pan-European Management of Biological toxin incidents through standaRdisAtion initiatives for Crisis response Enhancement

D2.3
A UCPM biotoxin response capacity - 1st Iteration

Funded by the European Union

EMBRACE is funded by the European Union's Horizon Europe Research and Innovation funding programme, Grant Agreement N° 101168322.

Lead author(s)	Luise Niebisch, Laura Essl
Lead beneficiary	Disaster Competence Network Austria (DCNA)
Status	First Iteration – Final Version
Version	1.0
Due Date	27/03/2026
Delivery Date	31/03/2026
Dissemination Level	Public
Work Package	WP2 Crisis management of biotoxin incidents
Task	T2.3 Requirements and CONOPs for an effective biotoxin response capacity
Contributors	Austrian Red Cross (ARC), Pompiers de l'Urgence Internationale (PUI)
Reviewers	Slovak Office of Standards, Metrology and Testing (UNMS); Resilience Advisors Network (RAN)
Language	English
Format	.pdf
Keywords	Biotoxin management, European emergency response system, civil protection, UCPM, rescEU
Abstract	Capability requirements for an effective pan-European biotoxin response capacity are defined based on identified needs and gaps. The requirements address key aspects of preparedness and response at strategic, operational, and technical levels within the UCPM and will be further refined through alignment with existing capacities and ongoing project activities.
Referencing this document	EMBRACE_D2.3_DCNA_Version_1.0
Disclaimer	The information and views set out in this publication are those of the author(s) and do not necessarily reflect the official opinion of the European Communities. Neither the European Union institutions and bodies, nor any person acting on their behalf, may be held responsible for the use which may be made of the information contained herein

Revision history

Version	Date	Partner	Description / Modification
0.1	05/01/2026	DCNA	Table of Contents
0.2	02/03/2026	DCNA	Draft for review
0.3	06/03/2026	RAN; UNMS	Reviewed draft
1.0	27/03/2026	DCNA	First Iteration – Final Version

Abbreviations

BTF	*Biotoxin Task Force*
FTX	*Field Trial Exercise*
HERA	*European Commission's Health Emergency Preparedness and Response Authority*
TTX	*Table Top Exercise*
UCPM	*Union Civil Protection Mechanism*

Table of Contents

1 INTRODUCTION AND APPROACH TO REQUIREMENTS FORMULATION

This deliverable builds on the findings of Deliverable 2.2 and contributes to Result R03 as defined in the Grant Agreement. Its objective is to formulate capability requirements for an effective biotoxin response capacity within the framework of the Union Civil Protection Mechanism (UCPM). The development of biotoxin-specific concepts of operations constitutes a complementary component of Task 2.3 and is addressed separately.

Deliverable 2.2 examined existing mechanisms for managing biotoxin incidents at both EU and Member State levels. The analysis covered general civil protection structures as well as CBRN-specific arrangements and was based on a structured review of relevant literature and official documents. It was complemented by semi-structured expert interviews and an interdisciplinary stakeholder workshop, which provided practical insights and supported validation of the findings. This approach enabled a systematic assessment of existing capacities and the identification of structural gaps and emerging needs related to biotoxin incidents.

The present deliverable builds directly on these findings. Rather than reassessing the current state, it translates the identified gaps and associated needs into a set of structured capability requirements. While Deliverable 2.2 described the existing situation, this document defines a target state by articulating the structural, coordination-related, and operational conditions necessary to enable an effective and timely pan-European response to biotoxin incidents.

In this context, requirements are understood as formally defined expectations regarding the conditions that should be in place to ensure coherent preparedness and response. They do not prescribe specific technical solutions or operational procedures but establish reference points for strengthening interoperability, harmonization, and strategic alignment within the existing EU crisis management framework. The requirements are designed to be compatible with established European mechanisms, in particular the UCPM and its strategic reserve component rescEU.

This document represents a first iteration of these requirements. Selected elements, particularly those related to operational aspects, may be further examined through upcoming table-top (TTX) and field exercises (FTX). In parallel, structured evaluation within the framework of Task 6.4 and continued consultation with relevant stakeholders, including first responders, technology providers, members of the EMBRACE Biotoxin Knowledge Network such as the Biotoxin Task Force (BTF) and the broader CMINE community, as well as actors within the UCPM framework, will inform further refinement.

