays (N2A), as well as the preparation of reference materials.
- **The research activities of the EURLMB are developed under the research funding of the University of Vigo team (CI8) lead by the EURLMB Director.**
- The characterization of the Ciguatera risk in the EU is being carried out through a research project cofounded by the University of Vigo (UVIGO) and EFSA. The UVIGO coordinates the Specific Grant 4 focused on the risk characterization and the development of standards and reference materials. The outcome of this project will be of a high value for the EURLMB, since the methods and reference materials developed through the project will help future EURLMB activities focused on method development and harmonization through the EURLMB Network. Implementations on the HILIC- LC-MS/MS multitoxin method for PSP, also including TTX to be used as a screening tool for the mentioned compounds, the research at this stage will be focused on the evaluation of alternative HILIC chromatographic columns to implement the method applicability. The implementation of this method will be valuable for the screening of TTXs and also PSPs.

Ongoing activities on the setting up, implementation and application of alternative assays, mostly focused on screening methods, in particular for the evaluation of the cytotoxicity by N2a.

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These assays are being applied to neurotoxins (CTXs, TTXs, PSPs) and as mentioned above are supported by the research team of UVIGO directly involved in this research through the development of PhD projects funded by the UVIGO research sources.

At present this research activity is mainly focused on Tetrodotoxins and Ciguatera toxins in seafood and human samples.

*4 PhD students with UVIGO funding are presently working in the research activities of the EURLMB*

**Expected Output:** Alternative methods for marine biotoxins control

**Duration:** January-December 2019-2020 (ongoing)

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## TO PROVIDE SCIENTIFIC AND TECHNICAL ASSISTANCE TO NRLs

Please, provided activities related to Regulation (EU) 2017/625:

(Number of Sub-activity boxes can be adjusted by EURL)

- **Art. 94.2.d** *Coordinating practical arrangements necessary to apply new methods of laboratory analysis, testing or diagnosis, and informing national reference laboratories of advances in this field.*
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- **Art. 94.2.e** *Conducting training courses for staff from national reference laboratories and, if needed, from other official laboratories, as well as of experts from third countries.*
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- **Art. 94.2.g** *Providing information on relevant national, Union and international research activities to national reference laboratories.*

### ***Sub-activity 2.1 Assist NRLs on the implementation, validation, accreditation of EU Reference methods for the analysis of marine biotoxins***

**Objectives:** *To contribute to the laboratories performance on EU Reference methods for marine biotoxins control*

#### ***Description:***

Support on issues related with analytical methods (Standard Operation Procedures, etc.) for marine biotoxins and their application will be facilitated. This support could be provided electronically, although visits of staff from NRLs to the EURLMB and viceversa when necessary could be also contemplated. EURLMB will also assist NRLs on the implementation and validation of alternative analytical methods of interest, by providing them with technical information, standards and contaminated materials if available, etc., at their request.



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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.

**Two priority necessities** have been identified regarding NRLs method performance, one is related to the need of a improved performance on the **application of AOAC 2005.06** (reference method for PSPs since Jan. 2019) **for the screening of PSP toxins** in routine control, and the other is related to the improvement on the performance on **HILIC-LC-MS/MS** for the control of the **Tetrodotoxin** in bivalves as a follow up on the Proficiency testing carried out in 2018 in which generally poor performance was observed.

**Expected Output:** Improvements in performance and evidence to support robust method performance criteria

**Duration:** January-December 2019-2020 (ongoing)

## *Sub-activity 2.2: Coordination of Working groups of experts among EU NRLs*

**Objective:** *To coordinate efforts to resolve specific issues related with the implementation of analytical methods for marine biotoxins (including emerging toxins) as well as to collaborate in the elaboration and revision of Community Guides for phytoplankton control, marine biotoxins and for microbiological monitoring of BM harvesting areas.*

### **Description:**

Four WG of experts have been identified to conduct the main current activities of the EURLMB: Instrumental methods for marine biotoxins (**Technical WG**) and Guides for the control of: **Phytoplankton, Marine Biotoxins** and **Microbiological** contamination.

Experts from the different areas ( marine biotoxins, phytoplankton and microbiological control of production areas) who are included in the activities of these WGs might work together in particular in the elaboration of the Guide for marine biotoxins and microbiological contamination with the aim of creating a multidisciplinary group of experts covering common areas of interest in the existing and new EURLMB tasks

The WGs will work under the EURLMB coordination through EURLMB experts on the different fields.

