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Single Market Programme (SMP Food)

Activities of the EU Reference Laboratories and EU Reference Centres in 2025-2027

SMP-FOOD-2025-EURL-EURC-PJG-IBA 2025-2027

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

SMP-FOOD-2025-EURL-EURC-PJG-IBA 2025-2027

Activities of the EU Reference Laboratories and EU Reference Centres in 2025-2027

Applicant shall provide information on each question contained in the Form.

The **information** filled in the Form, **shall be clear, concise, consistent and complete**.

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Applicant - COORDINATOR (Name of EURL)	European Union Reference Laboratory for monitoring of Marine Biotoxins (EURLMB)
Topic	SMP-FOOD-2025-EURL-EURC-PJG-IBA 2025-2027 - Activities of the EU Reference Laboratories and EU Reference Centres in 2025-2027
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1. LIST OF ABBREVIATIONS AND KEY WORDS

ASTs	Amnesic Shellfish Toxins
CBA	Cell Based Assays
CI	Cyclic Imines
CRM	Certified Reference Material
CTs	Comparative Tests
CTXs	Ciguatoxins
C-CTXs	Caribbean Ciguatoxins
FDMT	Freeze-Dried Mussel Tissue
HPLC-UV	High Performance Liquid Chromatography coupled to Ultraviolet detection
HR-MS/MS	High Resolution Mass Spectrometry
IEO-CSIC	Spanish Oceanographic Institute- Spanish National Research Council
LC-MS/MS	Liquid Chromatography coupled to tandem Mass Spectrometry
LTs	Lipophilic Toxins
NRLs	National Reference Laboratories
N2a	2a Murine Neuroblastoma cell line
PT	Proficiency Test
PSTs	Paralytic Shellfish Toxins
SOP	Standard Operation Procedures
TTXs	Tetrodotoxins

2. INTRODUCTION

[Regulation \(EU\) 2017/625](#) - Article 94(2)

European Union reference laboratories designated in accordance with Article 93(1) shall be **responsible for the tasks** described under section 3 below, 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.

According to these considerations, the European Union Reference Laboratory for the Monitoring of Marine Biotoxins (EURLMB) presents the 2025-2027 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 two EFTA Member States (Iceland and Norway) are included in the EURLMB Network for Marine biotoxins control and considered eligible for EURL assistance, 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 covering their own expenses.

The EURLMB Network for Microbiological control of bivalve mollusc production areas includes 21 Member States and two EFTA member States (Iceland and Norway) and are coordinated through a permanent e-Working Group. Additional Member States with minor production areas could be also included upon request.

3. WORK PACKAGES

3.1. Work Package 1 - AVAILABILITY AND USE OF HIGH-QUALITY METHODS

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

Sub-activity 3.1.1. Providing guidance and updated information on methods for marine biotoxin detection and quantitation to EU NRLs

Objectives: To improve the performance of the EU reference methods.

Description: The EURLMB keeps updated the institutional webpage <http://www.eurlmb.org> where information related to marine toxins, EURLMB functions and the EU NRLs network is published. On this website the most relevant issues related to marine biotoxin EU legislation, standard operating procedures (SOP), validation reports, activities of the EURLMB, meetings, minutes, conclusions and recommendations can be found. The website has a private area managed through the CIRCAB platform for specific network issues, with access restricted to NRLs.

As previously, the webpage and restricted area will be regularly updated, and once approved the work programme (WP) planned for 2025-2027 will be published on the “public documents” section.

Despite the SOP and analytical methods for marine biotoxins detection and quantitation being available on the webpage, an upgrade of the documents is planned. It is envisaged to complement the published procedures with visual workflows and video-tutorials, including a troubleshooting guide for each reference method. Additional information might also be provided, by email or any other possible source, when requested.

Currently, a “white-paper” issuing the monitoring of toxin-producing phytoplankton and the EU marine biotoxins guide are being reviewed. These guides are expected to be finished by 2027 and will be made available on the EURLMB webpage.

Expected Output: Updated protocols and guides available on the EURLMB webpage.

Duration: Webpage updating is expected to be ongoing for the 2025-2027 period. The new protocols and guides are envisaged to be available by 2027.

