EU REPORT



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POLICY REPORT - Patras Medicine iGEM 2026

BIOSAFETY AND BIOSECURITY IN THE EUROPEAN UNION AND GREECE

Key terms, EU stakeholders and measures, application across Member States and in Greece, and contemporary gaps and challenges

KEY TERMS: BIOSAFETY AND BIOSECURITY

BIOSAFETY

Biosafety refers to the containment principles, technologies and practices implemented to prevent unintentional exposure to biological agents or their accidental release. In laboratory settings, it includes risk assessment and the implementation of appropriate safety measures such as containment procedures, personal protective equipment, staff training and safe handling and disposal of biological materials. The World Health Organization (WHO) promotes a **risk-based approach** in which safety measures are selected according to the risks associated with the specific activity [1].

BIOSECURITY

Biosecurity refers to the principles, technologies and practices used to protect, control and maintain accountability for biological materials and the equipment, skills and information related to their handling. Its aim is to prevent **unauthorized access**, **loss**, **theft**, **misuse**, **diversion** or **release** of biological materials. In research environments, biosecurity also involves assessing the potential misuse of biological materials, technologies and research outputs. Relevant measures may include **access controls**, **inventory management**, **authorization procedures** and protection of sensitive biological information [1, 2].

KEY DIFFERENCES BETWEEN BIOSAFETY AND BIOSECURITY

Although biosafety and biosecurity are closely interconnected, they address different sources of biological risk. Biosafety primarily focuses on preventing **accidental exposure** and **unintended release**, whereas biosecurity focuses on preventing **unauthorized access** to or **misuse** of biological materials and related information. In practice, biosafety measures may include appropriate containment facilities, protective equipment, decontamination and waste management procedures. Biosecurity measures may include restricted laboratory access, secure storage of biological materials, inventory controls and procedures for authorizing access. Neither field can fully replace the other. A laboratory may have appropriate containment procedures but inadequate access controls, or strong security measures but insufficient safeguards against accidental exposure.

Effective biological risk management therefore requires **both biosafety and biosecurity measures**, supported by risk assessment, staff training and appropriate institutional oversight [1, 2].

EU STAKEHOLDERS & MEASURES IN PLACE

INTRODUCTION

In the **European Union (EU)**, biosafety and biosecurity are distinct but **interconnected regulatory fields**, meaning the EU legislative bodies - the European Parliament and the Council of the European Union - act on a **shared** competence. In practice, legislative powers are distributed between the EU and its Member States according to the specific subject matter and legal basis of the measures concerned. This report mainly focuses on biotechnology laboratory work, Research & Development, hence the following information centers around that specific area. The following section is split into two segments: the Stakeholders (EU Bodies, organisations and associations that legislate on and advocate for biosecurity and biosafety and the measures already in place regarding the field (existing Directives, guidelines and regulations). [3]

STAKEHOLDERS

EUROPEAN BIOSAFETY ASSOCIATION (EBSA)

The European Biosafety Association (EBSA) is a **non-profit** professional association bringing together stakeholders from across the scientific and technical fields, including researchers, laboratory professionals and other experts in biosafety and biosecurity. Its main objectives include raising awareness, promoting safe and effective laboratory practices, and providing scientific and technical expertise to inform policy development and legislative decision-making at the European level. To advance these objectives, EBSA organises **workshops**, **conferences** and **meetings** across Europe, facilitating knowledge exchange, professional collaboration and dialogue on emerging challenges in biosafety and biosecurity. [4]

DIRECTORATE-GENERAL FOR HEALTH & FOOD SAFETY (DG SANTE)

Directorate-Generals (DGs) are departments within the European Commission that focus on a specific policy area through **coordination**, **legislation** and **funding**. Since the European Commission constitutes the main institution responsible for drafting legislative proposals, its distinct departments are of vital importance. Within this framework, DG SANTE contributes to the development of policies and legislative proposals aimed at protecting **public health** from biological risks, including those associated with laboratory activities and the handling of biological materials. It also supports coordination between Member States and the development of measures and guidelines designed to promote safe laboratory practices and the appropriate management of biological risks. [5]

EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL (ECDC)

The European Centre for Disease Prevention and Control (ECDC) is an **agency** that plays an important role in biosafety and biosecurity, particularly in the context of public-health laboratories and safety against infectious diseases. It supports Member States by strengthening laboratory capacity, coordinating networks of public-health microbiology laboratories, providing scientific advice and promoting consistent diagnostic methods and good practices. In a nutshell, the ECDC prepares **extensive precautions** for biological threats and contributes to the safe and secure handling of biological materials. [6]

JOINT RESEARCH CENTRE (JRC)

The Joint Research Centre (JRC) is the European Commission's science and knowledge service, providing independent scientific evidence and technical expertise to support EU policymaking. In the fields of biosafety and biosecurity, the JRC contributes to the assessment and mitigation of chemical, biological, radiological and nuclear (CBRN) risks through scientific research, technical support and cooperation with European and international partners. Its role is **primarily scientific** and **advisory** rather than legislative or regulatory. [7]

> *Important Note:* This section primarily focuses on **EU-level** stakeholders with the authority to influence biosafety and biosecurity policies across the European Union. However, it is important to emphasise that **Member States** and their national competent authorities bear **primary responsibility** for implementing applicable legislation and guidelines, ensuring compliance with safe laboratory practices, and upholding biosafety and biosecurity standards within their respective national systems. This report will further discuss the Member States' conformity to those guidelines, in the following sections.

MEASURES IN PLACE

The aim of this section is to provide a **short overview** of some of the existing guidelines, binding legislation and regulatory frameworks designed to safeguard and strengthen biosafety and biosecurity across the European Union. Rather than offering an exhaustive account of all policies and instruments relevant to these fields, the section focuses on **key legal and policy developments**, highlighting particularly significant measures and recent initiatives that shape the EU's approach to biological risk management.

This report firstly outlines the binding policies and will further mention the non-binding recommendations and guidelines.

BINDING LEGISLATION

In 2000 the European Parliament and the Council of the EU formed a Directive on the **protection of workers** from risks related to exposure to biological agents at work (**Directive 2000/54/EC**). This constitutes a binding policy which establishes minimum requirements to protect workers against risks to their health and safety arising from occupational exposure to biological agents. It forms part of the EU's broader occupational health and safety framework under Directive 89/391/EEC. The Directive 2000/54/EC suggests means to prevent as well as incident management and incident reporting, while highlighting risk assessment as a key step in laboratory practices. [8]

Another binding policy from the EU legislative bodies, is the **Directive 2009/41/EC** on the **contained use of genetically modified micro-organisms (GMMs)**. It establishes common measures for activities involving GMMs carried out under specific containment conditions, with the objective of preventing adverse effects on human health and the environment. The Directive builds upon risk classification - in four classes - within laboratory practices that include the use of GMMs, stressing the course of action and the severity of the response in each case. It also urges Member States to establish procedures for notifying authorities in case of hazardous incidents and demands that high-risk activities require written consent before their execution. [9]

NON-BINDING FRAMEWORKS

In 2020, the **World Health Organisation (WHO)** released their fourth edition of the **Laboratory Safety Manual**, a complete document providing a comprehensive, evidence-based framework for managing biological risks in laboratory settings. The manual offers guidance on risk assessment, the selection and implementation of appropriate control measures, and the establishment of safe laboratory practices. The manual is supported by a series of seven subject-specific monographs addressing key areas such as laboratory design and maintenance, biological safety cabinets, personal protective equipment, decontamination and waste management, biosafety programme management, and outbreak precautions. Together, these resources help laboratories develop appropriate procedures, strengthen staff training, and foster a culture of safety and accountability. [1]