### **WG for the Marine biotoxins Guide**

The WG will be focused on the elaboration of a Guide for marine biotoxins has been also created and the experts on this WG have been identified and will work electronically starting the activities in the beginning of 2019. A restricted WG of three experts (EURLMB and two external experts) will lead the activity, the experts met already in 2018 to explore the items to include in this Guide. A physical meeting of the experts will be scheduled for the beginning of 2019 for an initial follow up. The experts will be called again at the end of 2019 to analyse the work of the electronic WG during the first year and to finalize the writing of the initial points. The activity will continue in 2020 working in a similar way with electronic discussions on the issues proposed by the restricted WG who will follow up the activity and will convey again to finalise the document by the end of 2020.

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## - **Technical Working group** (Instrumental methods for marine biotoxins)

As a result of the transition from animal assays for the control of marine biotoxins to chemical methods, in particular chromatographic methods. Only one technical working group of experts in instrumental analysis among the NRLs will be operating to deal with technical issues related to the application of these instrumental HPLC based methods for the control of existing and emerging marine biotoxins. The WG will be coordinated by the EURLMB and will be called when necessary. During 2019-2020 at least three WG meetings will be called, the first one in 2019 will be dealing with the application of the new reference method for PSP (AOAC 2005.06) as screening method since some NRLs experience problems in understanding the applicability of this method for screening purposes, a WG will be organised sometime in the first three months of 2019, to discuss and explain the screening version of this method to be applied in routine control. The EURLMB is collaborating with the expert who developed the method (Dr. J. Lawrence) to elaborate a SOP for the short version of the method, the expert will be also invited to collaborate with this WG. An additional WG meeting will be organised also in the beginning of 2019, to analyse the results of the Proficiency Testing of the LC-MS/MS method for TTX to explore the possible drawbacks and methods pitfalls and also to follow up the reasons for the underperformance of some NRLs involved in this exercise. It is also possible to plan a WG meeting during 2020 to analyse issues with the LC-MS/MS method for PSP or for emerging toxins, but scheduling this meeting is still premature.

## - **Working Group on Phytoplankton control:**

The Working Group (WG) on Phytoplankton is still active electronically, but a restricted WG including six experts has been selected and operated during 2018 to speed the discussions and to reach agreements in a more efficient way. The Guide is almost complete, but there is still one chapter on quality control that is being currently revised by the restricted WG, before is sent to the electronic WG for comments. The restricted WG will be called in the beginning of 2019 to finalize the revision of this chapter and to organize and approve the final version. Further issues of interest on the phytoplankton control might be addressed to be included in these guides and the continuation of the work will be also discussed in among the WG.

Phytoplankton experts involved in the elaboration of these Guides, might be also included in discussions related with the elaboration of the Guide for marine biotoxins and also in the activity related with the microbiological control of production areas. The reason that justifies this inclusion is based on the need for a multidisciplinary approach that would clearly benefit aspects related with the environmental, physical and oceanographic conditions that might affect the sampling and consequently the monitoring and control of bivalve molluscs under both marine biotoxins and microbiological aspects.

## - **Working Group on the Microbiological Monitoring of bivalve molluscs harvesting areas**

This activity will be initiated in January 2019 . A restricted group of experts will be coordinated by the EURLMB who will provide the adequate expertise in Microbiology through the University of Vigo, as it has been done in the past for the phytoplankton activity. The activity is planned based on the previous work carried out by CEFAS, taken into account the main priorities established by the former WG that was working on the implementation of these Guides, who identified two areas where they foresee changes for the next two years 2019-2020 . The work will be organised through discussions among the electronic WG as it was done in the past, and physical meetings will be also organised with a restricted WG of experts under the coordination of the EURLMB.

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In order to speed discussions and also increase the efficiency of the work carried out by the working group, two physical meetings of the restricted WG will be planned for 2019, while at least one physical meeting will be scheduled for 2020. In addition experts from EU NRLs from member States with production areas of bivalve molluscs will be called for the EURLMB Annual Workshop in which discussions and outcomes on the activity on the microbiological control of production areas will be included. Representatives from the EURLs on E.Coli, Salmonella and Virus will be also participating in the EURLMB Annual Workshop, at their own cost, with the aim of being included in the discussions of the Network and also to be updated on the methodological needs or other related issues in the field of the Microbiological control in production areas of bivalve molluscs.

As mentioned above two priority issues need to be considered to be included in the EURLMB WP for 2019-2020 , which are indicated as follows:

1. Changes required subsequent to the entry into force of the implementing regs for 2017/625. Replacing 854. These get voted on in December and will come into force in 2019/2020, there are some modifications to approach, and some additional precision re. sanitary survey review etc which would benefit from some additional clarification in the guides.
2. On the assumption that there will be a recommendation on norovirus standards following the EFSA report early next year, it will be necessary to include a separate section on viruses and additions to sections to cover viruses. Discussions among the group had been already initiated but have not progressed any draft text as yet.

