



EUROPEAN HEALTH AND DIGITAL EXECUTIVE
AGENCY (HADEA)
Department A Health and Food Unit A2 EU4Health/SMP



Single Market Programme (SMP Food)

SMP-FOOD-2023-EURL-EURC-AG-IBA
Activities of the EU reference laboratories and
EU reference centres in 2023-2024

SUBMISSION FORM: DESCRIPTION OF THE ACTION
(Annex 1 – Description of the action (part B))

SMP-FOOD-2023-EURL-EURC-AG-IBA

**Activities of the EU reference laboratories
and EU reference centres in 2023-2024**

Applicant shall provide information on each question contained in the Form. The information filled in the Form, shall be clear, concise, consistent and complete.

For questions on the information requested in this Form, please contact: please contact: HADEA-EURL@ec.europa.eu.

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Applicant - COORDINATOR (Name of EURL)	European Union Reference Laboratory for monitoring of Marine Biotoxins (EURLMB)
Topic	SMP-FOOD-2023-2024-EURL-EURC-AG-IBA - Activities of the EU reference laboratories and EU reference centres in 2023-2024
Implementation period	1/1/2023 – 31/12/2024

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1. LIST OF ABBREVIATIONS AND KEY WORDS

CRM	Certified Reference Material
FDMT	Freeze-dried mussel tissue
CTX	Ciguatoxin
PSTs	Paralytic Shellfish Toxins
LTs	Lipophilic Toxins
ASTs	Amnesic Shellfish Toxins
PT	Proficiency Test
IEO-CSIC	Spanish Oceanographic Institute
LC-MS/MS	Tandem liquid chromatography mass spectrometry

2. INTRODUCTION

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).

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 2023 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, 27 Member States and the two EFTA Member States (Iceland and Norway) are included in the EURLMB Network for Marine biotoxins control, 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.

Regarding the EURLMB Network for Microbiological control of bivalve molluscs' production areas, it includes nowadays 21 Member States as well as the two EFTA member States (Iceland and Norway). The three EURLs involved in the activities related to microbiological contamination of bivalve molluscs (*E. coli*, *Salmonella*, viruses) would be informed about the activity of the permanent e-WG

on the Classification and Monitoring of Production areas for Bivalve Molluscs, to be created in the beginning of 2023.

3. ACTIVITIES

3.1. 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 3.1.1 *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 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 2023, information about the activities related with the working group on emerging toxins will be included too.

Expected Output: Improved performance and standardisation across laboratories.

Duration: January 2023-December 2024.

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

Sub-activity 3.1.2 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.

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 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 possible development regarding RMs comes from the possibility of obtaining extracts from toxic phytoplankton strains maintained in the CCVIEO culture collection from the Spanish Oceanographic Institute in Vigo (IEO-CSIC). These materials could include amnesic, lipophilic and/or paralytic toxins. The use of CTX-containing dinoflagellate strains (*Gambierdiscus* spp.) 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 2023-December 2024.

- *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 3.1.3 Proficiency Testing studies on PSP, ASP and LPTs

Objectives: Proficiency Tests (PTs) are organised annually by the EURLMB according to 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.

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 (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 2023-2024 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. It is also contemplated to allow the participation of those laboratories able to use the LC/MS-MS method for PSTs analyses. This method is internationally validated, but not recognised by the EU NRLs. The EURLMB thinks, that in order to advance towards new methods, it would be very important to gather information on the performance of the LC-MS/MS method. This can be partially achieved by evaluating the performance of the participant laboratories in future PSTs PTs.

The schedule for the 2023-2024 PTs (registration form, samples dispatch, results submission and PT report) will be agreed by the EU-NRLs network in the first quarter of each year, and published at the "EU EURLMB/NRLs timetable of activities for 2023 and 2024. 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 EURLMB—Proficiency Testing will be presented by the EURLMB during the Annual Workshops of the European NRL network of marine biotoxins, which will be scheduled in October 2023 and 2024. 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.

Expected Output: Comparative testing reports published on the EURLMB website.

Duration: January 2023-November 2024.

Sub-activity 3.1.4 *Intercomparative study on Cyclic Imines by LC-MS/MS*

Objectives: To statistically evaluate the performance of Cyclic Imines analysis by LC-MS/MS with an interlaboratory trial as agreed during the XXIV Annual Workshop of the EU RLMB/NRLs in 2022.