Sub-activity 3.1.2. Development and improvement of methods for marine biotoxins analysis and control

Objectives: To develop new methods and improve the existing ones for the control of EU regulated and emerging marine biotoxins and harmful algal species.

Description: The advance in technology and the discovery of new biotoxin analogues push the development and improvement in the performance of existing methods and the implementation of new protocols for the detection of toxins and harmful algal species. Specifically, the development of methods for C-CTX and TTX screening and identification of its analogues is of high interest for NRLs.

These activities have been already initiated by the research team from IEO-CSIC (Vigo) and AESAN and supported by the department of Harmful Algae and Red tides (VGOHAB) from the Spanish Oceanographic Center in Vigo, during the last work plan 2023-24. Thus, the analyses of CTXs by LC-MS/MS and N2a CBA (microalgae and fish) initiated in the previous period will continue, with the aim of improving the performance of the extraction and detection methods and identifying new CTX analogues.

Collaboration will continue with staff from IRTA (Tarragona, Spain) for the activities focussed on the screening and analyses of CTXs.

The implementation of methods for TTXs detection is also envisaged for the new period. These works have already started, and several samples of marine gastropods and bivalve molluscs have been already collected and analysed by the EURLMB. However, further development of the methodology and improvement in the identification of TTX derivatives are still needed. The optimization of the chromatographic separation for effective MS/MS identification is envisaged. The Portuguese NRL is supporting us on these tasks.

Screening of TTX by CBAs can be possible and has been previously applied to identify TTX-like toxicity in gastropods from Portugal. The protocol for TTX screening will be tested and improved if possible.

The need for the development of methods for extraction and detection of biotoxins in non-traditional vectors (i.e. echinoderms, holothurians...) has been highlighted by NRLs. This activity is of great interest given the fact that some of the non-traditional vectors are already regulated in the EU legislation regarding marine biotoxins. These tasks have been initiated in the previous period. However, there is still a range of different matrices to be tested and biotoxin recoveries and uncertainty values for each matrix are still to be determined. Regarding new matrices it is aimed the study of toxins in seafood byproducts and in environmental samples.

The development of new analytical methods for phytoplankton control and monitoring was addressed during the WP 2023-24 and a specific WG was established for this purpose. In this new period the application of these techniques will be tested for the study of phytoplankton prevalence and toxicity with the help of IEO-CSIC centre of Vigo, taking advantage of their microalgae culture collection and wide experience in this field.

These research activities will be prioritised according to the current challenges and needs in the control of marine biotoxins and harmful microalgal species, which will be discussed and identified among the NRLs in the annual workshops and working groups and will be agreed with the EU Commission.

Besides, the EURLMB will provide support and reference materials to NRLs when requested and depending on availability, with the aim of helping NRLs with the implementation of the new methodologies in their laboratories.

Expected Output: At least one report or scientific publication on improved marine biotoxin/phytoplankton methods for marine biotoxins control, available on the EURLMB website.

Duration: Studies on improved methods for TTX and CTX are expected to be concluded by 2026. Optimized methods for non-traditional vectors/matrices and phytoplankton will be performed along the period 2025-2027.

Subcontractor 1: subcontracted tasks

-To review the analytical method results of CTXs by N2a CBA (microalgae and fish) & screening of TTX by CBAs. and to participate in the scientific publishing

-To develop at least one phytoplankton method

Sub-activity 3.1.3. Proficiency Tests for PSP, ASP and LPTs

Objectives: Optimal performance in the application of reference methods for marine biotoxins detection and quantitation by NRLs, according to Regulations (EC) Nos. 853/2004 and 2019/627. Performance of NRLs evaluated

Description: As a PT provider, the EURLMB coordinates annual Proficiency Tests (PTs) 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. For the period 2025-2027 EURLMB will keep organizing PTs yearly. The new accreditation ISO/IEC 17043/2023 is expected to be obtained in 2025 and applied afterwards.

The 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 the 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 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 2025-2027 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 on the website "EU EURLMB/NRLs timetable of activities for 2025-2027". NRLs and additional participants will receive all the documentation required to participate on the PTs and the PTs results will be submitted to the EURLMB before the established deadline. By the end of September, the EURLMB will complete and deliver to NRLs the report on the results of PT performance, which will be also published at the NRLs restricted area of the EURLMB website. A summary of this report will be also presented during the annual workshops of

the European NRL network. Results will be discussed with the participants in this meeting. 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 PT will be submitted to DG SANTE together with the EURLMB annual technical report.

