



The Future of Biosecurity: Can Regulations Keep Pace with Emerging Technologies?

Noor Dzuhaidah Osman^{1*}, Syahirah Abdul Shukor², and Mohamad Afiq Padeli³

¹Faculty of Syariah and Law, International Law Research Unit, Universiti Sains Islam Malaysia, Negeri Sembilan, Malaysia

²Faculty of Syariah and Law, International Law Research Unit, Universiti Sains Islam Malaysia, Negeri Sembilan, Malaysia

³Tamhidi Centre, Universiti Sains Islam Malaysia Negeri Sembilan, Malaysia
noordzuhaidah@usim.edu.my

Abstract. The swift advancement of synthetic biology, gene editing, and biotechnology presents unparalleled challenges to global biosecurity. As dual-use research and powerful biotechnological tools become more accessible beyond traditional scientific institutions, the risk of unintentional release or intentional misuse of biological agents grows significantly, often outpacing the capabilities of existing regulatory systems. This essay critically evaluates the adequacy of current national and international biosecurity policies in responding to these rapidly evolving threats. Employing doctrinal legal research and qualitative methods, such as interviewing relevant agencies, we analyse a range of statutes, international treaties, and policy frameworks to assess the coherence, sufficiency, and adaptability of current regulatory instruments. The paper identifies key regulatory blind spots and enforcement limitations and examines the socio-economic dynamics that contribute to policy inertia. Additionally, we explore recent technological developments that underscore the urgency of reform. Ultimately, the study argues for an adaptive, anticipatory governance model incorporating real-time risk assessment, global stakeholder collaboration, and flexible legal mechanisms. Our findings highlight the critical need for proactive, internationally coordinated regulatory responses to safeguard against emerging biosecurity threats in a technologically democratized world.

Keywords: Biosecurity, Synthetic Biology, Dual-Use Research, Legal Regulation, Emerging Technologies.

1 Introduction

Gao et al. assert that biosecurity is a subset of biosafety, the latter being a broader term established in the late nineteenth century that governs safety practices in laboratories, from which biosecurity has developed and expanded beyond laboratory environments [1],[2]. Academic discourse has differentiated between biosecurity and biosafety, categorising them as distinct, independent domains. Biosafety primarily addresses biological risks within laboratory environments, but biosecurity extends outside laboratories to include the threats of theft and misuse of biotechnology. Certain researchers distinguish the two terms based on their biological applications. Zeng et al. note that biosafety pertains to hazards arising from unintentional laboratory accidents, whereas biosecurity addresses intentional biological threats resulting from unauthorised entry, theft, misuse, or the deliberate release of biological organisms [3].

Public health is an essential aspect that cannot be overlooked and must be included in discussions regarding biosecurity and biosafety. Acheson characterised public health as "the art and science of preventing disease, prolonging life, and promoting health through the organised efforts of society," a description that has solidified the understanding of public health [4],[5]. Bakanidze et al. contended that biosafety and biosecurity are crucial for global health security [6]. The 2005 International Health Regulations (IHR) emphasise disease prevention and mandate that State Parties adhere to particular laboratory management requirements, underscoring the connection between public health and biosafety. Researchers have also established the link between biosecurity and public health. Gostin and Fidler contend that biosecurity integrates these two formerly distinct domains [7]. Prior to the advent of biosecurity, security policies neglected public health concerns, whilst public health policies disregarded the security threats posed by biological weapons. Therefore, it is imperative to consider biosafety and public health when addressing biosecurity, as these ideas are interconnected.

Essentially, biosecurity pertains to the deliberate misuse of biological agents outside laboratory environments, whereas biosafety aims to reduce risks within laboratories, and public health is dedicated to protecting population health and preventing the extensive spread of disease. Each of these notions serves a unique purpose and is regulated by diverse laws that provide specialised legal frameworks for their respective domains. Global biosecurity is chiefly regulated by the Biological Weapons Convention (BWC), while worldwide biosafety is managed under the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety

to the CBD. Conversely, the 2005 International Health Regulations (IHR) are the primary convention governing public health.