**Expected Output:** Implementation of analytical methods and implementation of the EU Regulation for the control of bivalve molluscs including phytoplankton, marine biotoxins and microbiological control in the production areas

**Duration:** January- December 2019-2020

## ***Sub-activity 2.3: Training activities***

**Objectives:** *To support the setting up of EU reference methods for the control of marine biotoxins in the EU NRLs.*

### ***Description:***

Trainings on methodological advances on Marine Toxins will be organised according to the NRLs needs. Special emphasis will be given to trainings related with implementations on analytical methods for regulated toxins, but training on methods for emerging toxins of particular interest in the EU could be also provided. Participation of Third countries in these training can be also accepted depending on the circumstances and upon the EU Commission approval.

Training activities might be also supported by external experts depending on the training activity and the specific issues involved in these trainings. A training on practical aspects related with the application of the **AOAC 2005.06 (so- called Lawrence method) as a fast screening tool** for PSP toxins will be organized as a continuation of the activities on the technical WG. This training could be scheduled for the first semester of 2019. NRLs with activities on the routine control of marine

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biotoxins in bivalve molluscs, will be invited to participate in this training. Dr Lawrence has accepted the invitation to participate in this training as external expert.

A further training on methodological advances for TTX and PSP by LC-MS/MS could be also provided and scheduled for the first semester of 2020

**Expected Output:** Improvements in performance o and method harmonization

**Duration:** *January-December 2019-2020*

## ***Sub-activity 2.4 Organization of the XXI Annual WORKSHOP of the EURLMB/NRL Network***

**Objectives:** *To coordinate the activities of the EURLMB/NRL Network*

### ***Description:***

The EURLMB will organise, host and coordinate the two Annual EURL Workshops of NRLs for marine biotoxins (2019 and 2020). The participation and involvement of NRLs will be emphasised by requesting the contribution of NRLs, presenting a summary of the activities carried out during 2019 and 2020 . All the activities carried out at the EURLMB will be presented and discussed among the Group.

The new activities on the microbiological monitoring of BM harvesting areas will be also presented and discussed in this Workshop. EU NRLs with activities related with the microbiological contamination of production areas will be invited to the meeting and the expenses will be covered by the EURLMB, also representatives from the 3 EURLs related with microbiological contamination in bivalve molluscs ( *E. Coli*, *Salmonella* and *Virus*) will be invited to participate in the meeting at their own cost. Due to the inclusion of this new activity the Workshop duration will be increased to one more day.

The EURLMB will edit the minutes and conclusions of the meeting which will be distributed to the participants and published at the EURLMB Website.

All the presentations and information of interest provided in the meeting will be also posted at the EURLMB Website in the area restricted to EU NRLs.

The participation of external invited experts in this workshop will be also emphasized in order to have independent views and advice also contributing to a global distribution of the advances and progress in the control of marine biotoxins

**Expected Output:** *Harmonization of official control of marine biotoxins, phytoplankton and microbiological monitoring across network of NRLs*

**Duration:** 2-3 days

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## TO PROVIDE SCIENTIFIC AND TECHNICAL ASSISTANCE TO THE EUROPEAN COMMISSION AND OTHER ORGANISATIONS

Please, provided activities related to Regulation (EU) 2017/625:

(Number of Sub-activity boxes can be adjusted by EURL)

- Art. 94.2.f ***Providing scientific and technical assistance to the Commission within the scope of their mission.***
- Art. 94.2.h ***Collaborating within the scope of their mission with laboratories in third countries and with the European Food Safety Authority (EFSA), the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC).***
- Art. 94.2.i ***Assisting actively in the diagnosis of outbreaks in Member States of foodborne, zoonotic or animal diseases, or of pests of plants, by carrying out confirmatory diagnosis, characterisation and taxonomic or epizootic studies on pathogen isolates or pest specimens.***

### ***Sub-activity 3.1: Provide scientific assistance to DG-SANTE***

**Objectives:** *To provide the expert scientific support and technical advice to the EU Commission when necessary*

#### ***Description:***

The EURLMB will assist DG-SANTE and Directorate on Health and Food Audits and Analysis when requested on issues related with the control of marine biotoxins in molluscs, phytoplankton control, during 2019-2020 the EURLMB will also carry out activities of the WG on microbiological monitoring of BM to take over the responsibility of providing future scientific assistance to DG SANTE on this particular issue.

