WORK PROGRAMME of EURL for THE MONITORING OF MARINE BIOTOXINS

PERIOD: 01/01/2021 – 31/12/2022

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CONTACT DETAILS

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SUMMARY

INTRODUCTION

The European Union Reference Laboratories (EURLs) are established and designated in accordance with Articles 92 and 93 of Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017, on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products.

The tasks carried out by EURLs must be detailed in their annual or multiannual work programmes, 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 these considerations, the European Union Reference Laboratory for the Monitoring of Marine Biotoxins (EURLMB) presents the 2021-2022 work programme compiling the tasks required to accomplish the responsibility as European Reference Laboratory. These tasks are specified in Article 94 of Regulation (EU) 2017/625 and in Article 2 of Commission Regulation (EU) 2018/222 amending Annex VII to Regulation (EC) n° 882/2004.

At the present time, 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. A limited number of third country laboratories are also invited to participate, as appropriate, in proficiency testing and training activities on a cost recovery basis.

The EURLMB Network has been expanded to include at least 7 Member States with Production areas as well as the 2 EFTA member States (Iceland and Norway). The three EURLs involved in the activities related to microbiological contamination of bivalve molluscs (*E. coli, Salmonella*, virus) will be also included at least on meetings and workshops related with their activities for a better coordination. Additional Member States with minor production areas could be also included among this Network upon request.

ACTIVITIES

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 16 of Regulation (EU) No 2021/690:
(Taking into account Art 147 of (EU) 625/2017)

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

- *Art. 94.2.a* ***Providing national reference laboratories with details and guidance on the methods of laboratory analysis, testing or diagnosis, including reference methods.***

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

2021-2022

Objectives: To contribute to the improvements in the performance of the EU harmonised methods
Description: Issues related with marine toxins EU Legislation, methodologies, standard operating procedures, validation reports, meetings, minutes, conclusions and recommendations, as well as the activities of the EURLMB will continue to be published and updated at the EURLMB Website (http://www.eurlmb.org). All the private Network information will be published in a restricted area of the EURLMB Website only accessible to NRLs by using a specific code. Additional information might also be provided, by email or any other possible source, when requested.
In 2022, analytical related working groups will be included too.
Expected Output: Improved performance and standardisation across laboratories.
Duration: January-December 2021-2022

- *Art. 94.2.b* ***Providing reference materials to national reference laboratories***

Sub-activity 1.2: Provide reference materials to EU NRLs

Objectives: To support laboratories in the implementation and validation of methodologies in order to reach or maintain ISO/IEC 17025:2017 accreditation.

2021

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 might provide at this particular moment consist on a 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. The list of commercially available reference materials is published and frequently updated at the EURLMB Website.

Laboratory Reference materials containing Caribbean Ciguatoxins, in particular C-CTX1 have been provided by the University of Vigo to the EURLMB as key objective of EUROCIGUA (research project co-financed by EFSA). These materials might be also available for distribution among EU NRLs with interest on CTX control. These materials are scarce and very valuable therefore the distribution will be conditioned to the ability of laboratories to perform LC-MS/MS methods for CTXs and this ability has to be demonstrated by showing initial studies on method development using standards for Pacific CTXs.

Expected Output: Improved analytical performance and increased harmonization across laboratories

Duration: January-December 2020-2021 (ongoing)

2022

Description: The EURLMB has FDMT with certified values for Lipophilic toxins and the Amnesic shellfish toxin Domoic Acid. Most of the vials provided have already been distributed among the EU NRLs to help them with method's implementations and development and also for accreditation purposes. A reduced number of vials are still available and could be distributed to NRLs upon request. These vials are expired and in the case of using them for recovery studies a traceability study to non-expired commercially available FDMT would be needed from the EU NRLs side. However, the CRM could also aid laboratories in the implementation of methods for the analysis of some congeners of the emergent toxins Pinnatoxins and Spirolides, which are present in the material