Having delineated the notions of biosecurity, biosafety, and public health, and highlighted the regulatory frameworks controlling each, it is imperative to elucidate another fundamental aspect of this paper: the consequences of developing technologies. Omelchenko asserts that technological evolution has engendered doubt and apprehension, particularly emphasising genome editing, which has garnered global attention [8]. Patrick and Barton recognise that the rapid advancement of discoveries and technologies has outpaced the legislation on biosecurity and biosafety [9]. Soleimani Sasani has raised concerns about emerging technologies, asserting that synthetic biology's dual nature makes it susceptible to exploitation for bioterrorism, and that existing legislation is inadequate to mitigate the complex and uncertain misuse of synthetic biology [10]. The existing legislative frameworks for biosecurity, biosafety, and public health are established; however, the rapid pace of technological innovation has raised concerns about the efficacy of these measures.

2 Problem Statement

The swift progression of synthetic biology, gene editing, and biotechnology has generated novel biosecurity threats that current national and international legislation is unprepared to address. As dual-use research and advanced biotechnological tools become more widely available outside conventional scientific institutions, the risk of unintentional release or intentional misuse of biological agents escalates more rapidly than existing legal and legislative frameworks can address. Numerous extant instruments were conceived before the emergence of these technologies, resulting in blind spots, inadequate enforcement mechanisms, and restricted adaptability. The disparity between technical advancement and regulatory capacity underscores the need for more proactive, adaptable governance frameworks to ensure global biosecurity.

3 Research Questions

To what extent are present national and international biosecurity policies sufficient in mitigating the hazards associated with the swift progress and widespread accessibility of synthetic biology, gene editing, and biotechnology, and what adaptive governance strategies are required to solve existing regulatory deficiencies?

4 Purpose Of Study

This study aims to critically assess the sufficiency of current national and international biosecurity legislation in addressing the hazards posed by rapidly evolving, increasingly accessible biotechnologies, including synthetic biology and gene editing. It aims to uncover regulatory deficiencies, enforcement obstacles, and socio-economic factors that contribute to legal inertia while examining the possibilities of adaptive and anticipatory approaches to improve global biosecurity resilience.

5 Research Methodology

This research employs a qualitative doctrinal legal technique. The doctrinal component systematically analyses essential legal sources, such as statutes, regulations, and policy documents that regulate biosecurity and biosafety at both international and national levels to assess coherence and alignment. The data obtained from the legal study were subsequently analysed thematically to discern recurring challenges, strengths, and areas necessitating improvement within national and international biosecurity governance.

6 Review Of Literature

Biotechnology is advancing rapidly. It offers numerous advantages, including improved health and novel scientific discoveries, but it also raises concerns, such as the exploitation of knowledge for detrimental ends. Diverse international agreements have been established to mitigate these dangers. The BWC seeks to prohibit nations from developing and stockpiling biological weapons. The CBD and the Cartagena Protocol on Biosafety address the safe use of living modified organisms. The 2005 International Health Regulations assist nations in addressing transboundary disease outbreaks. This study examines global and national regulations, their deficiencies, and the necessity for enhancements to align with contemporary biotechnology.

6.1 Global Biosecurity Regime: The Biological Weapons Convention

The 1925 Geneva Protocol, a by-product of the First World War, is the inaugural mechanism in contemporary history aimed at regulating the use of biological weapons in warfare. The 1925 Geneva Protocol contains a significant deficiency, as it solely forbids the use of biological weapons in warfare, while remaining silent on the research and development of such weapons by governments. The legal oversight has compromised the integrity of the 1925 Geneva Protocol, permitting parties to create

and accumulate biological weapons, thereby undermining the Protocol's original intent. To address this loophole, the international community assembled the BWC in Geneva in 1969 [11],[12].

In contrast to the 1925 Geneva Protocol, the BWC not only restricts the use of biological weapons in wartime but also prohibits their research and stockpiling. Another characteristic of the BWC that renders it ostensibly distinct from the 1925 Geneva Protocol is its failure to categorically prohibit the utilisation of biological weapons, as they may still be employed for peaceful purposes [13]. This tolerance for biological research and development for peaceful purposes indicates that states recognise the significant risks posed by biological weapons to international security, while acknowledging the potential benefits of biological agents to society.

Regrettably, the authorisation for the study and development of biological agents for beneficial purposes has rendered the Biological Weapons Convention susceptible, as modern biotechnological research is often dual-use, facilitating both beneficial applications and the potential militarisation of biotechnology. Gillum defines dual-use research by referencing the National Science Advisory Board for Biosecurity, which describes it as research likely to produce knowledge or technologies that could be deliberately misappropriated to jeopardise public health and safety [14]. Dual-use research presents a contradiction between reaping the benefits of scientific inquiry and endangering public security, characterising it as 'high risk-high benefit' [15]. Bielecka-Oder contends that, under the BWC framework, it is exceedingly challenging to ascertain whether dual-use technology is employed for benign or malevolent purposes, as the same technology might yield both outcomes [9],[16].