In this context, further work will also include a more detailed and systematic reflection of the proposed requirements against existing UCPM response capacities. This will encompass established, certified, and operationally tested modules, capabilities, and resources available through the voluntary pool and rescEU. The objective of this assessment is to better position the identified requirements in relation to current provisions, identify areas of complementarity, and avoid duplication of already existing capacities.

This step will allow for a more precise identification of where additional capacities, adaptations, or enhanced interoperability may be required in the specific context of biotoxin incidents, building on the existing CBRN response landscape within the UCPM framework.

Through this iterative process, the requirements will be progressively reviewed and specified in order to ensure that the final version remains operationally grounded, aligned with the UCPM context, and coherent with existing response capacities.

2 REQUIREMENTS FOR A UCPM BIOTOXIN RESPONSE CAPACITY

The following sections outline the identified needs and gaps in biotoxin response, structured by thematic category. The analysis builds on the findings of Deliverable 2.2, which examined existing capacities and structural weaknesses within the current biotoxin management landscape.

Based on these findings, key capability requirements are derived to strengthen biotoxin response at the strategic, operational, and technical levels. These requirements translate the assessment results into structured capacity objectives.

A dedicated section following the thematic chapters describes the added value and alignment of these requirements with EU-level mechanisms, including the UCPM and rescEU.

2.1 Planning and procedures

2.1.1 Needs and gaps

The analysis identified substantial structural gaps in planning and procedural preparedness for biotoxin incidents across Member States. Existing contingency planning frameworks are predominantly generic and not sufficiently tailored to the specific characteristics of biotoxins. As a result, dedicated planning scenarios addressing biotoxin-specific exposure pathways, environmental persistence, decontamination requirements, and recovery phases remain underdeveloped or absent.

Operational guidelines for response, decontamination, and re-classification of affected areas are either lacking or not harmonised, leading to inconsistent approaches and reduced interoperability in cross-border contexts. The absence of clearly defined responsibilities for crisis declaration further complicates timely activation of response mechanisms. Unclear governance structures may delay escalation and hinder coordinated action at national and EU levels.

In addition, regulatory coverage does not comprehensively address biotoxin-specific contingencies, increasing the likelihood of ad hoc decision-making during incidents. This fragmented procedural landscape undermines predictability, consistency, and coordinated preparedness for biotoxin-related emergencies.

2.1.2 Derived requirements

R1 Establishment of a harmonized biotoxin-specific emergency response planning framework

A harmonized EU-level emergency response planning framework for biotoxin incidents shall be established, incorporating dedicated contingency planning scenarios and clearly defined escalation pathways.

R2 Development of standardized operational guidelines

Standardized, biotoxin-specific guidelines for response, decontamination, and re-classification shall be developed to ensure coherent and interoperable implementation across Member States.

R3 Clarification of crisis declaration and governance responsibilities

Clear responsibilities and activation mechanisms for crisis declaration in biotoxin incidents shall be defined within the relevant governance structures to ensure timely and coordinated response.

R4 Strengthening of regulatory preparedness for biotoxin incidents

Regulatory frameworks shall ensure adequate coverage of biotoxin-specific scenarios to prevent ad hoc responses and to support predictable and legally robust crisis management.

2.2 Coordination and management

2.2.1 Needs and gaps

Structural gaps in coordination and management arrangements for biotoxin incidents have been identified. Clear management structures and defined role allocation are not consistently established, resulting in a lack of clarity regarding responsibilities in crisis situations.

Coordination mechanisms are frequently fragmented within a country. The absence of centralized coordination structures or predefined coordination nodes contributes to duplication of efforts, unclear information flows and reduced strategic oversight. Domestic inter-agency coordination, particularly between relevant authorities, is not yet systematically institutionalised and requires strengthening.

At the international level, coordination mechanisms for biotoxin incidents are not systematically structured, particularly regarding pan-European risk assessment and joint situational awareness. Cross-border information sharing is further constrained by the lack of secure, interoperable communication channels that enable timely and reliable exchange of sensitive data across sectors.

In addition, structured frameworks for civil-military collaboration in the context of biotoxin response are not consistently defined, resulting in limited formalisation of cooperation arrangements.