Description: As a request of the EU NRLs participating in the 2022 Working Group in Emerging Toxins, the EURLMB has agreed to organise an interlaboratory trial for Cyclic Imines (Spirolides, Gymnodimine and Pinnatoxins) by LC-MS/MS. This study will be conducted provided the EU NRLs are able to provide any contaminated materials. This trial will be open to a reduced number of laboratories experienced in the analyses of these compounds. EURLMB will contact Greece NRL and other countries (i.e. France) to seek for samples. Moreover, EURLMB will check with EU NRLs analysing these toxins their interest in participation. At least 8 participants should be appointed in order to proceed to statistical evaluation). This activity will be organised in parallel with the 2023 PTs, but will not be considered as a PT itself (i.e. homogeneity and stability studies for samples containing only CIs will not be conducted). This activity will not be open to third countries.

Expected Output: Comparative testing reports published on the EURLMB website.

Duration: January-November 2023

- *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 3.1.5 *Development of analytical methods for marine biotoxins control*

Objectives: To develop or implement new 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 or implementation of 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. After the celebration of the 2022 WG on Emerging Toxins and the 2022 EU NRLs/ EURLMB Workshop priority tasks have been identified. The main task is the analyses of Ciguatoxins by LC-MS/MS and N2a CBA (*Gambierdiscus* spp. strains and fish). Another important task is the implementation of methods for analyses of TTXs in marine gastropods and bivalve molluscs. These methods were employed at the EURLMB in the past, but the trained team in these tasks left. Therefore, the new team needs training and an important effort to continue these tasks. The EURLMB has already been establishing contacts with lead researchers in order to get help with these activities. Collaboration is foreseen with staff from IRTA (Tarragona, Spain) and the National Research Council, Canada for the activities focussed on the analyses of ciguatoxins. The Portugal NRL has also agreed to support us on the analyses of TTXs.

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, a researcher has been already incorporated who is 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 ciguatoxins and tetrodotoxins by LC-MS/MS. Another researcher will be incorporated in the first quarter of 2023.

Another research task that the IEO has been already undertaking (through the 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. echinoderms, tunicates...) are already regulated in the EU legislation regarding marine biotoxins. The collaboration with the IEO-CSIC center of Vigo through projects and opportunistic samplings is an advantage in order to obtain a diverse and large number of samples from different marine fauna, mostly invertebrates, areas and habitats.

The combination of EURLMB and IEO-CSIC resources will be extremely important for the success of this research activity. The IEO-CSIC / EURLMB teams have already collected 240 samples and started their analyses for PSTs, ASTs and Lipophilic toxins (including cyclic imines). The preliminary results of these activities have been presented in the XXIV Annual Workshop in 2022. This is an ongoing activity that will continue until the end of these projects in 2023. However, the EURLMB contemplates to continue with these activities outside the projects scope in 2024.

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 explored possible collaborations with other institutions involved in cytotoxic assays and other methods like LC-MS/MS (IRTA, NRCC).

These research activities will be prioritised according to the current challenges and needs in the control of marine biotoxins and harmful microalgal species, which were also discussed and identified among the NRLs during the Workshop in 2022, and will be agreed with the EU Commission.

Expected Output: Advances in analytical methods toward existing and emerging toxins in the EU

Duration: January 2023-December 2024.

Sub-activity 3.1.6 Development of new analytical methods for phytoplankton control and monitoring

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 of potential risk for human health relies on molecular methods including both PCR and PCR-independent techniques. To this purpose, a new WG for detection of toxic phytoplankton was created in late 2022 to address the state of the art of molecular methods and their application for targeting potentially toxic and noxious species for monitoring purposes. As announced during the annual workshop in 2022, this WG includes experts from the research field related with molecular methods, devoted to specific detection of potentially harmful species, and those EU NRLs interested to contribute with their expertise and feedback. In the case of EU NRLs that do not intend to participate, it was also suggested they could invite official laboratories (OLs) from their network upon their agreement.