A more recent development is the 2024 Council’s **Recommendation on enhancing research security**. It recognises that scientific research and international collaboration can create security risks if knowledge, technologies or research results are misused or transferred inappropriately. The Recommendation therefore encourages the Member States, the European Commission and research institutions to take a more coordinated approach to safeguarding research. While it is not directly linked to its effect on laboratory research and experimentation and fails to mention any similar setting whatsoever, its content strongly outlines the importance of safeguarding information. We can therefore connect it to the importance of taking the necessary measures to prevent a detrimental impact that could possibly derive from the wrongful treatment of biological results and equipment. [10]

APPLICATIONS OF BIOSAFETY & BIOSECURITY MEASURES BY THE EUROPEAN UNION MEMBER STATES

INTRODUCTION

Based on the analysis of the legal Framework implemented by the European Union, as well as measures adopted by member states, this section of the report examines how these are applied in practice and how individual member-states approach Biosafety and Biosecurity altogether.

To analyse the applications of said framework, we will have to take into account how theoretical measures such as European, WHO [1], and UN laws and guidelines translate into enforceable laws and guidelines, and where national law is complementarily taken into consideration. This section of the Report will therefore analyse the stakeholders responsible for enforcing the existing Biosafety & Biosecurity Framework (*the entirety of laws, guidelines, regulations and directives), the Framework's level of strictness, and therefore where member-states differ in approaching Biosafety and Biosecurity, and how this is practically built into science and everyday life.

In this section, the word Framework will include and refer to the entirety of laws, guidelines, regulations and directives not only proposed and passed by the EU, the WHO and the United Nations.

MAIN BODY

For the purpose of this analysis, the Framework applies across multiple pillars of science and includes [9]:

- **HOSPITALS, LABORATORIES AND INDUSTRIAL FACILITIES**: To ensure pathogen containment while handling microorganisms and biological material (BSL 1-4), protecting workers of said environments (PPE protocols, containment facilities, and training to personnel working with biological agents), and Physical Asset Security (access control, background and inventory checks) [1, 8]
- **GMOs**: Regulating research, dev and industrial application of GMMs within lab environments to ensure no environmental leakage (GMOs are tested to ensure the retention of biodiversity, GMO derived food or other products are thoroughly evaluated by EFSA and labeled as such before entering the EU Market.) [9]
- **SYNTHETIC BIOLOGY & BIOTECHNOLOGY, USES OF AI IN BIOLOGICAL SCIENCES**: Genetic Material & Sequencing Screening, Dual-Use Regulation (strict control of biological material and software), AI Guardrails (regulating the use of AI models that are capable of designing novel biological threats or helping in the optimization of pathogens)
- **FOOD, ANIMAL AND PLANT HEALTH** (controlling the spread of animal to human pathogens, and invasive species-pests)
- **WASTE DISPOSAL** (Standards for transporting and tracking infectious biological samples within the union).
- And broader biosafety and biosecurity practice in **public health** [11]

In these sectors the enforcement and application of the Framework mentioned previously depends on national legislation as well as the European Laws and guidelines.

In 2011, a major European biosafety event was organised and in this event several topics on the applications of a framework were discussed as well as the importance of Biosafety Associations in pursuing advancements in Biosafety.

In the aforementioned event, it is noted that all Member-States have the **EU Directives** implemented as national legislation, some countries more extensively than others and some with focus on containment of genetically modified microorganisms. Meanwhile training regarding Biosafety is available in member states to a varying degree from technical and theoretical in one country to no training at all. [11]

As highlighted in the Important Note of the section “EU Stakeholders & Measures in Place”, Member States and their national competent authorities bear primary responsibility for implementing the applicable legislation and guidelines within their national systems. Therefore, although these sectors are regulated through common European legislation, the degree to which member states expand upon these requirements varies significantly. Consequently, differences emerge in training standards, oversight mechanisms, institutional structures, and national biosecurity and biosafety strategies.