(values non certified). Some third countries have also been provided with this CRM, but distribution to new countries would depend on availability.
The EURLMB will seek contaminated samples of several bivalves with different biotoxin profiles from the EU NRLs. These samples will be used to prepare homogeneous and stable materials that will be employed in the Proficiency Testing Studies. Once analysed by the EU NRLs a consensus assigned value will be obtained and the remaining samples (now RMs) could be distributed to EU NRLs (or even to third countries) when requested depending on the availability. NRLs are also informed about all the different sources of certified and non-certified RMs commercially available. The list of commercially available reference materials is published and frequently updated at the EURLMB Website.
A novel possible development regarding RMs comes from the possibility of obtaining extracts from toxic phytoplankton strains maintained in the culture collection CCVIEO from the Spanish Oceanographic Center in Vigo (IEO, CSIC). These materials could include lipophilic toxins and/or paralytic toxins. The use of CTX-containing dinoflagellate strains is also contemplated. Toxic phytoplankton extracts could be prepared and, provided a good stability is achieved, they could be included as materials for future Proficiency Tests. This way we could calculate assigned values for the toxins present in them. Alternatively, the toxic extracts could be added to blank shellfish tissues in order to produce contaminated samples.
Expected Output: New Tissue Reference Materials. Possibility of toxic culture extracts with assigned values. Improved analytical performance. Aid in staff training purposes.
Duration: January-December 2022.

- *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.***

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

Objectives: Proficiency Tests (PTs) are organised annually by the EURLMB according ISO/IEC 17043/2010 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 2019/627. The equivalence of the methods applied for the different toxin groups included in the EU Regulation is also evaluated through these tests.

2021

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.
In order to advance on the evaluation of the performance of the most recent methodological implementations, the PTs that are planned for 2020-2021 will be focused on the evaluation of

specific issues methodological issues affecting the performance criteria of the methods used for the control of the marine biotoxins included in the Legislation and in particular PSP and LP toxins.
Additional intercomparison exercises in particular to test the proficiency on alternative methods might be considered depending on the availability of participants. 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) will be agreed by the EU-NRLs network and published at the "EU EURLMB/NRLs timetable of activities for 2021. This schedule could be modified and accommodated to the NRLs´s needs due to the uncertain situation with COVID 19. The EURLMB will plan the activities accordingly.
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 2021 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 the October-November 2021 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 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 group is planned for 2021 to discuss analytical criteria and provide indications with the overall objective of Harmonization.

Intercomparison study for the analysis of hydrophilic toxins by HILIC-LC-MS/MS

As mentioned above the inclusion of new alternative methods for existing and emerging toxins might be considered and in this particular case, an intercomparison on the LC-MS/MS methodology to be applied to hydrophilic toxins might be planned and will be carried out depending on the availability of participants and also depending on the availability of contaminated materials. The use of materials "artificially" contaminated with reference materials commercially available might be considered.

Intercomparison study for the analysis of CTXs by LC-MS/MS

As a result of the efforts and achievements on the EUROCIGUA project and after having transferred the LC-MS/MS method from the UVIGO research team to the EURLMB with the UVIGO funding, the methodological transference to the NRLs could be also included in this WP by providing NRLs with reference materials from the University of Vigo to be tested by LC-MS/MS. NRLs will be encouraged to implement LC-MS/MS methods in their labs and the evaluation of their performance might be considered by organizing this intercomparison. The scarcity and high value of the reference materials developed by UVIGO justify the need to ensure that these materials are going to be provided only to laboratories with ability and proved experience to perform LC-MS/MS for the analysis of such complex analytics.
Expected Output: Comparative testing reports published on the EURLMB website. Intercomparison study report published on the EURLMB website
Duration: March -November 2021