Furthermore, the EURLMB will participate itself in PT organised by independent institutions and PT providers.

Expected Output: PT reports (published on the EURLMB CIRCABC restricted area).

Duration: The PTs will be organised yearly between March and September in 2025, 2026 and 2027.

Sub-activity 3.1.4. Comparative Tests (CTs) for the detection of CTX by CBA

Objectives: Standardization of methods for extraction and detection of CTX by N2a CBA.

Description: Due to the lack of reference material for the analytical detection of C-CTXs the screening of fish extracts with N2a CBA has been increasingly used by laboratories around the world. The assay is highly specific and sensitive, allowing for the detection of CTX-like activity and is currently applied in CTX monitoring at the regional level. However, despite its usefulness and widespread acceptance among laboratories the homogenization and standardization of this method is still needed. In the previous WP-period a specific WG of experts was created with the aim of working towards the CTX N2a-CBA SOP harmonization. During these meetings differences in extraction and assay procedures were observed and thus the need of CT was evidenced. This task will be coordinated from the EURLMB and it is expected that all laboratories joining the WG on CTX N2a-CBA SOP harmonization will participate. The invitation will be extended to third countries, as well. At least two CT will be organized in 2026 and 2027, after agreeing the specific procedures, dates and performance criteria to be evaluated, which will be discussed during the 2025's WG meetings.

The EURLMB will also provide the reference material needed for performing the assays. NRLs and research centers may contribute by providing contaminated fish, but microalgae extracts could be obtained as well through the collection of IEO-CSIC centre of Vigo.

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

Duration: At least one CI will be performed in 2026 and another one in 2027.

Subcontractor 1: subcontracted tasks

To review the analytical method results of CTXs by N2a CBA (microalgae and fish) and to participate in the scientific publishing

Sub-activity 3.1.5 Comparative test for the detection of ASP, PSTs and CI toxins by LC-MS/MS

Objectives: Evaluation of the use of LC-MS/MS for ASP, PSTs and CI toxins detection.

Description: LC-MS/MS for ASP toxins detection has been previously used in different studies. Certain laboratories have consulted the EURLMB about the possible application of this method instead of or besides the validated procedure based on HPLC-UV detection. Despite the complete substitution of the current reference method being not possible in the short-term, the evaluation of the performance

of different technologies may facilitate the advancement towards the incorporation of improved protocols and techniques and may be of interest for EU and third countries.

Likewise, LC-MS/MS for PSTs is internationally validated, but not recognised by the EU NRLs. However, to advance towards new methods, it would be very important to gather information on the performance of the LC-MS/MS method. The performance of the LC-MS/MS method for Cyclic Imines (CI) detection and quantitation can be also evaluated along with LPTs PTs.

Thus, the use of the LC-MS/MS method for ASP, PSTs and CI analyses is contemplated if a minimum number of laboratories are interested in testing it and could be scheduled in parallel with PTs for regulated toxins.

The EURLMB will launch a survey to inquire about the number of NRLs interested on the evaluation of the LC-MS/MS method no later than the end of 2025. This survey may be extended to national and international research groups on the study of biotoxins, as well. If the number of laboratories willing to participate in the comparative testing study is enough for this purpose, the EURLMB will plan and coordinate the comparative tests, tentatively scheduled for the beginning 2026 and 2027 along with PTs.

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

Duration: NRLs will be consulted in 2025 and CTs will be organized in 2026 and 2027.