Any other scientific assistance of interest for DGSANTE will be also provided when requested.

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

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- Technical assistance for CODEX Alimentarius, (participation in Working Groups, meetings, etc. as a part of the EU Delegation) will be provided. Any other technical support requested by DG-SANTE will be also facilitated.
- Assistance to DG-SANTE with issues related with the control of marine biotoxins and phytoplankton also with the microbiological monitoring in bivalves production areas (*new task*)
- Provide scientific advice to EFSA in any issue related with analytical methods for control of marine biotoxins, in particular with toxins emerging in the EU

The EURLMB will participate on an ongoing activity of DG-SANTE through a Working Group on bivalve molluscs in which specific issues of interest related to their control (marine biotoxins control, phytoplankton, microbiological monitoring) are discussed.

The issues affecting marine biotoxins might require the debate through a specific Working group of experts among the EU NRLs. These Working Group meetings will be therefore scheduled during 2019-2020 according to the needs.

**Expected Output:** Supporting EU regulation

**Duration:** January-December 2019-2020

## **Sub-activity 3.2:** *Scientific and technical support and cooperation to other Organizations*

**Objective :** *To provide scientific support and to cooperate with organizations involved in seafood safety In particular bivalve molluscs safety*

### **Description:**

- Participation in relevant EU and International scientific committees (AOAC, EFSA, ICMSS, FAO/WHO)
- Participation in forums of discussions and scientific events (conferences, seminars, meetings, etc.) related with the advances on the field of Phytoplankton, Marine Biotoxins and their Analysis.
- The EURLMB will participate in meetings of special interest for the marine toxin field (AOAC USA 2019, ICMSS Mexico 2019, Gordon Conferences USA 2019-2010 , etc)
- Participation in the CODEX committees related to the control of existing and emerging marine biotoxins (contaminants for Ciguatera Poisoning, analytical methods, etc) 2019-2020

**Expected Output:** Improved analytical performance and harmonization across laboratories involved in EU trades

**Duration:** January- December 2019-2020 (*ongoing*)

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## ***Sub-activity 3.3: Collaboration with third countries within the scope of their mission***

**Objectives:** *To provide support on analytical methods and other issues related with official control of marine biotoxins in bivalve molluscs under the scope of the EU Legislation*

### ***Description:***

- Supply information on analytical methods for marine biotoxins (SOP, performance criteria, validation reports, etc) issues related with marine toxins legislation, information about seminars, missions, etc. Updated information will be posted at the EURLMB Website. Information could be also directly provided by email.
- Technical assistance to third countries on the development, implementation and validation of EU Reference methods for the control of marine biotoxins. Reference materials consisting on contaminated samples from different matrices with different toxic profiles and assigned values for the toxins involved could also be facilitated upon request for own testing on methods performance and internal validation and accreditation.
- Participation in Proficiency Testing could be also contemplated upon request and according to availability. Priority should be given to third Countries with limited resources and involved in commercial trades with the EU. Laboratories from third countries will be responsible for shipping expenses or any other additional fees.

**Expected Output:** Improved analytical performance and harmonization across laboratories involved in EU trades

**Duration:** *January- December 2019-2020*

## ***Sub-activity 3.4 Training activities for third countries***

**Objectives:** *To contribute to the setting up and implementation of EU reference methods for control of marine biotoxins in laboratories from third countries*

### ***Description:***

Participants from Third Countries or from other non EU-NRLs laboratories interested in these trainings could be admitted, upon request and according to availability. These participants will be responsible for their own expenses. The EURLMB will provide the technical expertise, as well as the materials and instruments required for the training activities

Participants could join trainings organized for EU NRLs (depending on availability) but additional trainings could be also provided during 2019-2020 provided that these participants will be responsible for their own expenses. The training needs will be requested with enough anticipation and the EURLMB would approve the training once the request is evaluated also with the EU Commission approval.