2022

Description: The EURLMB organises trials for each of the regulated marine biotoxins group Paralytic Shellfish Toxins (PSTs), Lipophilic Toxins (LTs) and Amnesic Shellfish Toxins (ASTs) 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. Official Laboratories from third countries of interest for the EU Commission might be also included upon request although these laboratories should cover the shipping costs.
The PTs that are planned for 2022 will be focused on the evaluation of specific methodological issues affecting the performance criteria of the methods used for the control of the marine biotoxins included in the Legislation.
The schedule for the 2022 PTs (registration form, samples dispatch, results submission and PT report) will be agreed by the EU-NRLs network early in 2022 and published at the "EU EURLMB/NRLs timetable of activities for 2022. This schedule could be modified and accommodated to the NRLs´ needs due to the uncertain situation with COVID 19. The EURLMB will plan the activities accordingly.
NRLs and additional participants will receive all the documentation required to participate on the PTs. Laboratories will follow the EURLMB instructions and recommendations for the Tests and will confirm the reception of all the documentation. The PTs results will be submitted to the EURLMB on the Reporting Files by the established deadline.
The results on 2022 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 the October-November 2022. Results will be discussed by the group of participants.
A final and detailed report including 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. Each report will be circulated to the study participants for comments and revision. Thereafter the report will be published at the NRLs restricted area of the EURLMB website.
With the aim of evaluating the reasons for certain Laboratories underperformance, follow-up actions will be taken when required. A follow-up report on the management of cases of NRLs underperformance in the Proficiency Testing will be submitted to DG SANTE together with the EURLMB Annual Technical report.
Individual follow up actions for specific issues of interest will be carried out. However, a Working group of NRLs experts in instrumental analysis could be planned for 2022 to discuss analytical criteria and provide indications with the overall objective of harmonisation.
Expected Output: Comparative testing reports published on the EURLMB website.
Duration: January-November 2022

- *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 1.4 Development of analytical methods for marine biotoxins control

2021

Objectives: To develop new or implemented methods for the control of existing and emergent toxins in the EU
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 and founded by research projects from the UVIGO team lead by the EURLMB Director.
As mentioned above, 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.

NO financial resources for research are taken from the EURLMB budget, nevertheless if there is a particular request from the Commission, regarding the inclusion of an activity, related to a new method development, additional testing, etc for new or emerging toxins, the resources for this particular research will come from the Commission 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 2021 will be focus on:

- 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 (CTXs, Cyclic Imines, Tetrodotoxins, Brevetoxins, etc. 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 these emerging toxins by LC-MS/MS.

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. These assays are being applied to neurotoxins (CTXs, TTXs, PSPs, etc) 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.

Expected Output: Alternative methods for marine biotoxins control

Duration: January-December 2021 (ongoing)

2022

Objectives: To develop new or implemented methods for the control of EU existing and emerging marine biotoxins and harmful algal species

Description: Where appropriate, and depending on the available resources, the development of new methods for the control of existing and emerging toxins and harmful algal species will be considered, with the assessment of the research team from IEO, CSIC (Vigo). These activities will be supported by the department of Harmful Algae and Red tides (VGOHAB) from the Spanish Oceanographic Center in Vigo.

This research, complementary and related with the activities of the EURLMB will be supported by the projects in which the VGOHAB team is involved. In this sense, it is planned the incorporation of a researcher hired by IEO, CSIC with the corresponding annual budget allocated for the EURLMB. This staff member will work on the implementation and development of methods for the analyses of emerging toxins (cyclic imines, tetrodotoxins, brevetoxins, etc) by LC-MS/MS.

Regarding cyanotoxins, following an EU JRC technical report issued in 2017 on methods and approaches for cyanotoxins analysis and detection (Sanseverino et al 2017), and attending the interest raised by some NRLs after cyanotoxins detection in shellfish, it is considered to use the available HPLC AOAC 2005.06 OMA method for the evaluation of PSTs of cyanobacterial origin in cyanobacterial strains or shellfish samples. The initiation of the setup of LC/MS-MS methods for other cyanotoxins in the EURLMB could also be contemplated provided it is of interest for the European Comission. Contaminated material could be obtained from NRLs, together with cultures as well as field samples available for this purpose. The cultivation of cyanobacterial strains of interest could be implemented at the IEO, CSIC, and/or in collaboration with other research institutions involved in their study.