ANALYSING THE DIFFERENT TYPES OF APPROACHES

The proposed classification of each member state’s Biosafety and Biosecurity measures is done according to **four indicators**:

- The presence of dedicated national biosafety or biosecurity legislation.
- The existence of specialised oversight authorities, agencies, or national strategies.
- The availability of structured biosafety training programmes and awareness initiatives and
- The adoption of additional measures aligned with WHO guidance, UN frameworks, and stakeholder recommendations.

So, the three following categories are identified according to the extent to which they implement Biosafety and Biosecurity beyond minimum requirements:

IN CATEGORY 1 (thereby referred as c1)(strictest): Countries included enforce not only European legislation, and additionally align their national practices with WHO guidance, UN frameworks, and stakeholder recommendations, and go beyond that by having specific national legislation separate from EU ones, and host Associations and Organizations promoting Biosafety and Biosecurity.

IN CATEGORY 2 (thereby referred as c2)(intermediate): Countries included enforce European legislation, WHO and UN guides, as well as stakeholders guidelines and proposals. However, they do not possess the same specialised national legislation and oversight institutions and mechanisms

IN CATEGORY 3 (thereby referred as c3)(minimum compliance): Countries included primarily rely on the minimum European legislation established through EU directives that as mentioned act as national legislation in all 27 EU member-states.

CONCLUSION

The analysis demonstrates that while EU legislation establishes a common ground on biosafety and biosecurity, **substantial differences** remain regarding how each member state implements the non-binding framework, oversees training and capacity. This is relatively more evident in newly emerging sectors of the biological sciences, such as synthetic biology, bioinformatics and the use of AI in the biological Sciences, due to the difference in how quickly these sectors advance in comparison to the regulatory frameworks.

Complementarily, it should be noted that, the lack of awareness on the importance of said measures, financial issues, and the lack of guidance on how to implement non binding measures, further worsen the dissimilarity in the legal framework of member states. [11]

Therefore, **strengthening cooperation** between EU institutions, organisations and national authorities could fill in the legal gaps and protect the sectors that could be affected by a biosecurity crisis, creating a more harmonised and resilient biosafety and Biosecurity environment across Europe.

APPLICATION OF BIOSAFETY & BIOSECURITY MEASURES IN GREECE

INTRODUCTION

Greece addresses biosafety and biosecurity through **European Union legislation**, **national legal measures** and **international commitments**. The relevant frameworks cover occupational exposure to biological agents, the contained use of genetically modified microorganisms, the deliberate release of genetically modified organisms into the environment and controls on specified dual-use items [9, 12–15].

However, the existence of a regulatory framework does not, by itself, demonstrate how consistently or effectively measures are implemented in practice. This section examines the main areas covered by the available legal and institutional frameworks and identifies implementation challenges documented in Greece's latest national report under the Cartagena Protocol on Biosafety.

MAIN BODY

The application of biosafety and biosecurity measures in Greece can be examined across the following areas:

1. HOSPITALS, LABORATORIES AND RESEARCH FACILITIES

Presidential Decree 102/2020 establishes requirements for protecting workers from risks arising from exposure to biological agents at work. It implements the European framework established by **Directive 2000/54/EC**, as amended by subsequent European legislation. The relevant framework addresses occupational risks associated with biological agents and should not be interpreted as a comprehensive assessment of all laboratory biosafety practices in Greece [12].

2. GENETICALLY MODIFIED ORGANISMS (GMOS)

Greece operates within the European Union framework governing genetically modified organisms. **Directive 2001/18/EC** addresses the deliberate release of GMOs into the environment, while **Directive 2009/41/EC** regulates the contained use of genetically modified microorganisms. **Regulation (EC) No 1829/2003** establishes requirements for genetically modified food and feed [9, 13, 14].