The advent of dual-use technology has exposed a further deficiency of the BWC: the lack of a verification mechanism within the Convention. The verification system is essential to ensuring that State Parties to the BWC adhere to and fulfil their obligations under the Convention. The absence of verification tools within the BWC complicates monitoring compliance by State Parties, hence hindering the ability to determine whether a State Party is utilising dual-use technology for peaceful purposes or otherwise. The Implementation Support Unit (ISU), as the primary oversight body for the BWC, lacks the authority to monitor state parties' compliance with the Convention, unlike the Chemical Weapons Convention (CWC), which provides comprehensive on-site verification to prevent the diversion of nuclear materials for nefarious purposes.

6.2 International Biosafety Framework: The Convention on Biological Diversity and the Cartagena Protocol

The Cartagena Protocol, implemented under the Convention on Biological Diversity (CBD), is a crucial instrument for global biosafety. The primary aims of the CBD are to conserve biological variety, sustain the utilisation of its components, and guarantee fair and equitable distribution of the benefits derived from these resources; conversely, the Cartagena Protocol delineates a specific objective of biosafety. The preamble of the Protocol indicates that the Parties recognised the scientific advancements in biotechnology and the associated hazards, especially those to human health. Therefore, the discourse on the CBD and Cartagena Protocol is pertinent to this paper, as advancing biotechnology will influence the significance of both legal frameworks.

The swift advancement of biotechnology, however, introduces new concerns that undermine the sufficiency of the Cartagena Protocol. The advent of modern biotechnology has rendered the definitions within the Protocol obsolete, creating challenges for regulators in determining whether the new biotechnology complies with the Protocol. Keiper and Atanassova provide an example questioning the continued relevance of the concept of "modern biotechnology" under the Protocol, as emerging technologies like genome editing may not be encompassed by that description [19]. The comprehension of specific terminology in the biosafety domain persists to this day. The phrase "synthetic biology" has been deliberated by the CBD Conference of the Parties since 2014, given that the Parties have differing interpretations of it.

Emerging biotechnologies pose an additional challenge for the Parties in their capacity to implement the Protocol. Komen contends that numerous Parties to the Protocol still lack the requisite national-level capability for implementation [20]. Keiper and Atanassova indicate that nations have expressed apprehensions regarding their resources and capabilities to manage hazards associated with rapidly advancing technology, particularly among poorer countries and those yet to adopt the Protocol [19].

6.3 Global Public Health Regulation: The International Health Regulations (2005)

In 2005, the International Health Regulations (IHR) were updated by the World Health Organisation (WHO), leading to significant changes in their scope, state obligations, and the authority of the WHO. This change occurred due to the inadequacy of the 1969 version, which was ineffectual in addressing global public

health crises, exacerbated by weak state compliance and limitations imposed on the WHO regarding information management. Article 2 elucidates the mission of the amended IHR, which aims "to prevent, protect against, control and provide a public health response to the international spread of disease" and "avoid unnecessary interference with international traffic and trade." Kamradt-Scott proposed that the amended clause of Article 2 inhibits disease transmission while concurrently minimising disturbance to international trade and travel [23].

6.4 Malaysian Biosafety and Biosecurity

The swift progression of biotechnology has outpaced current legislative frameworks regulating biosafety and biosecurity, rendering many of them increasingly obsolete. However, the Malaysian Biosafety Act 2007, for example, encounters the same challenges posed by biotechnology innovation. The research on genetic engineering in Malaysia, propelled by the nation's ambition to enhance its biotechnology sector, has introduced possible threats associated with bioterrorism, notwithstanding its achievements in fostering scientific advancement in the country [24],[25]. The 2007 Biosafety Act, deficient in some areas of biosecurity such as synthetic biology and bioterrorism, necessitates an assessment of the Malaysian biosecurity legislative framework to determine if it adequately addresses contemporary advancements in biotechnology.