Another research task that the IEO is already undertaking (through the recently finished EU-INTERREG Atlantic Area project PRIMROSE and TOXEMER (Grant from Xunta de Galicia) is the

sampling of non-traditional vectors of marine biotoxins in order to analyse regulated and emerging toxins. This activity is of great interest given the fact that some of the non-traditional vectors (i.e. equinoderms, tunicates...) are already regulated in the EU legislation regarding marine biotoxins. The possible collaboration with other IEO, CSIC units through projects could be an advantage in order to get a larger number of samples from different marine fauna and areas. The combination of EURLMB and IEO, CSIC resources would be extremely important for the success of this research activity.
Implementation and application of alternative assays, mostly focused on screening methods, e.g. the evaluation of the cytotoxicity by N2a are of great interest due to their application in assays for CTXs, TTXs, PSTs, etc.). The EURLMB will explore possible collaborations with other institutions involved in this and other assays.
These research activities will be prioritised according to the current challenges and needs in the control of marine biotoxins and harmful microalgal species, which are also discussed and identified among the NRLs.
Expected Output: Advances in analytical methods toward existing and emerging toxins in the EU
Duration: January-December 2022

Sub-activity 1.5 Development of new analytical methods for phytoplankton control and monitoring

2022

Objectives: To develop new or implemented methods for the control of EU harmful algal species
Description: The implementation of fast, sensitive and quantitative methods for detection of harmful algae and cyanobacteria of potential risk for human health relies on molecular methods including both PCR and PCR-independent techniques. After the elaboration of the technical guide for monitoring of toxin-producing phytoplankton in bivalve mollusc harvesting areas, next steps towards the application of molecular methods for specific detection of toxic phytoplankton species of interest should be considered. To this purpose, participants in the WG for phytoplankton control could be revised and pursue their activity in 2022 to address molecular methods of interest and target species for monitoring purposes. The results from this WG would be complementary and could be added as a technical annex on molecular methods to the Guide on Phytoplankton control. Further testing and implementation of these methods on selected target species could be launched in collaboration with IEO, CSIC and interested NRLs, together with external experts from the WG for phytoplankton control. Regarding the latter, assessment from the ICES - IOC Working Group on Harmful Algal Bloom Dynamics (WGHABD), among others, is also considered.
Expected output: To provide protocols for the detection of toxic phytoplankton species of interest for the EU monitoring programmes based on molecular methods.
Duration: January-November 2022

2 TO PROVIDE SCIENTIFIC AND TECHNICAL ASSISTANCE TO NRLs

- *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.***

Sub-activity 2.1 Assistance to NRLs on the implementation, validation, accreditation of EU Reference methods for the analysis of marine biotoxins

2021-2022
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. 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. **Expected Output:** Improvements in performance and evidence to support robust method performance criteria. Coordination of the activities of the EURLMB/NRL Network (official control of marine biotoxins, phytoplankton and microbiological monitoring). **Duration:** January-December 2021-2022 (ongoing)

- *Art. 94.2.g* ***Providing information on relevant national, Union and international research activities to national reference laboratories.***

Sub-activity 2.2 Coordination of working groups of experts among EU NRLs

2021
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 are working 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 the EURLMB experts on the different fields

External experts have been also included in these groups with the aim of having independent and impartial external expert scientific advice.

Working Group for the Marine biotoxins Guide

The WG is focused on the elaboration of a Guide for marine biotoxins. Experts for this WG have been identified and are currently working electronically. A restricted WG of experts including the EURLMB experts as well as external experts are leading the WG and are working on the preparation of the draft in order to speed up the outcome of the activity. The draft document will be distributed among are considered as a preference, but are subjected to the restrictions imposed with the COVID-19 situation. Virtual resources will be considered as a contingency plan. A draft document of the final Guide is expected for December 2021.

- **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 with different detection modes, for the control of existing and emerging marine biotoxins. The WG will be coordinated by the EURLMB and will be call when necessary.