List of Indicators WP1:

- Number of laboratory methods available in the EURL
- Number of laboratory methods for which details and guidance as regards their techniques, validation and interpretation are available in the EURL website (intranet + public domain)
- Number of new laboratory methods developed in the reporting period
- Number of laboratory methods improved in the reporting period
- Number of Proficiency Tests (PTs) organised by the EURL for national reference laboratories/NRLs + ORLs
- Cost of PTs (€) – only transport costs for PT samples
- Success rate of Member States NRLs+OLs in PTs (%)
- Number of Comparative Tests (CTs) organised by the EURL for NRLs
- Cost of CTs – only transport costs for CT samples
- Success rate of Member States NRLs+OLs in CTs (%)
- Number of corrective actions undertaken (aggregated data on corrective actions for all NRLs)

3.2. Work Package 2 - SCIENTIFIC AND TECHNICAL ASSISTANCE TO NRLs

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

Sub-activity 3.2.1. Assistance to NRLs on the implementation, validation, accreditation of EU reference methods for the analysis of marine biotoxins and provide technical support to national bodies and competent authorities

Objectives: To contribute to the NRLs performance on EU reference methods for marine biotoxins control and inform competent authorities on technical and regulatory issues in this field.

Description: As previously stated (sub-activity 3.1.1), protocols for the analysis of the different groups of marine biotoxins regulated in the EU are published on the EURLMB website. Information on regulations and legal issues involving biotoxins is also uploaded on the webpage and available to check.

Besides, any specific information or support related with the application of these protocols as well as legal considerations regarding marine biotoxins will be also directly provided to the EU NRLs, national bodies and competent authorities. The EURLMB will assist on these issues mainly through e-mail and virtual meetings. However, visits of staff from EU NRLs to the EURLMB will be also facilitated and stays of EURLMB staff at NRLs could be also considered, if necessary. EURLMB will help 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, at their request.

Expected Output: List of technical and scientific enquires replied.

Duration: This activity will be ongoing all year round for the period 2025-2027.

Sub-activity 3.2.2. Follow-up of NRL individual work programs and case by case evaluation of the monitoring implementation in NRL's country

Objectives: To provide advice in the application of reference methods to NRLs and apply individual correction factors in PT evaluation if necessary.

Description: NRLs have the legal duty to ensure food safety in mollusc harvesting areas. However, countries have distinct contexts and socioeconomic importance in terms of shellfish production and trade, differing greatly among European countries. Thus, the bulk of samples that each NRL receive for biotoxin analyses, and the routine use of reference methods also vary significantly among these

laboratories. Considering this fact, in those countries where the seafood sector is most relevant, NRL are expected to perform better in PTs as their performance is uttermost for guaranteeing public health and the economic fabric of the region.

Being aware of this diversity, the EURLMB will perform a case-by-case evaluation for each LNR and their individual work-programs with the aim of provide better advice in the application of reference methods and resources allocation. The formulation of common indicators established by consensus to measure laboratory's relevance will assist in the task of LNRs assessment. This appraisal may be of use when interpreting PT's result, providing a reference on the weight of each laboratory in the global performance and their contribution to the reference values.

Expected Output: Report(s) on case-by-case evaluation of NRLs' work programs.

Duration: Information will be gathered during 2025, evaluation of NRLs work program will be completed in 2026 and reports delivered in 2027.

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

Objectives: To joint efforts to solve specific issues related with the implementation of methods for emerging toxins and performance criteria, as well as those activities related with toxic phytoplankton and microbiological monitoring of bivalve mollusc harvesting areas.

Description: Four WG of experts have been created so far to address several activities of relevance for the EURLMB/EU NRL network: 1) WG on emerging toxins, 2) WG for ciguatoxin cell-based assay SOP harmonisation, 3) WG on phytoplankton detection and 4) WG on the classification and monitoring of production areas for bivalve molluscs. The need of a new WG on performance criteria will be discussed during the upcoming 2024's Annual Workshop of the EURLMB/NRL Network and may be planned for the 2025-2027 work programme. 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 work under the EURLMB coordination, and the same structure is planned to continue for the period 2025-2027 with a new WG envisaged. The WGs that will continue as previously will be:

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. 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 are considered to follow up and coordinate its activity.

2) WG for CTX CBA SOP harmonisation

This group, requested by the WG on emerging toxins, deals with this specific task regarding the SOP harmonisation of a cell-based assay for ciguatoxic activity. It includes invited experts from different institutions who are familiar with this method. This WG has been created in 2023 to share methods and procedures, as well as to decide the harmonised protocol that is expected to be tested in CTX CBA interoperative assays.