Overall, the coordination and management landscape is characterised by fragmentation, limited interoperability, and insufficiently formalized cross-sectoral and cross-border cooperation.

2.2.2 Derived requirements

R5 Establishment of clear management structures and role allocation

Clearly defined management structures and explicit role allocation for biotoxin incidents shall be established to ensure clarity of responsibility and decision-making bodies.

R6 Development of centralised coordination mechanisms

Centralized coordination mechanisms shall be established to reduce fragmentation and ensure coherent management of biotoxin incidents across sectors and jurisdictions.

R7 Strengthening of domestic inter-agency coordination

Structured and institutionalized inter-agency coordination frameworks shall be implemented at national level to ensure effective cooperation among relevant authorities.

R8 Enhancement of international coordination mechanisms

Structured international coordination mechanisms, including arrangements enabling pan-European risk assessment, shall be strengthened to support coherent cross-border response.

R9 Implementation of secure cross-sectoral information exchange systems

Secure and interoperable information exchange mechanisms shall be established to enable protected and reliable cross-sectoral data sharing in a timely manner, including interoperable data exchange formats enabling structured sharing of epidemiological, toxicological and environmental monitoring data across agencies and Member States.

R10 Formalisation of civil-military collaboration frameworks

Clear and structured frameworks for civil-military collaboration in biotoxin response shall be defined to ensure coordinated cooperation where applicable.

2.3 Laboratory, detection and risk assessment

2.3.1 Needs and gaps

Laboratory, detection, and risk assessment capacities relevant to biotoxin incidents show several areas for improvement. Laboratory infrastructures are not yet sufficiently developed or harmonized, either within individual countries or across Member States, resulting in uneven analytical capabilities and methodological inconsistencies. Detection and identification methods likewise require further refinement and alignment to ensure consistent and reliable results. In addition, laboratory systems face limitations in scaling operations during crisis situations. Restricted surge capacity can constrain the ability to meet increased analytical demand in biotoxin-related emergencies.

Risk assessment approaches for biotoxin incidents remain only partially integrated and would benefit from a more proactive and forward-looking framework. Current structures do not yet provide a fully coherent basis for anticipatory preparedness and response.

International laboratory collaboration also remains limited in its level of institutionalization. Joint exercises and structured laboratory networks are not consistently embedded, reducing opportunities for harmonization, shared capacity building, and coordinated preparedness at the European level.

Overall, laboratory and analytical preparedness for biotoxin incidents is characterized by gaps in harmonization, limited scalability, and fragmented international cooperation.

2.3.2 Derived requirements

R11 Harmonized and expanded laboratory capacity

Laboratory capacities relevant to biotoxin detection and analysis shall be expanded and harmonized to ensure consistent analytical standards and comparable capabilities across Member States.

R12 Accessibility of laboratory networks and availability of mobile laboratory capacities

Accessibility of relevant laboratory networks shall be ensured, and mobile laboratory capacities shall be maintained and made available for biotoxin incidents.

R13 Strengthened detection and identification capabilities

Detection and identification methods for biotoxins shall be enhanced and aligned, supported by harmonised validation protocols, certified reference materials, and clearly defined performance criteria (such as sensitivity, specificity, and limits of detection), to ensure reliable, accurate, and timely

confirmation of biotoxin presence as well as comparability and consistency across laboratories and field-deployable systems.

R14 Scalable laboratory surge capacity

Mechanisms shall be established to ensure adequate laboratory surge capacity, enabling rapid scaling of analytical operations during biotoxin incidents.

R15 Integrated and proactive risk assessment frameworks

Integrated and proactive risk assessment mechanisms for biotoxin incidents shall be established.

R16 Performance standards for field-deployable detection systems

Performance standards for field-deployable biotoxin detection systems shall be developed and established.

2.4 Resources and equipment

2.4.1 Needs and gaps

The analysis identified gaps in the availability and structured management of key resources required for responding to biotoxin incidents. Adequate stockpiles of personal protective equipment are not consistently maintained, and antidote reserves are similarly not systematically secured.

Mechanisms for international resource sharing and joint procurement are also not fully established, which can limit coordinated access to critical equipment during cross-border events.