Greece is also a Party to the **Cartagena Protocol on Biosafety**, which establishes an international framework for addressing potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking into account risks to human health. Greece's ratification of the Protocol is recorded in its national report as having taken place through Law 3233/2004 [15].

3. BIOTECHNOLOGY, SYNTHETIC BIOLOGY AND DUAL-USE RISKS

Regulation (EU) 2021/821 establishes a European Union system of controls on the export, brokering, technical assistance, transit and transfer of specified dual-use items. Its scope includes certain biological agents, toxins and related technologies listed under the relevant control provisions [16].

The UNIDIR/VERTIC database on national implementation measures for the Biological Weapons Convention records Greek legal measures relevant to biological risk management and dual-use controls. However, the database states that it has not identified publicly available information on the oversight of dual-use research in the life sciences in Greece. This is a limitation in the information identified by that database and **does not** establish that no oversight mechanisms exist [17].

4. FOOD, ANIMAL AND PLANT HEALTH

The European Union framework also addresses potential risks associated with genetically modified food and feed and the environmental release of GMOs. Regulation (EC) No 1829/2003 concerns genetically modified food and feed, while Directive 2001/18/EC addresses the deliberate release of GMOs into the environment [13, 14].

Greece's Fifth National Report under the Cartagena Protocol identifies the European Union legislative framework as the basis for several aspects of national implementation. These measures concern specific risks associated with GMOs and should not be taken as evidence that every area of food safety, animal health or plant health is governed by a single biosafety system [15].

5. BIOLOGICAL MATERIAL HANDLING AND TRANSFER

The contained use of genetically modified microorganisms is regulated by Directive 2009/41/EC, which establishes requirements relating to risk assessment and containment [9]. Separately, Regulation (EU) 2021/821 governs specified activities involving dual-use items, including certain transfers and exports [16].

These frameworks address different regulatory objectives. They should not be interpreted as a single system covering every type of biological material or every activity involving its handling and transfer.

IMPLEMENTATION CHALLENGES IDENTIFIED IN THE NATIONAL REPORT

Greece's Fifth National Report on the Implementation of the Cartagena Protocol on Biosafety was submitted on 18 September 2026 and covers the period ending on 28 February 2026. In the report, Greece indicates that national measures for implementing the Protocol are partially in place [15].

The report identifies several challenges specific to the implementation of the Cartagena Protocol:

- **RESOURCES:** Greece reports that no resources for biosafety are available from the national budget.
- **STAFFING:** The report records between five and nine qualified staff members whose functions are directly related to biosafety and assesses this number as inadequate.
- **PUBLIC COMMUNICATION:** Biosafety is reported to be incorporated into educational and training programmes. However, the report indicates that Greece has no national communication strategy or dedicated awareness and outreach programmes on biosafety.
- **PUBLIC PARTICIPATION:** The report indicates that Greece has not established a mechanism to facilitate and promote public participation in decision-making concerning living modified organisms during the reporting period.

These findings are taken from Greece's self-reported assessment under the Cartagena Protocol. They should not be generalised to all areas of laboratory biosafety, occupational safety or biosecurity in the country [15].

CONCLUSION

Greece has legal and institutional measures addressing several aspects of biological risk management, including occupational exposure to biological agents, genetically modified organisms and specified dual-use items. At the same time, Greece's latest national report under the Cartagena Protocol identifies limitations in resources, staffing and public communication within the implementation of that Protocol.

The available sources therefore support the conclusion that a legal framework exists while also documenting specific implementation challenges. Assessing how effectively biosafety and biosecurity measures operate across all Greek institutions would require additional evidence on institutional procedures, training, compliance and research oversight.

GAPS AND CONTEMPORARY CHALLENGES IN BIOSAFETY AND BIOSECURITY

INTRODUCTION

Despite established regulatory frameworks, challenges remain in implementing biosafety and biosecurity measures and adapting them to emerging risks. These include institutional capacity, public participation, oversight of dual-use research and the governance of rapidly developing

technologies. National reporting and international guidance highlight areas requiring continued attention [2, 15, 18, 19].