3) WG on phytoplankton detection

This WG has been working in a report about molecular methods that is expected to be published in the upcoming months. This report is at present under revision by the different members of the WG and will be made available on the EURLMB webpage. The report covers both, the 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. Indeed, these techniques will be of use for specific detection and monitoring of toxic species difficult to identify and quantify using traditional microscopic means and the work of this WG is a first step towards their application. Virtual meetings of this e-WG will be programmed for 2025 and 2026.

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. Considering EURLMB's limited capabilities and staff with expertise on this issue, in 2023, a permanent eWG was organised, as requested by the Commission. This WG includes external experts, competent authorities and related EU NRLs. Coordinated by the EURLMB, this WG addresses any issues regarding the microbiological classification and monitoring of bivalve mollusc production and relaying areas.

5) The need of regulations based on performance criteria instead of fixed official methods has been raised by several NRLs and is an increasing trend in food safety legislation. This new strategy may entail advantages for EU NRLs but requires certain constraints and updated regulations. For this reason, the advancement towards this model needs to be carefully planned. As a first step, a debate on this topic has been scheduled for the 2024's Annual Workshop of the EURLMB/NRL Network. There, the activation of a specific WG focused on this topic will be considered together with the NRLs.

Expected Output: Report of the main WG conclusions on the implementation of methods for emerging marine biotoxin, toxic phytoplankton, and microbiological control

Duration: The WGs will meet regularly during 2025-2027.

Subcontractor 1: subcontracted tasks

-WG on emerging toxins: To participate with investigation tasks results

-WG for CTX CBA SOP harmonisation: To review the analytical method results of CTXs by N2a CBA (microalgae and fish)

-WG on phytoplankton detection: to participate as an expert

Sub-activity 3.2.4. Coordination of working groups of experts related to the classification and monitoring of production areas for bivalve molluscs among EU NRLs

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

Description: 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

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

Expected Output: List of assistance provided on activities related to the classification and monitoring of production areas for bivalve molluscs

Duration: 2025-2027.

Sub-activity 3.2.5. Training activities

Objectives: To support the setting up of EU reference methods for the control of marine biotoxins in the EU NRLs and improve their performance and harmonization. Improvements in performance and methods harmonisation.

Description: Trainings on analytical methods for marine biotoxins will be organised according to the NRLs needs. As previously, the EURLMB will circulate in early 2025 a survey form for checking the EU NRLs training needs on official methods for biotoxin detection. Requests will be evaluated and organised according to the EURLMB 2025-2027 work plan and its priorities, but at least one course on official methods per year is foreseen. Some of the suggested trainings that will be offered to potential participants are a problem-solving course for PSP toxins analysis and a training course on cell-based assays for CTX screening and detection. This course will be scheduled for 2026 and 2027.

Participants from third countries or from other non-EU-NRLs laboratories interested in these trainings could be admitted, upon request and according to availability. The EURLMB would approve the training 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: List of training courses to NRLs and training course materials

Duration: Training courses on official methods for marine biotoxins detection will be performed in 2025, 2026 and 2027. CBA for CTX screening training course will be organised for 2026 and 2027.

Sub-activity 3.2.6. Organization of workshops and meetings

Objectives: To coordinate the activities of the EURLMB/NRL network and exchange relevant findings on the field of marine biotoxins.

Description: The EURLMB organises and coordinates the Annual EURL Workshop of NRLs for marine biotoxins. This meeting gathers every year the heads of the NRLs to present a summary of the activities carried out during the previous period in their laboratories and analyse the state of the art of biotoxins monitoring and control. All the activities developed at the EURLMB will be also presented and discussed in these workshops, including the results of PTs and the new WP. The annual workshops will last no less than one and a half days in a hybrid format, to facilitate participation. The EURLMB staff will be in charge for the participants' registrations and will arrange the facilities needed for holding the event and accommodation for the attendees.

During the meeting the EURLMB staff will guide and moderate the debates and roundtables. They will also gather all the relevant information and write the minutes and conclusions of the meetings which will be distributed to the participants and made available on the restricted area of the EURLMB's website.

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

Besides the Annual EURLMB/NRL Network Workshop, other events will be programmed. At least two in-person meetings of the previously mentioned WG will be programmed in 2025 and 2026, and a three-day seminar on emerging toxins will be organised in 2027.