Considering the aforementioned criteria, the Malaysian Biosafety Act neglects biosecurity concerns, including bioterrorism and synthetic biology, and primarily focuses on biosafety issues that govern the release, importation, exportation, and contained use of LMOs. For instance, the Biosecurity Law of the People's Republic of China 2020 encompasses both biosafety and biosecurity, regulating the prevention of bioterrorism and threats from biological weapons, features that are lacking in the Malaysian Biosafety Act.

Malaysia's authorities need to incorporate a bioterrorism provision within its legal structure. The progression of synthetic biology has significantly simplified and reduced the cost of bioweapon production, earning it the designation "the poor man's atom bomb" [29].

6.5 The Emerging Technologies

Emerging technologies, such as synthetic biology, gene editing, and artificial intelligence, are swiftly altering the scientific landscape, presenting new challenges that call into question the robustness and relevance of contemporary biosecurity frameworks. A difficulty is the rapid advancement of biotechnology, particularly

synthetic biology, over the past decade. Getz and Dellaire assert that rapidly advancing technology often raises issues related to dual-use research, in which findings may have both beneficial and detrimental consequences [30]. Gene-editing technology that can modify cells to combat cancer may also increase susceptibility to illnesses. Furthermore, democratising technology has empowered individuals with fundamental knowledge of technology and biology to undertake independent experiments, thereby heightening the risk of bioterrorism [31]. Patrick and Barton assert that the increased accessibility of dual-use biotechnology and the application of artificial intelligence (AI) to augment scientific discoveries heighten the risk of bioterrorism, particularly by non-state actors [9]. These conditions have raised a significant point: whether the Convention can effectively keep pace with evolving technologies.

7 Analysis

After delineating the principal global and national frameworks for biosecurity, biosafety, and public health, it is imperative to rigorously assess their effectiveness in addressing the challenges posed by contemporary biotechnology. Although mechanisms such as the BWC, the Cartagena Protocol, and the 2005 IHR aim to mitigate biological risks, their shortcomings are more evident in light of the rapid pace of scientific progress. Emerging technologies have presented novel threats that transcend conventional boundaries among biosafety, biosecurity, and public health. These discoveries prompt critical enquiries on the adequacy of current legal frameworks regarding flexibility, enforceability, and foresight to address dual-use challenges, avert bioterrorism, and safeguard global society against the misuse of scientific advancements.

7.1 Challenges in Regulating Technology through Law

The interaction between law and technology has always been marked by friction due to their differing rates of advancement. Lawmaking is intended to be intentional, inclusive, and responsible, while technological innovation is swift, disruptive, and frequently unforeseen. This disparity presents significant regulatory issues, especially in biosecurity, cybersecurity, and artificial intelligence (AI). This discussion critically analyses five interconnected challenges: (1) democratic legislative processes and delays, (2) the disparity between legal and technical expertise, (3) limitations in enforcement capacity, (4) the rise of hybrid threat actors, and (5) the rapid advancement of technology in relation to legal adaptability.

Democratic Processes and Legislative Lag. A primary problem in regulating technology stems from the very framework of democratic administration. The passage

of legislation, such as a biosecurity or cybersecurity bill, necessitates legislative debate, several readings, committee evaluations, and frequent public consultation. This process, while improving legitimacy and accountability, is intrinsically sluggish. Consequently, when legislation is implemented, the technology it aims to govern may have evolved or changed substantially. This phenomenon is termed the "pacing problem," in which the law fails to keep pace with advancing technologies [32]. Fenwick et al. further note that the rapid advancement of technology and societal transformation often result in legislative processes that yield obsolete laws by the time they are enacted [33]. Consequently, democratic lag engenders persistent susceptibility within governance frameworks responsible for overseeing developing technology.

The Expertise Gap between Legal and Technical Domains. Effective technology regulation necessitates amalgamating legal thinking with scientific and technical expertise. Nevertheless, legislators often lack familiarity with the technical intricacies of emerging technologies, and scientists and technologists may not fully comprehend the difficulties of legal drafting and enforcement. This disconnection may result in regulatory tools that are either excessively ambiguous or excessively inflexible, thereby hindering flexibility. To address this deficiency, it is essential to establish interdisciplinary advisory committees comprising legal scholars, policymakers, and scientists to ensure that legislation is technically robust and legally enforceable. Without collaborative frameworks, lawmaking may either excessively regulate, hindering innovation, or inadequately regulate, leaving significant vulnerabilities unresolved.