The work from this WG in 2023 has been discussed, after obtaining a final list of participants on 15th November, during a first virtual meeting held on 15th December 2022. The main objective will be to elaborate a report with the state of the art of molecular techniques, already used or immediately available, for specific detection of toxic phytoplankton. Such document will include guidelines on protocols with full details in order to enable their implementation in laboratories concerned with monitoring of phytoplankton.

Therefore, the activity of this WG is expected to provide a link between current developments in research of molecular methods and their practical implementation in monitoring programs. The final document should be publicly available and it would be presented during the XX International Conference on Harmful Algae, next 5-11th November in Hiroshima (Japan). Testing and implementation of these methods on selected target species could be launched in collaboration with IEO-CSIC and interested EU NRLs/OLs, together with external experts from the WG. This would consist in a practical training course that could be planned for 2024 regarding specific and simple assays of interest for the EU NRLs and OLs involved in the WG. Regarding the elaboration of the document from the WG, assessment from the ICES - IOC Working Group on Harmful Algal Bloom Dynamics (WGHABD), among others, is also welcome and 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 2023-December 2024

3.2. 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 3.2.1 Assistance to 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, but visits of staff from EU NRLs to the EURLMB and *vice versa* if necessary could be also considered. EURLMB will also assist EU 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 EU NRLs when necessary.

Expected Output: Improvements in performance and evidence to support robust method performance criteria. Coordination of the activities of the EURLMB/EU NRL Network (official control of marine biotoxins, phytoplankton and microbiological monitoring).

Duration: January 2023-December 2024

- *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 3.2.2 *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 analytical methods for marine biotoxins will be organised according to the NRLs needs. The EURLMB will circulate in early 2023 a form for checking the EU NRLs training needs. Requests will be evaluated on a case by case basis and organised according to the EURLMB 2023 Working Plan and its priorities. 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.

Expected Output: Improvements in performance and methods harmonisation.

Duration: January 2023-December 2024.

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

Sub-activity 3.2.3 *Coordination of working groups of experts among EU NRLs*

Objectives: To coordinate efforts to resolve specific issues related with the implementation of analytical methods for emerging toxins, as well as those activities related with toxic phytoplankton and microbiological monitoring of BM harvesting areas.

Description: Four WG of experts have been identified to address several activities of relevance for the EURLMB/EU NRL network: 1) WG on emerging toxins, 2) WG for ciguatera cell-based assay SOP harmonisation, 3) WG on phytoplankton detection and 4) WG on the classification and monitoring of production areas for bivalve molluscs.

Experts from the different areas (emerging marine biotoxins, phytoplankton and microbiological control and classification of production areas) who are included in the activities of these WGs are working together with the aim of creating multidisciplinary WGs covering areas of interest related with the EURLMB tasks. The WGs will work under the EURLMB coordination.

1) WG on emerging toxins

This WG works on analytical issues, but also evaluates the situation in the different EU countries regarding emerging toxins, the studies conducted and the approach followed by the different Member States. It is a group to exchange and share experiences, samples, etc. Its activities continue some of those carried out in the past by the Technical WG (instrumental methods for marine biotoxins).

This WG is intended to share methods and procedures, and addresses the priorities for method development, harmonisation and their implementation for emerging toxins which have been identified as most urgently needed by the EURLMB/EU NRL network.

Virtual and physical meetings, when necessary, are considered to follow up and coordinate its activity, in accordance with the conclusions reached by the WG after its first meeting in October 2022.

2) WG for CTX CBA SOP harmonisation

This group, as requested by the WG on emerging toxins, will deal with this specific task regarding the SOP harmonisation of a cell-based assay for ciguatoxic activity. It will include invited experts who are familiar with these methods from IRTA, IUUSA and EU NRLs interested. This e-WG will be created in 2023 to share methods and procedures, decide the harmonised protocol, etc. Finally, an in person meeting will take place during the WG meeting on emerging toxins.

3) WG on phytoplankton detection

It is expected that this WG will produce a report by the end of the year about molecular methods, both state of the art and recent advances, readily applied for monitoring purposes of harmful algae. This report will be of general interest for the EU NRLs and official laboratories dedicated to phytoplankton, and a first step towards a more widespread application of these techniques for specific detection and monitoring of toxic species difficult, or cumbersome, to identify and quantify using traditional microscopic means. In addition to that, practical workshops could be considered on specific assays of interest for the participants in the WG. Virtual meetings of this e-WG are considered, as well as an in person meeting if necessary, in accordance with the conclusions reached by the WG after its first meeting in December 2022.