Overall, resource preparedness for biotoxin incidents is characterized by inconsistencies in stockpiling practices and limited structuring of international resource-sharing mechanisms.

2.4.2 Derived requirements

R17 Adequate personal protective equipment stockpiles

Adequate and strategically managed stockpiles of personal protective equipment shall be ensured to support safe and sustained response to biotoxin incidents, and such equipment shall comply with biotoxin-specific performance criteria based on harmonized European standards or validated technical specifications.

R18 Standardized and validated biotoxin-specific decontamination procedures

Standardized and validated biotoxin-specific decontamination procedures for personnel, equipment, and infrastructure shall be developed and implemented.

R19 Secured antidote stockpiles

Appropriate and accessible antidote stockpiles shall be established and maintained to enable timely medical response in biotoxin exposure scenarios.

R20 Structured mechanisms for shared resources and joint procurement

Mechanisms for shared international resources and joint procurement shall be established or strengthened to support coordinated acquisition and availability of critical equipment for biotoxin response.

2.5 Training and awareness

2.5.1 Needs and gaps

Structural gaps remain evident in training and awareness related to biotoxin preparedness and response. Comprehensive and standardized training for relevant actors is not consistently implemented, and dedicated training centres focusing specifically on biotoxin-related scenarios are generally not established. As a result, preparedness levels vary and the development of structured, specialized capabilities remains limited.

International training and simulation exercises addressing biotoxin incidents are also not systematically organized, reducing opportunities for coordinated cross-border preparedness and for practical testing of response mechanisms.

Within the broader CBRNe preparedness landscape, biotoxins are only partially embedded as a distinct risk category and are not consistently addressed as a domain requiring dedicated consideration. Public awareness campaigns addressing biotoxin-related risks are not systematically implemented, and broader public understanding of associated risks and appropriate response behavior remains limited.

Risk communication protocols for informing the public during biotoxin incidents are also not clearly defined or standardized, creating uncertainty regarding communication approaches in crisis situations.

Taken together, training arrangements, institutionalized exercise formats, awareness measures, and public communication structures related to biotoxin response remain only partially harmonized and formalized.

2.5.2 Derived requirements

R21 Comprehensive and standardized training for all relevant actors

Comprehensive and standardized training for all relevant actors involved in biotoxin response shall be established, including defined qualification standards and the adaptation and extension of existing basic training programs.

R22 Harmonized qualification profiles and certification mechanisms

Harmonized qualification profiles and, where applicable, certification mechanisms for biotoxin response personnel shall be developed to ensure comparable competency levels across Member States.

R23 Dedicated biotoxin training centres

Dedicated training centers for biotoxin preparedness and response shall be established or designated.

R24 International operations-based exercises with relevant stakeholders

Structured international training and operations-based exercises for authorities and response entities addressing biotoxin scenarios shall be established and conducted on a regular basis.

R25 Recognition of biotoxins as a distinct risk category

Biotoxins shall be formally recognized and addressed as a distinct risk category within preparedness and response frameworks.

R26 Crisis communication protocols for the public

Clear and standardized crisis communication protocols for the public shall be developed and implemented for biotoxin incidents.

R27 Improved public awareness campaigns

Structured and sustained public awareness campaigns addressing biotoxin-related risks shall be developed and implemented.

2.6 Knowledge, networking and policy

2.6.1 Needs and gaps

Structural gaps are evident in knowledge management, networking, and policy alignment related to biotoxin preparedness and response. Systematic knowledge-sharing mechanisms are not consistently in place, limiting the structured exchange of expertise, lessons learned, and technical information. Networking and contact-building structures at both domestic and international levels are not comprehensively embedded in existing frameworks, which constrains sustained professional exchange and formal cooperation.

Real-time data systems are underdeveloped and lack interoperability, reducing the ability to access and share up-to-date information in a timely manner. In addition, a dedicated early warning mechanism specifically focused on biotoxin risks is not in place, limiting the structured detection and communication of emerging threats.

Policy frameworks addressing biotoxin preparedness and response show limited harmonization at national and EU levels, contributing to inconsistencies in regulatory approaches and strategic alignment.

Taken together, knowledge exchange arrangements, data management systems, networking structures, and policy frameworks remain fragmented and only partially aligned.