**Expected Output:** improvements in performance and harmonisation across laboratories

**Duration:** *January - December 2019-2020*



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### REAGENTS AND REFERENCE COLLECTIONS

Please, provided activities related to Regulation (EU) 2017/625:

(Number of Sub-activity boxes can be adjusted by EURL)

- Art. 94.2.j ***Coordinating or performing tests for the verification of the quality of reagents and lots of reagents used for the diagnosis of foodborne, zoonotic or animal diseases and pests of plants.***
- Art. 94.2.k ***Where relevant for their area of competence, establishing and maintaining:***
  - i. ***reference collections of pests of plants and/or reference strains of pathogenic agents;***
  - ii. ***reference collections of materials intended to come into contact with food used to calibrate analytical equipment and provide samples thereof to national reference laboratories;***
  - iii. ***up-to-date lists of available reference substances and reagents and of manufacturers and suppliers of such substances and reagents.***

**Sub-activity 4.1:** Verification of toxin content in contaminated samples to be used as Laboratory reference materials

**Objectives:** *To obtain laboratory reference materials to be used for setting up analytical methods, method implementation and validation*

**Description:** The limited availability of reference materials for all the marine biotoxins and also for all the matrices involved in the contamination, in particular for new or emerging toxins, makes difficult the progress on the implementation of analytical methods for these particular toxins in these particular matrices. This activity will be focused in the coordination of specific tests among EU NRLs to verify the toxin content, and to provide an assigned value as a result of the intercomparison of the results obtained. These samples could be further used as laboratory reference materials with the mentioned assigned value and would be available to distribute among the EURLMB Network.

This activity is considered an ongoing activity that will continue during 2019-2020. The main focus will be on reference materials consisting on samples naturally contaminated with TTX to have materials available to help NRLs with the implementation of methodologies for the control of TTX. Additional work could be also focused on the verification of the content of additional toxins according to the needs.

**Expected Output:** Increased availability of reference materials for existing and emerging marine biotoxins

**Duration:** January-December 2019-2020



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## REQUIREMENTS RELATED TO OTHER LEGISLATION

Please specify applicable legislation:

(Number of Sub-activity boxes can be adjusted)

*Sub-activity 5.1 (name of Sub-activity)*

Objectives:

Description:

Expected Output:

Duration:

*Sub-activity 5.2 (name of Sub-activity)*

Objectives:

Description:

Expected Output:

Duration:

*Sub-activity 5.3 (name of Sub-activity)*

Objectives:

Description:

Expected Output:

Duration:

*Sub-activity 5.x (name of Sub-activity)*

Objectives:

Description:

Expected Output:

Duration:

# EURL for marine biotoxins

## REMARKS

As a result of the reorganization of the tasks covered by the EURL for viral and bacteriological contamination of bivalve molluscs after BREXIT. The EU Commission assigned new tasks to the EURLMB related with the classification and monitoring of production areas for bivalve molluscs. These activities are mostly related with the provision of technical advice and any necessary revision to Community Guidance on microbiological monitoring of bivalve molluscs. The EURLMB organised this activity following the recommendations provided by the former EURL (CEFAS) and following the same scheme of a WG of experts coordinated by an expert at the EURLMB. The network will be identified focusing on the EU member States with production areas of bivalve molluscs. At least seven Member States are known with significant production areas of bivalve molluscs, additional Member States with minor production could be also included upon request. In order to work on a harmonised way, the EURLs to which other related activities were assigned, will be also included in this Network to be updated in the activities of the working group. The EURLMB will take care of the organization of the Annual Workshop involving the Network related with this new task in which the activities carried out by the WG will be presented and discussed.

The activities carried out to accomplish the new EURLMB Task, related with the classification and monitoring of production areas for bivalve molluscs are summarised as follows:

- Identification of experts among the EU Member States with production areas of bivalve molluscs, and identification of the EURLMB Network for this particular activity. This Network will include representatives from Laboratories EU Member States with production areas of bivalve molluscs, as well as Representatives from EURLs (Salmonella, E. Coli and Viruses).
- Under the coordination of an expert at the EURLMB, a restricted WG of experts on the microbiological monitoring of bivalve mollusc harvesting areas will be convened to operate on a similar way as previously done by the former EURL (CEFAS). Based on their recommendations, the experts on this WG will be selected by invitation among Laboratories from Member States with interest in bivalve molluscs harvesting areas. The experts must have experience on laboratory work. The invitation of external independent experts has been also considered.
- Coordination of the activities of the WG: Definition of the scope of the activities, a physical meeting of the WG of experts will be organised in the beginning of 2019 and a second one will be organised at the end of the year to review the work carried out by the group. At least one additional WG is scheduled for 2020 to review and update the Guides according to issues of particular interest in this period. Additional meetings could be scheduled in 2020 if necessary.
- The Annual EURLMB Workshop will be expanded to include the new Network on classification and monitoring of production areas for bivalve molluscs with the aim of sharing information among the whole Network, as well as to enhance collaboration and communication. The duration of the Annual Workshop will be therefore extended to one more day.

\*The EURLMB estimation budget has been increased to carry out the new activities above indicated