Expected Output: Minutes and main conclusions of the EU NRLs network workshops and meetings (available on the EURLMB website)

Duration: Annual EURLMB/NRL Network Workshop and WG meetings and seminars will be celebrated in 2025, 2026 and 2027.

Subcontractor 1: subcontracted tasks

To participate as investigation tasks scientific consultancy

List of Indicators WP2:

- Number of workshops & meetings organised
- No. of participants in workshops & meetings
- Cost for workshops & meetings (€)
- Number of technical assistance provided by the EURL to NRLs enquiries

3.3. Work Package 3 - SCIENTIFIC AND TECHNICAL ASSISTANCE TO THE EUROPEAN COMMISSION AND OTHER ORGANISATIONS

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

Sub-activity 3.3.1. Scientific and technical support to EC

Objectives: To provide the expert scientific support and technical advice to the EC.

Description: As previously, the EURLMB will provide scientific and technical assistance to DG-SANTE on issues related to the control of marine biotoxins and in the investigation of outbreaks, when required. The EURLMB may enquire the different WGs and NRLs, if necessary to accurately address the requests of the EU Commission. For instance, the WG on microbiological monitoring of bivalve molluscs harvesting areas will take over the responsibility of providing scientific assistance to DG-SANTE on this particular issue.

Other scientific assistance of interest for DG-SANTE that may be provided by the EURLMB are cases where the results of analysis are contested.

Expected Output: List of scientific and technical support provided upon request by the EC.

Duration: 2025-2027.

Subcontractor 1: subcontracted tasks

To participate as investigation tasks scientific consultancy

Sub-activity 3.3.2. Collaboration activities with other organisations

Objectives: To provide scientific support and to cooperate with organisations involved in seafood safety.

Description: Following the work of previous years the EURLMB will participate in relevant EU and international scientific committees, such as CEN, EFSA, ICMSS and FAO/WHO as well as in the CODEX committees related to marine biotoxins.

As part of their duties, the EURLMB will take part in forums of discussions and scientific events (conferences, seminars, meetings, etc.) related with the advances on the field of toxic phytoplankton and marine biotoxins. These events will provide opportunities for divulgation of the research activities performed at the EURLMB and for networking with other institutions. Taking advantage of the involvement of the IEO-CSIC in the scientific coordination of the EURLMB, the participation in national and international projects as a partner or external assessor is also expected.

Expected Output: Report of scientific events (conferences, seminars, meetings, etc.) attended; oral/poster/other presentation delivered at scientific events

Duration: 2025-2027.

Subcontractor 1: subcontracted tasks

To participate as investigation tasks scientific consultancy

Sub-activity 3.3.3. Collaboration with third countries within the scope of their mission including training activities

Objectives: To provide support on analytical methods and other issues related with official control of marine biotoxins in bivalve molluscs to third countries, under the scope of the EU legislation. Improved analytical performance through their participation in EURLMB's training courses and PTs.

Description: Despite updated information on analytical methods for marine biotoxins being posted at the EURLMB website, the EURLMB will supply information on methods for marine biotoxins (SOP, performance criteria, etc.) to third countries when required, as well as other issues related with marine toxins such as legislation, information about seminars, missions, etc. This information will be provided mainly by email or videoconference. Participants from third countries or from other non-EU-NRLs laboratories interested in EURLMB's trainings could be admitted, upon request and according to availability. The EU Commission will also evaluate the request for their approval. These participants will be responsible for their own expenses, but the EURLMB will provide the technical expertise, as well as the materials and instruments required for the training courses.

The collaboration with third countries would imply the exchange of contaminated samples from different places and matrices with different toxic profiles and assigned values for the toxins involved. This will be of great interest for the study of emerging toxins. Reference material can be also requested to EURLMB by third countries for testing on methods performance and internal validation and accreditation.

Similarly, participation in PTs could be also contemplated upon request and according to availability. Priority should be given to third countries with limited resources and involved in commercial trades with the EU. Laboratories from third countries will be responsible for shipping expenses or any other additional fees.

Expected Output: List of information provided upon request by third countries

Duration: 2025-2027.

