PERDANA
INTERNATIONAL JOURNAL OF ACADEMIC RESEARCH
eISSN: 2600-9463

# OVERVIEW OF BIOSECURITY LEGISLATION IN MALAYSIA

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**Vol. 19. No. 1**
**April Issue**
**2024**

**Abstract**
*This study delves into the complexities and efficacy of the Malaysian Biosecurity Law in addressing contemporary challenges through in-depth legal analysis. It evaluates the legislation's adaptability and comprehensiveness in the face of evolving biosecurity threats. The research begins by examining the global biosecurity landscape, emphasising the growing importance of robust legal frameworks in curbing the spread of dangerous diseases and regulating the development of biotechnology. A conceptual framework outlining the critical elements of an effective biosecurity legal system is constructed through a meticulous review of existing literature. Subsequently, the study scrutinises the Malaysian Biosecurity Law and its institutional framework by carefully examining compliance with established protocols by relevant bodies and institutions. This research contributes valuable insights to the ongoing discourse on the nation's biosecurity resilience, benefiting academics, policymakers, and legal practitioners. The findings are expected to inform future legislative modifications, ensuring that Malaysia's biosecurity legal framework remains adaptable, dynamic, comprehensive, and aligned with international best practices.*

Keywords: *Biosecurity, Law, Biosafety, Biotechnology, COVID-19 Pandemic*.

## INTRODUCTION

Within the contemporary global landscape, biotechnology has demonstrably exerted a significant influence on both human health and the environment. While it presents the potential to positively reshape the world, its applications can also endanger biodiversity. As highlighted by Bielecka (2014), security measures are paramount in safeguarding societal well-being and commercial endeavours.

A recent European Commission document titled "Communication on Biotechnology and Biomanufacturing" (2024) serves as a relevant source for exploring the intersection of biotechnology with various sectors. This Q&A format likely addresses the multifaceted nature of biotechnology's impact. It could delve into its applications across diverse fields such as environment, industry, agriculture, human health, and animal science. The document might discuss both the potential for global progress facilitated by biotechnology and the potential threats it poses to biodiversity. While holding promise for global improvement, biotechnology also poses threats to biodiversity. Past instances of deliberate misuse, such as the creation of bioweapons, accidental releases of organisms from laboratories, and diseases transmitted within lab settings, highlight these risks (Ronit Langer & Shruti Sharma, 2020). Factors such as geography, history, culture, and religion also

contribute to the varied perceptions of the potential hazards associated with biotechnological products and procedures concerning human health and the environment (Herdegen, 2023).

Hence, it is imperative to implement measures for biosecurity aimed at managing both deliberate and accidental dissemination of viruses and pathogens to prevent their rapid spread. Safeguarding human, animal, and environmental well-being against biological hazards constitutes a paramount responsibility for the initiatives, regulations, and readiness plans concerning biosecurity (Alshehri, 2022). Current advancements in biotechnology necessitate a robust biosecurity framework in Malaysia, a nation rich in biodiversity and agriculture. The absence of a comprehensive and adaptable biosecurity law is concerning, particularly in light of the evolving threats posed by emerging infectious diseases and the potential spread of genetically modified organisms (GMOs). As highlighted by Osman (2022), effective biosecurity governance strategies are paramount to safeguarding public health and the environment.

However, the emergence and subsequent rise in fatalities associated with COVID-19 since 2019 has ignited discussions on the need to strengthen biosecurity legislation in Malaysia. This urgency is underscored by the alarming trend of COVID-19-related deaths, highlighting the profound human and environmental consequences of such outbreaks. Robust biosecurity frameworks are therefore critical to mitigate such risks. According to a report authored by Latifah Arifin and published in Berita Harian on December 17, 2023, the Ministry of Health Malaysia disclosed that from December 10 to December 16 of the same year, there were 20,696 recorded cases of COVID-19 infection, accompanied by 28 further fatalities. The report further delineated the existence of 28,375 active cases, with 588 individuals undergoing hospitalization, 22 patients admitted to the Intensive Care Unit (ICU), and 14 individuals requiring ventilator assistance.

Malaysia has established regulatory frameworks to mitigate biosecurity risks and ensure adherence to biosecurity protocols. To this end, the current study proposes a comprehensive evaluation of the Biosecurity Law with the objective of identifying potential improvements that could mitigate the risks of a worsening situation.

> **RQ1:** Whether the existing Malaysian Biosecurity legal and institutional framework is sufficient in mitigating all potential biosecurity threats, with particular emphasis on its effectiveness during the COVID-19 pandemic?
>
> **RQ2:** What is the optimal biosecurity regulatory strategy that can achieve a balance between biodiversity conservation and safeguarding human health?

## METHODS

In recent years, qualitative methodologies have emerged as increasingly prominent tools for understanding complex realities and informing the development of innovative projects (Suada, 2023). Qualitative methodologies have found application across a broad spectrum of disciplines, including the social sciences, humanities, design fields, and clinical psychology (Udo et al., 2020). The incorporation of qualitative research methods has demonstrably fostered scientific advances and the generation of critical knowledge across diverse fields. This study employed a qualitative methodology to conduct a comparative analysis of national biosafety and biosecurity laws and policies related to COVID-19 in Malaysia and other countries. The research methodology involved a thorough examination of a diverse range of data sources, including academic publications, official legal documents, reference materials, and official state documents. This comprehensive approach ensured that the research findings were grounded in both established knowledge and current practice. Content analysis was utilised to gather and analyse information regarding the scope and limitations of existing regulatory provisions on biosafety and biosecurity, as well as the relationship between national biosecurity legislation, biodiversity, and public health. The methodology employed in this study was essential for achieving its objectives, as it

provided a rigorous and structured approach to data collection and analysis. The doctrinal legal method, which emphasises the critical examination of primary and secondary legal sources, was chosen as the most appropriate methodology for this research.