2.6.2 Derived requirements

R28 Systematic knowledge sharing mechanisms

Structured and systematic mechanisms for knowledge sharing related to biotoxin preparedness and response shall be established and maintained.

R29 Real-time data databases

Real-time data databases relevant to biotoxin incidents shall be developed, maintained, and made accessible to relevant authorities, following interoperable data structures that enable structured cross-border exchange and integration into European situational awareness platforms.

R30 Dedicated biotoxin early warning mechanism

A dedicated early warning mechanism addressing biotoxin risks shall be established.

R31 Structured domestic and international networking mechanisms

Formalized networking and contact-building mechanisms at domestic and international levels shall be established to support sustained cooperation in biotoxin preparedness and response.

R32 Policy harmonization at national and EU level

Policy frameworks related to biotoxin preparedness and response shall be harmonized at national and EU levels to ensure greater consistency and alignment.

R33 Structured reachback mechanisms and access to expertise networks

Structured reachback mechanisms shall be established to ensure timely access to specialized expertise and existing knowledge networks in support of biotoxin response, including, for example, the Biotoxin Task Force and other relevant expert networks within the civil protection framework.

2.7 Funding and sustainability

2.7.1 Needs and gaps

Structural gaps are evident in the area of funding and the long-term sustainability of biotoxin preparedness and response capacities. Sustainable financing mechanisms are not consistently established, creating uncertainty regarding the continuity of core capabilities.

For projects addressing biotoxin-related topics, provisions for sustainability beyond the lifetime of individual initiatives are typically included at the project level. However, capacities developed within time-limited projects are not systematically integrated into stable and enduring structures, and longer-term embedding in institutional frameworks remains uneven.

Taken together, funding arrangements and sustainability mechanisms for biotoxin-related capacities provide limited long-term security and structural continuity.

2.7.2 Derived requirements

R34 Sustainable long-term financing mechanisms

Sustainable long-term financing mechanisms for biotoxin preparedness and response capacities shall be established to ensure continuity and stability.

R35 Project sustainability beyond project lifetime

Mechanisms shall be established to ensure that capacities developed within projects are sustained and embedded beyond the project lifetime.

R36 Structured innovation uptake and use of existing EU funding instruments

Existing EU funding instruments relevant to civil protection and health security shall be strategically and systematically utilized to support the uptake of innovative solutions in biotoxin preparedness and response, including instruments under the UCPM or HERA.

2.8 Contribution to the European crisis management framework

The proposed requirements define the structural and operational conditions for strengthening biotoxin preparedness and response within the existing European crisis management architecture. They build on established EU instruments and are designed to enhance coherence, interoperability, and system maturity without creating parallel frameworks or duplicating existing mechanisms.

In the areas of planning, procedures, and coordination, the requirements support clearer role allocation and more structured governance. This reduces ambiguity in crisis situations, facilitates coherent decision-making, and improves the reliability of cross-border cooperation.

With regard to laboratory, detection, and risk assessment capacities, the requirements promote greater analytical consistency and comparability across Member States. Strengthened laboratory networks, improved detection approaches, scalable surge arrangements, and more integrated risk assessment practices provide a more reliable technical basis for operational decisions and shared assessments.

Resource-related measures, including stockpiling and joint procurement approaches, improve the availability of and coordinated access to critical assets, supporting more balanced material preparedness across countries.

Training, awareness, and knowledge-related requirements enhance interoperability at both human and institutional levels. More consistent training approaches, structured exercises, strengthened networking, improved data exchange, and greater policy alignment foster sustained cooperation and shared understanding across sectors and borders. Clear recognition of biotoxins as a distinct risk category ensures systematic consideration within broader preparedness frameworks.

Funding and sustainability-related requirements reinforce longer-term continuity by promoting stable financing arrangements and the sustained integration of capacities developed through time-limited projects into enduring structures.

In relation to rescEU, the requirements strengthen the governance, technical compatibility, and resource environment within which strategic reserve capacities operate. Clear planning frameworks, aligned standards, structured coordination, and coordinated stockpiling arrangements enable predictable integration of reserve assets into national and cross-border response settings, thereby increasing the added value of EU-level capacities in biotoxin scenarios.