Enforcement and Capacity Constraints. Implementing legislation in biosecurity and cybersecurity necessitates substantial infrastructural and human resources. Laboratories must be adequately equipped to detect and respond to pathogenic threats for biosecurity, whereas cybersecurity enforcement necessitates digital forensic capabilities and prosecution proficiency. However, in numerous jurisdictions, these resources are constrained or inequitably allocated. Mutesi emphasises the need to cultivate technical proficiency among regulators, researchers, and law enforcement personnel to reconcile legislative intent with execution [35].

Emergent Hybrid Threat Actors. Technological convergence has generated new categories of threat actors, such as bioterrorists utilising synthetic biology, cyberterrorists exploiting digital vulnerabilities, and hostile entities weaponising artificial intelligence. Current anti-terrorism frameworks are inadequate for addressing these complex threats beyond conventional jurisdictional and conceptual limits. De Haro emphasises the need for specialised biosecurity risk-assessment frameworks to mitigate AI-enabled risks in synthetic biology [36]. The Harvard Law

Review has criticised conventional, state-centric governance models, advocating co-governance frameworks that integrate official authority with knowledge from industry, academia, and civil society. The rise of hybrid threats highlights the inadequacy of rigid legal frameworks in an era of evolving technological challenges.

The Collingridge Dilemma and the Acceleration of Technology. The link between law and technology is characterised by the Collingridge conundrum, which holds that the effects of technology are difficult to foresee at the time of creation; once recognised, these effects are too established for effective regulation. This difficulty, along with the pacing issue, creates structural obstacles for legal flexibility. Hagemann et al. contend that "soft law" methods, including voluntary standards, best practice recommendations, and multi-stakeholder workshops, provide a flexible alternative to inflexible legislative tools [39]. Nevertheless, dependence on soft law prompts normative enquiries of accountability, legitimacy, and enforceability.

7.2 Rapidly Evolving Biosafety and Biosecurity Threats: Malaysia Context

In 1998, the Nipah Virus epidemic in Malaysia resulted in over 250 illnesses and more than 100 deaths. No cases of Nipah illness have been reported in Malaysia since 1999; nonetheless, nations like Bangladesh and India continue to report instances of the disease. Furthermore, Abdul Rahim and Abdullah indicate that the Nipah Virus possesses potential as a bioterrorism agent [41].

Malaysia experienced an influenza A(H1N1) outbreak in 2009, recording 627 cases by July 2009 and 74 fatalities by September 13, 2009.

A subsequent outbreak series in Malaysia transpired in West Malaysia, with the initial case reported in July 2017 [44]. As of July 24, 2023, there have been 68 reported cases in Sarawak, resulting in 61 fatalities, with all 12 divisions in Sarawak designated as rabies zones.

The most recent outbreak in Malaysia is the COVID-19 virus, with the first case documented on January 25, 2020. A total of 4,456,736 cases have been registered, resulting in 35,579 fatalities from 2020 to 2022, signifying a grim chapter in Malaysian biosecurity.

Although Malaysia has had several lethal biological outbreaks, there is no documented instance of bioterrorism involving the deliberate dissemination of deadly agents. Abdul Rahim and Abdullah recognise that the Nipah Virus, which previously impacted Malaysia, has the potential to be utilised as a bioterrorism agent [41].

7.3 Enforcement Limitations: The Convergence –Divergence Paradox

The swift advancement of biotechnologies exacerbates the issue of dispersed enforcement. The 2005 IHR and Cartagena Protocol reflect global agreement on enhancing biosafety, biosecurity, and public health; nonetheless, their institutional frameworks were established during a period characterised by relatively stable and predictable biological dangers. The emergence of rapid technologies like synthetic biology, gene editing, and AI-enhanced bioengineering has fundamentally transformed the environment, creating unprecedented hazards that exceed the adaptability of current regulatory systems.

For example, established indicators and regular reporting intervals assess compliance with the 2005 IHR's laboratory biosafety and biosecurity standards. Nonetheless, these indicators fail to adequately encompass the hazards posed by new technologies, such as gene-drive organisms or AI-engineered infections, which may exceed conventional laboratory environments and proliferate across digital-biological interfaces. Likewise, while focusing on biosafety, the Cartagena Protocol primarily addresses genetically modified organisms (GMOs) and living modified organisms (LMOs) and does not adequately address the dangers associated with synthetic biology constructs or dual-use biotechnology.