At least two meetings of the Technical WG are being considered during 2021 mostly related to discussion of performance criteria, harmonization on the methods currently used for the control of marine biotoxins as a follow up of the PTs, as discussed above. An additional meeting of the Technical WG will be considered to discuss priorities for method development and implementations for new and emerging toxins. Physical meetings are considered as preference but virtual meetings could be also considered depending on the restrictions imposed by the COVID situation

- Working Group on Phytoplankton control:

The Working Group (WG) on Phytoplankton will remain active but no activities are planned unless a revision of the Guide is requested by the Commission.

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

The WG is currently working on this activity and the revision of the Guide. The EURLMB coordinates this activity with the immediate support of microbiology experts from UVIGO and CSIC (Vigo). An external independent expert in microbiology of bivalve production areas directly supports this activity. An electronic WG of experts with activity on the microbiological control of production areas which has been already working on the activity with the former EURL (CEFAS).

The revision of the Community Guide by the experts is ongoing and it is expected to be finalized by October 2021 as the latest.

Physical meeting of the WG of experts, in particular of the restricted Group are considered but virtual meetings are also considered, this last involving all the member of the WG.

As mentioned in previous WP two priority issues are being considered:

1. Changes required subsequent to the entry into force of the implementing regs for 2017/625, replacing 854/2004. These get voted on in December and will come into force in 2019/2020; there are some modifications to approach, and some additional precision 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, it will be necessary to include a separate section on viruses and additions to sections to cover viruses. In this case the inclusion of the EURL for virus is considered.

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 2021

2022

Objectives: 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: This activity requires coordinated efforts through the corresponding Working Groups (WG) to resolve specific issues related with the implementation of analytical methods for marine biotoxins (including emerging toxins) as well as to culminate the Community Guides for marine biotoxins and microbiological monitoring of bivalve mollusc harvesting areas.

In recent years, four WG of experts were 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) worked together, in particular in the elaboration of the Guides for the control of (1) phytoplankton, (2) marine biotoxins and (3) microbiological contamination. These WGs created a multidisciplinary group of experts covering common areas of interest in the existing EURLMB tasks. The WGs worked under the EURLMB coordination supported by EURLMB, EU NRLs and external experts on the different fields.

The WGs that finished the elaboration of the corresponding Guides will remain dormant until new activities of interest are envisaged. This is the case of the WG on phytoplankton control, which already finished and submitted the Guide to the Commission. Nevertheless, sub-activity 1.5 would require its activation and update of participants in order to accomplish the proposed objective. In addition, if required by NRLs and third countries, the assessment on identification and characterisation of toxic phytoplankton species would be available through the EURLMB, in collaboration with the research group VGOHAB from IEO, CSIC.

Regarding the active WGs (2,3), their composition will be revised and pending tasks will be continued in 2022. These WGs and their tasks are detailed as follows:

- (2) WG for the Marine Biotoxins Guide

A draft document of the final Guide is expected to be issued in December 2021. A restricted WG of experts including the EURLMB experts as well as external experts will work on the preparation of the final document in 2022. This will be distributed electronically among the members of WG for comments and discussion. Physical meetings of the restricted WG of experts are not disregarded, but subjected to the restrictions imposed by the COVID-19 situation. Unless restrictions change substantially, virtual meetings will be prioritised.

- **(3) WG on the Microbiological Monitoring of bivalve molluscs harvesting areas (see II: Regulation (EU) 2018/222)**

It is expected that the WG will provide a revised version of the Guide in October 2021. The EURLMB coordinated the WG activities with the immediate support of microbiology experts from UdV, CSIC and external institutions. As mentioned before, its composition will be revised and updated in 2022. The WG will continue the elaboration of the Guide in 2022 in order to prepare a final version to be sent to the Commission. Virtual meetings will be prioritised over physical ones unless sanitary restrictions are significantly lifted.

In previous Working Plans two priority issues were also considered in this WG:

1. Changes required subsequent to the entry into force of the implementing regulations for 2017/625, replacing 854/2004 that came into force in 2019/2020.