MAIN BODY

1. IMPLEMENTATION CAPACITY AND PUBLIC PARTICIPATION IN GREECE

Greece's Fifth National Report under the Cartagena Protocol on Biosafety identifies several challenges in implementing the Protocol. Although Greece has established relevant legislation, the report states that national measures are only partially in place. It also indicates that **no national budget resources** are allocated to biosafety and that the number of qualified staff responsible for biosafety functions is considered inadequate. Further gaps concern public participation and communication: Greece reports **no established mechanism for public participation** in decision-making concerning living modified organisms, **no national biosafety communication** strategy and **no dedicated awareness** or outreach programmes [15]. These findings relate specifically to implementation of the Cartagena Protocol and should not be interpreted as a comprehensive assessment of every aspect of biosafety and biosecurity in Greece.

2. OVERSIGHT OF DUAL-USE RESEARCH

Life sciences research can generate knowledge and technologies with both beneficial applications and potential for misuse. The World Health Organization emphasises the importance of **responsible governance**, **risk mitigation** and **shared responsibility** among researchers, institutions, policymakers and other stakeholders. A key challenge is to prevent and mitigate biological risks while enabling legitimate scientific research to continue [18].

3. EMERGING TECHNOLOGIES AND REGULATORY ADAPTATION

Developments in synthetic biology and their convergence with artificial intelligence and automation create new opportunities while introducing evolving biosafety and biosecurity challenges. The OECD highlights the need for forward-looking monitoring, anticipatory governance and international collaboration to address the implications of these developments [19]. The WHO also identifies cybersecurity, information security and emerging technologies as important considerations in laboratory biosecurity [2].

CONCLUSION

Addressing these challenges requires sustained **institutional capacity**, **responsible oversight of dual-use research** and regulatory approaches that can adapt to scientific developments. Cooperation among researchers, institutions, public authorities and other stakeholders is essential to strengthen biological risk management and support the responsible development of the life sciences [2, 15, 18, 19].

FINAL REMARKS

Biosafety and **biosecurity** are complementary pillars of responsible life sciences. While biosafety focuses on preventing accidental exposure and the unintended release of biological agents, biosecurity addresses the prevention of unauthorized access to, loss of or misuse of biological materials, technologies and knowledge. Together, they provide a foundation for managing biological risks across research, healthcare and biotechnology [1, 2].

At the European level, **binding legislation** establishes common requirements in areas such as occupational exposure to biological agents and the contained use of genetically modified microorganisms. International guidance from organisations such as the World Health Organization further supports risk assessment and responsible research practices. Nevertheless, the effectiveness of these frameworks depends not only on their existence but also on their implementation through appropriate institutional capacity, training and oversight.

This distinction between regulatory frameworks and their implementation is also relevant to Greece. National legislation addresses several important areas of biological risk management. However, the country's **Fifth National Report under the Cartagena Protocol** identifies challenges in implementing the Protocol, including limited dedicated budget resources, insufficient staffing and gaps in public communication and participation. These findings highlight specific implementation challenges without constituting a comprehensive assessment of all biosafety and biosecurity activities in Greece.

In light of these challenges, **key priorities** include strengthening institutional capacity, expanding biosafety and biosecurity education, improving public communication and participation where relevant and reinforcing responsible oversight of research with potential dual-use implications. At the same time, regulatory and institutional approaches must continue to adapt to developments in synthetic biology, artificial intelligence and automation. Addressing these priorities requires risk-based assessment, scientific expertise and sustained cooperation among public authorities, research institutions and the wider scientific community.

Ultimately, effective biosafety and biosecurity depend on translating established requirements into **consistent** and **responsible practice**. Strengthening implementation while adapting to emerging risks is essential to building a more resilient and responsible life sciences environment.

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