List of Indicators WP3:

- Number of technical and scientific feedback provided by the EURL based on European Commission enquiries
- Number of collaboration activities with other organisations

3.4. Work Package 4 - REAGENTS AND REFERENCE COLLECTIONS

- *Art. 94.2.j Coordinating or performing tests for the verification of the quality of reagents and lots of reagents used for the diagnosis of foodborne, zoonotic or animal diseases and pests of plants.*
- *Art. 94.2.k Where relevant for their area of competence, establishing and maintaining:
 - i. reference collections of pests of plants and/or reference strains of pathogenic agents;*

- ii. *reference collections of materials intended to come into contact with food used to calibrate analytical equipment and provide samples thereof to national reference laboratories;*
- iii. *up-to-date lists of available reference substances and reagents and of manufacturers and suppliers of such substances and reagents.*

Sub-activity 3.4.1. Preparation of internal laboratory materials

Objectives: To provide materials containing marine biotoxins of interest. Increased availability of reference materials for existing and emerging marine biotoxins.

Description: Currently, the limited availability of reference materials for certain marine biotoxins and matrices hampers the progress on the implementation of analytical methods for toxin identification and quantitation. This is particularly true for new or emerging toxins.

The EURLMB will seek contaminated samples of several bivalves with different biotoxin profiles from the EU NRLs or by collecting samples during toxic episodes. These samples will be used to prepare homogeneous and stable materials that will be employed in the PT Studies. The EURLMB will verify the toxin contents and profile and provide an assigned value.

Besides, the possibility of obtaining extracts from toxic phytoplankton strains maintained in the CCVIEO culture collection from the Spanish Oceanographic Institute in Vigo (IEO-CSIC) will be explored. The use of marine organisms artificially contaminated with toxic microalgae is also contemplated. Toxic phytoplankton extracts and artificially contaminated material could be then employed as reference material for PTs and CTs.

NRLs are also informed about all the different sources of certified and non-certified RMs commercially available. Furthermore, the list of commercially available reference materials is published and frequently updated at the EURLMB Website.

Expected Output: List of commercially available reference materials

Duration: 2025-2027.

Subcontractor 1: subcontracted tasks

To prepare toxic phytoplankton extracts

To prepare toxic phytoplankton extracts CTX contaminated tissues and toxin profile

Objectives: To obtain CTX-contaminated tissues from marine organisms to identify toxin profiles and metabolization products.

Description: Vectors artificially contaminated with purified standards or internal reference material will be used to study the distribution of toxins in the different tissues, as well as their differential accumulation and elimination rates. The investigation of toxin transformation and metabolization will be also envisaged. These studies will allow for a better understanding of specific toxin allocation and the relative risk of the consumption of certain seafood portions or preparations with respect to others. This understanding is of high interest for emerging toxins, since research on this issue is still limited to a few species and organs. For instance, certain fish species seem to accumulate CTXs mainly in their livers. This knowledge is also useful to select the tissues with the highest concentration of toxins with the aim of obtaining reference material.

Moreover, the study of the toxin profiles is key to elucidate metabolization and depuration pathways and assign the toxicity of specific metabolites. The discovery of unknown metabolization products and new analogues has been hampered by the lack of reference material and the difficulties in molecule identification. However, the great advancements in mass spectrometry, especially after the development of High-Resolution Mass Spectrometry (HR-MS/MS) and the increase in computing capacity has allowed for the description of several insofar unknown congeners (*i.e.* C-CTX-5). The use of a HR-MS/MS would be essential for unravelling toxin profiles of emerging toxin producers and vectors and for achieving the targets set out in this activity.

The collaboration with the IEO-CSIC will ease these tasks, providing the facilities needed for the development of toxin-exposure experiments.

Also, contaminated tissues obtained after the experiments may be used as reference material for their use as internal control in the EURLMB or provided to NRLs upon availability.

Expected Output: List of toxin target tissues identified, and species-specific toxin profiles determined and available as internal reference material

Duration: 2026-2027.