This technological advancement intensifies the convergence-divergence contradiction. The shared goals of public health and biosafety indicate the necessity for cohesive governance. Conversely, the disparate institutional oversight, exemplified by the World Health Assembly (WHA) overseeing the implementation of the 2005 International Health Regulations (IHR) and the Conference of the Parties serving as the Meeting of the Parties (COP-MOP) supervising the Cartagena Protocol, engenders administrative rigidity, hindering States' capacity to respond promptly to emerging threats. If State X is a WHO member and has ratified the Cartagena Protocol, it must harmonise its national biosafety standards with the IHR (2005) and the Protocol, thereby creating administrative and institutional obstacles to coordinating focal points and meeting reporting obligations.

The difficulty extends beyond disjointed reporting to the incapacity of existing legal frameworks to adapt to swift technological advancements. Without coordinated, proactive enforcement, international law may remain reactive rather than preventive, thereby jeopardising global health security in the era of advanced biotechnology.

7.4 Socio-Economic Dynamics in Biosafety and Biotechnology Governance

Governance of biosecurity and biosafety in Southeast Asia is intrinsically linked to the socio-economic conditions of the governments. Although prosperous economies may allocate substantial resources to scientific infrastructure and regulatory monitoring, numerous developing ASEAN nations, including Laos and Cambodia, face challenges due to constrained resources, expertise, and finance. These dynamics affect states' capacity to govern biotechnology, ensure biosecurity, and convert scientific innovation into socio-economic advancement.

Capacity Gaps in Developing ASEAN Nations. Certain ASEAN member states, including Cambodia, Laos, and Myanmar, face significant obstacles in developing biosecurity competence due to limited experience, technology, and financial resources. International partners frequently provide essential external money and technical assistance to build biosafety frameworks, conduct risk assessments, and establish national laboratories. Without continuous investment, these nations may rely on external expertise, hindering the establishment of autonomous biosafety infrastructures.

Prevention/Strategy: The Malaysian National Biosafety Board (NBB) exemplifies a strategy that convenes specialists from several fields to assess the socio-economic implications of emerging technologies [48]. As developing states, ASEAN countries might adopt this policy to enhance their capacity to manage biosecurity and biosafety in the region.

Socio-Economic Considerations in Biosafety Decisions. Biosafety governance necessitates socio-economic effect studies in addition to solely scientific risk evaluations. These evaluations are intrinsically subjective, influenced by each state's developmental priorities, cultural values, and economic frameworks [49]. In Malaysia, biotechnology approvals frequently balance agricultural priorities, especially the palm oil industry, with environmental and public health risks [50].

Case Example: Genetically modified (GM) palm oil has been suggested to enhance production and improve incomes. Regulatory authorities must weigh potential benefits, including higher incomes and improved living standards, against long-term environmental risks and trade consequences.

Recommendation: Biosafety approval processes should integrate socio-economic checklists, guaranteeing that judgements embody scientific safety and economic benefit [24].

Public Participation and Governance. The extent of public participation in biosafety governance is inconsistent. Regarding food safety and genetically modified organisms, consumers underscore the need to be educated about the characteristics of the items they ingest [51]. Conversely, sensitive domains, including pathogen research, laboratory biosafety, and national security risks, are predominantly regulated by state authorities, resulting in limited public transparency [52]. This distinction illustrates a practical equilibrium between democratic engagement and security requirements.

Implication: Although LMOs in food production require public oversight for legitimacy, more complex biosecurity issues related to diseases and viruses should remain under stringent governmental oversight. This dual strategy maintains social cohesiveness and national security.

Balancing Development, Public Health, and Security. Biosafety governance in developing contexts requires a delicate developbalance between fostering socio-economic advancement through biotechnology and safeguarding public health and national security. Effective governance requires incorporating several criteria, encompassing scientific, economic, social, and ethical factors, into decision-making processes. This comprehensive strategy embodies global trends towards "responsible research and innovation" [53].

8 Recommendation

Confronting the challenges posed by evolving technology requires more than incremental changes to existing legislation; it demands innovative, progressive governance. Contemporary biosecurity and biosafety frameworks frequently fail to adapt to rapid technological advancements, resulting in significant deficiencies in oversight, capacity, and coordination. Some essential actions may be contemplated to address these deficiencies, offering a pragmatic framework for more adaptive, resilient, and ethically sound biosecurity governance.