2. On the assumption that a recommendation on norovirus standards was issued by EFSA (EFSA Journal 2019;17(7):5762) mentioned that “the current bacteriological microbiological criteria applicable to live bivalve molluscs might be complemented by a norovirus criterion”, it will be

necessary to include a separate section on viruses and additions to sections to cover viruses. In this case the inclusion of the EURL for virus should be considered.

- Technical WG on Instrumental methods for Marine Biotoxins

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 HPLC based methods with different detection modes, for the control of existing and emerging marine biotoxins. The WG will be coordinated by the EURLMB and will be called when necessary.

A meeting of the Technical WG will be considered to discuss priorities for method development and implementations for new and emerging toxins. As in the previous case, while restrictions imposed by the COVID situation are still active, virtual meetings will be prioritised over physical ones.

One of the issues that should be considered is the recent publication by EFSA on the "Evaluation of the shucking of certain species of scallops contaminated with DA with a view to the production of edible parts meeting the safety requirements foreseen in the Union legislation" (EFSA Journal 2021;19(8):6809).

The EURLMB is considering the creation of a specific WG on Emerging Toxins. This WG would not only work on analytical issues, but would also evaluate the situation in the different EU countries regarding emerging toxins, the studies conducted and the approach followed by the different Member States. It would be a group to exchange and share experiences, samples, etc. and work towards the future. This WG could be created from scratch or could be founded as an extension of the Technical WG on Instrumental methods for Marine Biotoxins.

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

Duration: January- December 2022

- *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.***

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.

2021

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.

A further training on methodological advances for TTX and PSP by LC-MS/MS could be also provided and scheduled 2021

The format of these trainings is also subjected to the COVID restrictions, physical meetings are preferable but virtual trainings, tutorials are also considered.

Expected Output: Improvements in performance o and method harmonization

Duration: March- December 2021

2022

Description: Trainings on analytical methods for marine biotoxins will be organised according to the NRLs needs. Special emphasis will be given to trainings related with implementations of analytical

methods for regulated toxins, but training on methods for the determination of emerging toxins of particular interest in the EU could be also contemplated. Participation of third countries in these training could be also accepted depending on the circumstances and upon the EU Commission approval.
In order to plan this activity, NRLs will be contacted at the beginning of 2022 to gather their interests and prepare the corresponding annual schedule for the training courses.
The format of these trainings is also subjected to the COVID restrictions, physical meetings are preferable but virtual trainings and tutorials will also be considered.
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
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. The particular situation of COVID 19 might affect to this activity, and virtual trainings could be considered.
Expected Output: Improvements in performance and methods harmonisation.
Duration: January-December 2022

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

2021 XXI Annual WORKSHOP **2022** XXII Annual WORKSHOP
Objectives: To coordinate the activities of the EURLMB/NRL Network **Description:** The EURLMB will organise, host and coordinate the Annual EURL Workshops of NRLs for marine biotoxins (2021 and 2022). The participation and involvement of NRLs will be emphasised by requesting the contribution of NRLs, presenting a summary of the activities carried out during 2021. All the activities carried out at the EURLMB will be presented and discussed among the Group. An Annual Workshop for discussing the activities on the microbiological monitoring of BM harvesting areas will be also organised among the EU NRLS involved in this control. The list of NRLs has not been completed yet since some MS did not make yet the formal designation. The updated list of NRLs will be posted at the EURLMB Website as soon as the information is completed. The workshop will be organised also considering the invitation of the 3 EURLs involved in related activities regarding the microbiological contamination in bivalve molluscs (E. Coli, Salmonella and Virus). These EURLs will be invited to participate in the meeting at their own cost. The duration of the meeting will be one full day. The EURLMB will edit the minutes and conclusions of the meetings 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 days (MB) 1 day (Microbiology)

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

- *Art. 94.2.f* ***Providing scientific and technical assistance to the Commission within the scope of their mission.***