Beyond governance and technical compatibility aspects, the requirements also strengthen the operational relevance of rescEU capacities in the context of biotoxin incidents, particularly with regard to strategic stockpiling and the availability of critical response assets. Biotoxin scenarios may require rapid access to specialized personal protective equipment, detection systems, medical countermeasures, antidotes, or deployable laboratory capabilities that are not consistently available at national level. By promoting harmonized planning assumptions, standardized operational guidelines, and structured mechanisms for shared procurement and resource management, the proposed requirements facilitate the effective integration and deployment of rescEU stockpiles in support of national response operations.

In this regard, improved alignment between national preparedness planning and EU-level reserve capacities enhances the usability and responsiveness of rescEU assets during cross-border or high-

impact incidents involving toxic biological substances. Requirements related to surge laboratory capacity, mobile analytical capabilities, and coordinated stockpiling arrangements contribute to ensuring that rescEU-supported resources can be activated in a timely and operationally meaningful manner. This strengthens the material basis for a European response to biotoxin emergencies and supports more equitable access to critical equipment and medical countermeasures across Member States in situations where national capacities are exceeded.

In addition, the proposed requirements contribute to improved functional linkage between the UCPM and the European Commission's Health Emergency Preparedness and Response Authority (HERA), particularly in relation to preparedness planning, medical countermeasure availability, and joint situational awareness. Biotoxin incidents represent a cross-sectoral risk domain in which public health and civil protection response capacities must be activated in parallel. The establishment of harmonized planning assumptions, scalable laboratory surge mechanisms, and structured reachback arrangements supports the alignment of operational response activities under the UCPM with health security preparedness measures coordinated through HERA.

Strengthened interoperability between UCPM response modules, rescEU capacities, and HERA-supported stockpiling, procurement, and threat assessment functions enables a more integrated European approach to managing biotoxin-related emergencies. In particular, coordinated approaches to antidote availability, medical countermeasures, and laboratory diagnostics benefit from the complementary mandates of both frameworks. This reduces fragmentation between crisis response and health preparedness domains and supports more coherent activation of European-level assistance in complex incidents involving toxic biological substances.

Furthermore, the integration of training, exercises, and knowledge-sharing arrangements across UCPM and HERA-relevant stakeholder communities contributes to the development of a shared operational understanding of biotoxin risks. Embedding biotoxin-specific scenarios in joint preparedness activities, including UCPM-funded training and simulation exercises, facilitates cross-sectoral learning and supports the progressive institutionalization of cooperation between civil protection authorities and health emergency preparedness actors at national and EU level.

The proposed requirements may also inform future contributions to relevant European Standardization Technical Committees and address disaster preparedness, decontamination procedures and crisis management frameworks.

3 CONCLUSION AND OUTLOOK

This deliverable translates the findings of Deliverable 2.2 into a structured set of capability requirements addressing identified needs and gaps in biotoxin preparedness and response. The assessment confirmed that the observed shortcomings extend beyond isolated technical issues and reflect broader structural, governance, and interoperability challenges across strategic, operational, and technical levels.

The proposed requirements articulate a coherent target state for strengthening biotoxin response capacities within the existing European crisis management architecture. They provide a capability-oriented reference framework that supports harmonization, institutional embedding, and longer-term sustainability while remaining aligned with established EU instruments.

By addressing planning and governance, coordination and information exchange, laboratory and analytical capacities, resource management, training and awareness, knowledge structures, and sustainable financing, the requirements contribute to greater coherence, interoperability, and scalability of response arrangements across Member States. In doing so, they help define the structural conditions necessary for a more predictable and integrated approach to biotoxin-related risks.

At the same time, this set of requirements represents an initial iteration rather than a finalized framework. It establishes a structured baseline for further refinement and targeted development. In the next phase, the proposed requirements will be reviewed and discussed with relevant stakeholders in order to assess feasibility, prioritization, and alignment with operational realities.

This iterative process will support the progressive adaptation and specification of the requirements, with the objective of formulating targeted recommendations that contribute to the further strengthening of the UCPM. The present deliverable therefore lays the foundation for a structured continuation of work toward a more coherent and strategically aligned European approach to biotoxin preparedness and response.