8.1 Bridging the Gap Between Law and Technology

Regulators must cultivate proficiency in legal principles and scientific breakthroughs to properly control hazards related to dual-use research, LMOs, and artificial intelligence in biotechnology. As technologies and life sciences advance, collaborative efforts across sectors, including specialists from the life, social, and technology sciences, are crucial to address the complex challenges arising at the convergence of science and technology [54]. This integration would diminish the epistemic gap and ensure that regulatory responses are based on scientific facts.

8.2 Government Prioritisation of Technology and Expertise

Government prioritising via specific financing channels, investment in laboratory equipment, and cultivating homegrown knowledge is imperative. High-impact biosecurity resources require enduring financial reforms, as reliance on short-term financing jeopardises long-term access, diminishes the cultivation and retention of expertise, and compromises the quality of operations and services [55]. Investing in qualified biosafety experts to ensure staffing, regulatory compliance, and transparent incident reporting, while incorporating accessible biosafety training into higher education curricula, is crucial for shaping the thinking and behaviour of future laboratory personnel [56]. Robust and consistent governmental support for financing, infrastructure, expertise, and training is essential to maintain biosecurity's safety, efficacy, and preparedness for the future.

8.3 Hard Law, Soft Law, and Ethical Governance

Effective governance requires a judicious blend of hard law (binding rules and regulations) and soft law (guidelines, codes of conduct, and ethical standards). Complex law delineates minimal safety standards, such as biosafety regulations, standard operating procedures (SOPs), and obligatory laboratory manuals, whereas soft law promotes responsible innovation without hindering technological advancement. This dual approach corresponds with anticipatory governance models that advocate for adaptable systems, ethics-based frameworks, and international collaboration to mitigate risks while facilitating advantageous technological advancement [53].

8.4 Centralised Biosecurity Databases

A significant deficiency in several national systems is the absence of an integrated data infrastructure. Creating a centralised database of hazardous diseases, living modified organisms, dual-use technologies, and laboratory inventories would enhance traceability, accountability, and preparation. A national biosecurity database offers governments a centralised system to document and oversee hazardous pathogens, LMOs, and other high-risk biological materials, thereby facilitating enhanced safety and accountability measures, promoting secure laboratory practices, ensuring adherence to international obligations, improving inter-agency coordination, and bolstering overall preparedness and rapid response to biological threats. This project would also enable cross-border data sharing with reliable partners under international agreements such as the BWC.

8.5 Emergency Response Teams and Multilevel Coordination

Forming professional biosecurity emergency response teams (ERTs) is essential to ensuring swift, coordinated responses to biological incidents. Well-defined quick reaction plans are imperative as they mitigate disease transmission, enhance the efficacy of therapies, and delineate the necessary actions to diminish the impact of a threat [59]. Individuals in high-containment laboratories must undergo specialised training, be supervised by qualified scientists, and operate within a framework that ensures their understanding of hazards, effective risk management, and reporting of incidents [60]. Collectively, these methods emphasise that establishing robust biosecurity systems requires specialised teams, explicit response plans, and a proficient workforce that adheres to stringent safety protocols to ensure swift, coordinated, and successful defence against biological threats.

9 Conclusion

The swift advancement of synthetic biology, gene editing, and biotechnology has altered the global biosecurity landscape, revealing deficiencies in current legal and legislative frameworks. Although instruments such as the BWC, the Cartagena Protocol, and IHR (2005) lay significant foundations, they were conceived during a period of gradual scientific advancement and thus face challenges in addressing dual-use problems, the democratisation of technology, and the hybrid risks posed by developing biotechnologies. The Biosafety Act 2007 of Malaysia similarly falls short in addressing biosecurity threats, including bioterrorism and synthetic biology, resulting in weaknesses in enforcement and preparedness. These issues are exacerbated by socio-economic differences among states, affecting their capacity to invest in infrastructure, knowledge, and regulatory frameworks.

Mitigating these limits requires adaptive, anticipatory governance that harmonises stringent legal frameworks with adaptable soft-law strategies, grounded in ethical principles and international cooperation. Enhancing institutional capacity, reconciling law and technology, and establishing transparent coordinating channels are essential for fostering resilience. International law will likely remain reactive rather than preventive without coordinated, proactive efforts. Ultimately, ensuring global health security in the biotechnology era requires proactive legal innovation, strong institutions, and sustained international collaboration.

Contributions of Authors. All authors contributed to the conception and design of the study. They participated in data analysis, manuscript preparation, and essential edits. All writers have reviewed and endorsed the final version for submission.

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