Sub-activity 3.1 Provide scientific assistance to DG-SANTE

2021-2022
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 2021. 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) • 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 DGSANTE will be also facilitated. • Assistance to DGSANTE with issues related with the control of marine biotoxins and phytoplankton also with the microbiological monitoring in bivalves production areas • Provide scientific advice to EFSA representing the EURLMB (when requested) 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 during2021 according to the needs. **Expected Output:** To support EU regulation. To provide scientific support and to cooperate with organisations involved in seafood safety, in particular with bivalve molluscs safety. **Duration:** January-December 2021-2022

- *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).***

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

2021-2022

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
- Participation in the CODEX committees related to the control of existing and emerging marine biotoxins (contaminants for Ciguatera Poisoning, analytical methods, etc) 2021-2022

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

Duration: January- December 2021-2022(ongoing)

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

2021-2022

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.
- In 2022, the EURLMB will provide scientific advice to EFSA representing itself (when requested) in any issue related with analytical methods for control of marine biotoxins, in particular with emerging toxins.

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

Duration: January- December 2021-2022

Sub-activity 3.4 Training activities for third countries

2021-2022

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 2021-2022 provided that these participants will be

responsible for would approve the training once the request is evaluated also with the EU Commission approval.
The particular situation of COVID 19 might affect to this activity, therefore considering virtual trainings as contingency plan.
Expected Output: improvements in performance and harmonisation across laboratories
Duration: January - December 2021-2022

4 REAGENTS AND REFERENCE COLLECTIONS

- *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 Preparation of internal laboratory materials

2021

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.
Expected Output: Increased availability of reference materials for existing and emerging marine biotoxins
Duration: January-December 2021

2022

Objectives: To provide materials containing marine biotoxins of interest.
Description: A new project for the EURLMB is the preparation of internal laboratory materials containing marine biotoxins of interest. This task will be carried out taking advantage of the source organisms for marine biotoxins available at IEO (Vigo) (see 94.2.b). Materials could be used for PTs in order to establish assigned values for different toxins. These materials will be extremely useful for setting up analytical methods, methods implementation and validation purposes.
Currently, the limited availability of reference materials for all the marine biotoxins and the different seafood matrices involved in the toxic episodes hampers the progress on the implementation of analytical methods for certain toxins and matrices. This is particularly true for new or emerging toxins. The EU NRLs could supply contaminated materials to the EURLMB where interlaboratory studies among the EU NRLs could be organised in order to verify the toxins contents, and to provide

an assigned value. These materials could be further used as laboratory reference materials and would be available to distribute among the EU NRLs Network. This task would depend much on the materials the EU NRLs could provide.
Expected Output: Increased availability of reference materials for existing and emerging marine biotoxins
Duration: January-December 2022

5 REQUIREMENTS RELATED TO OTHER LEGISLATION

Commission Regulation (EU) 2018/222 of 15 February 2018 amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the European Union reference laboratory for monitoring the viral and bacteriological contamination of bivalve molluscs

• Art. 2. […] The EU reference laboratory for the monitoring of marine biotoxins shall take over the activities related to the classification and monitoring of production areas for bivalve molluscs.

Sub-activity 5.1 Coordination of working groups of experts among EU NRLs

2022

Objectives: Guidelines for the classification and monitoring of production areas for bivalve molluscs
Description: The Working Group on the Microbiological Monitoring of bivalve molluscs harvesting areas is expected to provide a revised version of the Guide in October 2021. The EURLMB coordinated this activity with the immediate support of microbiology experts from UdV, CSIC and external institutions. If the Guide requires further elaboration during 2022, the composition of the WG will be revised and updated, with the aim of submitting the final version as soon as possible in that year.
Expected Output: Guide for the microbiological monitoring of bivalve molluscs harvesting areas.
Duration: January-June 2022

REMARKS

This Work Programme includes the activities of 2021 and 2022; in some cases these appear differentiated in the headings. The director of the laboratory for the period corresponding to the year 2022 is a different person from the director of the year 2021 period. Each director will be responsible with the final report on the activities you have designed and carried out.