4) WG on the Microbiological Monitoring of bivalve molluscs harvesting areas (see Art. 2: Regulation (EU) 2018/222)

Current EU regulation established after Brexit that the EURLMB shall take over the activities related to the classification and monitoring of production areas for bivalve molluscs. At this moment, the EURLMB staff does not have the capabilities and staff with expertise on this issue. Therefore, as requested by the Commission, a permanent eWG including external experts, competent authorities and related EU NRLs, must be created and work, coordinated by the EURLMB, to address any issues regarding this activity. To that purpose, the involved countries have been proposed by the Commission and agreed with the EU NRLs during the annual workshop in 2022. External experts will be contacted in the beginning of 2023, based on those of the Advisory Group for the Community Guide for the microbiological classification and monitoring of bivalve mollusc production and relaying areas.

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

Duration: January 2023-December 2024.

Sub-activity 3.2.4 Organization of the Annual WORKSHOP of the EURLMB/NRL Network

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

Description: The EURLMB will organise and coordinate the Annual EURL Workshop of NRLs for marine biotoxins. The participation and involvement of NRLs will be emphasised by requesting the contribution of NRLs, presenting a summary of the activities carried out during 2023 and 2024. All the activities developed at the EURLMB will be also presented and discussed in these workshops.

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

All the presentations and information of interest provided in the meetings 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: Harmonisation of official control of marine biotoxins across the EU NRLs network.

Duration: 2 days, each meeting

3.3. 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 3.3.1 Scientific and technical support and cooperation to other Organisations

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

Description: The EURLMB will assist DG-SANTE when requested on issues related with the control of marine biotoxins in molluscs and phytoplankton control during 2023 and 2024. The EURLMB through the eWG on microbiological monitoring of bivalve molluscs harvesting areas will take over the responsibility of providing 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 bivalve 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 DGSANTE 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 (such as the WG on emerging toxins) and the EU NRLs. These issues could lead to specific meetings during 2023 and 2024 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 2023-December 2024

- *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 3.3.2 Scientific and technical support and cooperation to other Organisations

Objectives: To provide scientific support and to cooperate with organisations involved in seafood safety in particular bivalve molluscs safety

Description: Participation in relevant EU and International scientific committees (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. In particular, it is planned to participate (at least) in the XX International Conference on Harmful Algae (Hiroshima, 5-11th November 2023). It is also considered a training and research stay on ciguatoxins analysis at the NRCC (Halifax, Canada) during the first part of the year 2023. In 2024 it is planned to participate also in international conferences, such as, at least, REDIBAL (the Iberian meeting on harmful algae) to be held in Spain.
- Participation in the CODEX committees related to marine biotoxins (CCMAS) 2023-2024.

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

Duration: January 2023- December 2024

Sub-activity 3.3.3 Collaboration with third countries within the scope of their mission

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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 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 2023 and 2024, 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 harmonisation across laboratories involved in EU trades.

Duration: January 2023-December 2024.

Sub-activity 3.3.4 *Training activities for third countries*

Objectives: 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 during 2023 and 2024, upon request and according to availability, once the request is evaluated also with the EU Commission approval. 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.

Expected Output: Improvements in performance and harmonisation across laboratories.

Duration: January 2023-December 2024.

3.4. 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 3.4.1 *Preparation of internal laboratory materials*

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 phytoplankton strains from the CCVIEO culture collection available at IEO-CSIC in 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 2023-December 2024.

3.5. 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 3.5.1 *Coordination of working groups of experts related with this task among EU NRLs*

Objectives: Guidelines for the classification and monitoring of production areas for bivalve molluscs.

Description: As stated in the sub-activity 3.2.3, a permanent Working Group on the classification and monitoring of production areas for bivalve molluscs will be created in the beginning of 2023, coordinated by the EURLMB, to take over any issues and official requests on this subject.

Expected Output: Assistance on the activities related to the classification and monitoring of production areas for bivalve molluscs.

Duration: January 2023-December 2024

4. REMARKS

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