Subcontractor 1: subcontracted tasks

The development of emerging toxin-exposure experiments & related publications

3.5. REQUIREMENTS RELATED TO OTHER LEGISLATION

4. REMARKS

Work Package	Sub-activity	AESAN	Part of the action tasks carried out in each work package by the subcontractor 1:
WP 1 Availability and use of high-quality methods	Sub-activity 3.1.1. Providing guidance and updated information on methods for marine biotoxin detection and quantitation to EU NRLs	Updated protocols and guides available on the EURLMB webpage.	
	Sub-activity 3.1.2. Development and improvement of methods for marine biotoxins analysis and control	At least one report or scientific publication on improved marine biotoxin/phytoplankton methods for marine biotoxins control, available on the EURLMB website.	- To review the analytical method results of CTXs by N2a CBA (microalgae and fish) & screening of TTX by CBAs and to participate in the scientific publishing - To develop at least one phytoplankton method
	Sub-activity 3.1.3. Proficiency Tests for PSP, ASP and LPTs	Carries out annual Proficiency Tests (PTs) according to ISO/IEC 17043/2010 for the three groups of marine biotoxins included in the EU legislation. PT reports (published on the EURLMB CIRCABC restricted area).	

	Sub-activity 3.1.4. Comparative Tests (CTs) for the detection of CTX by CBA	Carries out comparative tests (CTs) for the detection of CTX by CBA, according to ISO/IEC 17043/2010. Comparative testing reports (published on the EURLMB website)	- To review the analytical method results of CTXs by N2a CBA (microalgae and fish) and to participate in the scientific publishing
	Sub-activity 3.1.5 Comparative test for the detection of ASP, PSTs and CI toxins by LC-MS/MS	Carries out comparative tests (CTs) for the detection of ASP, PSTs and CI toxins by LC-MS/MS, according to ISO/IEC 17043/2010. Comparative testing reports (published on the EURLMB website)	
WP 2 Scientific and technical assistance to NRLs	Sub-activity 3.2.1. Assistance to NRLs on the implementation, validation, accreditation of EU reference methods for the analysis of marine biotoxins and provide technical support to national bodies and competent authorities	Assistance and technical support.	
	Sub-activity 3.2.2. Follow-up of NRL individual work programs and case by case evaluation of the monitoring implementation in NRL's country	Report(s) on case-by-case evaluation of NRLs' work programs	
	Sub-activity 3.2.3. Coordination of working groups of experts among EU NRLs	-WG on emerging toxins: coordination and participation -WG for CTX CBA SOP harmonisation: coordination and participation -WG on phytoplankton detection: coordination -WG on the microbiological monitoring of bivalve molluscs harvesting areas (see Art. 2: Regulation (EU) 2018/222): coordination and participation	-WG on emerging toxins: To participate with investigation tasks results -WG for CTX CBA SOP harmonisation: To review the analytical method results of CTXs by N2a CBA (microalgae and fish) -WG on phytoplankton detection: to participate as an expert
	Sub-activity 3.2.4. Coordination of working groups of experts related to the classification and monitoring of production areas for bivalve molluscs among EU NRLs	Coordination and participation	
	Sub-activity 3.2.5. Training activities	Trainings on analytical methods for marine biotoxins will be organised according to the NRLs needs	
	Sub-activity 3.2.6. Organization of workshops and meetings	To organize and coordinate the Annual EURL Workshop of NRLs for marine biotoxins.	To participate as investigation tasks scientific consultancy
	Sub-activity 3.3.1. Scientific and technical support to EC	Provide scientific and technical assistance	To participate as investigation tasks scientific consultancy
WP 3 Scientific and technical assistance to the European Commission and other organisations	Sub-activity 3.3.2. Collaboration activities with other organisations	Provide scientific and technical assistance	To participate as investigation tasks scientific consultancy
	Sub-activity 3.3.3. Collaboration with third	Assistance and technical support. Training and missions	

	countries within the scope of their mission including training activities	activities*. EURLMB PTs results evaluation* *The EU Commission will evaluate the request for their approval	
WP 4 Reagents and reference collections	3.4.1. Preparation of internal laboratory materials	To provide materials containing marine biotoxins of interest	To prepare toxic phytoplankton extracts
	3.4.2. CTX contaminated tissues and toxin profile	To supervise of emerging toxin-exposure experiments and participation in related publishing	The development of emerging toxin-exposure experiments & related publications