**Data Collection**

Research methodology hinges on library research, a process of systematically gathering and analysing primary and secondary sources. Primary sources, such as scholarly books, articles, thesis, and legal documents, offer firsthand data. Researchers also utilize secondary sources such as reports, reviews, and databases to synthesize existing knowledge. The objective, as emphasized by George (2019), is to obtain information from experts and individuals relevant to the research topic. To achieve this, researchers leverage library catalogues, databases, and reliable online resources to access these materials. Rigorous source evaluation is crucial to ensure data quality. Additionally, researchers may utilize resources from various Malaysian libraries to bolster their investigations.

**Data Analysis**

The selection of appropriate data collection methods is crucial for robust statistical analysis and successful research endeavours. This process involves acquiring data, followed by its systematic organisation and interpretation through coding, thematic analysis, and ultimately the development of broader insights. In this study, a multifaceted data collection approach will be employed, drawing from diverse relevant sources to gather the information necessary to address the research questions and achieve the study's objectives.

## FINDINGS

### 1. The Current Malaysian Legal and Institutional Framework on Biosecurity Law

**Theme 1: Overview of Biosecurity Law**

As emphasised by the Belgian Biosafety Server, the principle of biosecurity centres on preventing malevolent activities involving biological agents, encompassing the prevention of their loss, theft, diversion, or intentional release, including pathogens, toxins, and related materials (Belgian Biosafety Server). The notion of biosecurity has garnered widespread international recognition and is now integrated into various sector-specific strategic documents.

Notably, biosecurity refers to a range of strategies and practices aimed at averting the introduction, dissemination, and consequences of infectious diseases caused by pathogens. These measures entail actions such isolation, regulating movement, maintaining hygiene, and enhancing sanitation to minimize the transmission of pathogens within and between agricultural settings, poultry populations, and humans. Over time, the scope of biosecurity has broadened to encompass concerns regarding bioterrorism, bio attack, and biosafety. Different geographical areas have prioritized distinct facets of biosecurity, such as controlling agricultural pests and diseases in Europe, mitigating the impact of invasive species on native flora and fauna in Australia, and curtailing the dissemination of biological agents into human populations in the United States. Recent events, notably the COVID-19 pandemic, underscore the critical importance of robust biosecurity measures in safeguarding public health and curtailing the propagation of infectious diseases (MacLeod, 2020; Derek, 2014; Behailu, 2022; Mihai, 2020; Bingham, 2008).

Biosecurity interventions function across various levels, delineated as primary, secondary, and tertiary strategies. These strategies operate synergistically to forestall, manage, and alleviate the infiltration, dissemination, and repercussions of biological hazards (Huber et al., 2022). The efficacy of biosecurity execution hinges upon resilient political, statutory, and cooperative structures. This underscores the necessity for a thorough and cohesive delineation of biosecurity, enabling concerted efforts across diverse governance echelons and stakeholder cohorts (Renault et al., 2021).

Ongoing research endeavours continue to explore the effects of biosecurity interventions on diminishing health risks, contributing essential evidence-based understandings to guide forthcoming public health approaches (Youssef, 2021). The literature review provides a nuanced examination of the evolving nature of the biosecurity paradigm, its diverse definitions, and the multifaceted interventions essential for effective governance and mitigation of biological hazards.

**Theme 2: Focus Areas of Biosecurity Law**

Biosecurity law governance, a multifaceted and evolving field, encompasses procedures and legislation to protect against biological threats. A thorough review in this area should explore the definition and development of biosecurity measures, alongside the challenges and advancements in its governance. To effectively address threats from invasive species, emerging pathogens, and advancements in biotechnology, robust biosecurity legal frameworks are critical for safeguarding public health, environmental well-being, and national security. These frameworks typically encompass regulations for managing non-native species introduction, responsible biotechnology development, and mitigating risks associated with pathogens.

The concept of biosecurity has evolved, leading to diverse interpretations and explanations. In the context of animal health and production, biosecurity is defined as a comprehensive framework of managerial strategies and tangible measures aimed at reducing the entry and spread of animal diseases, infections, and infestations within, between, and beyond animal populations (Renault et al., 2021). This underscores the multifaceted nature of biosecurity and its crucial role in protecting human, animal, and environmental health from biological threats.

Dao et al. (2022) analyse the perceptions and beliefs of laboratory workers in Mali regarding biosafety and biosecurity in their article "Building a Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences: A View from Mali." The study employs a 20-item survey to assess these workers' views on biosecurity and biosafety, encompassing Dual Use Research of Concern (DURC) and cyberbiosecurity. Highlighting the importance of a culture of accountability within the life sciences, particularly in the wake of the COVID-19 pandemic, the research investigates how such a culture can contribute to protecting human, animal, and environmental health.

**Theme 3: The Need of Comprehensive Current Malaysian Legal and Institutional Framework on Biosecurity Law in Managing the COVID-19 Threats and Risk**

The establishment of a comprehensive and up-to-date Malaysian legal and institutional framework for biosecurity law is critical for effectively managing the threats and risks associated with modern biotechnology (Irma et al., 2022). Malaysia's pursuit of advancements in modern biotechnology necessitates a robust and comprehensive legal and institutional framework within the biosecurity landscape. While these initiatives have undoubtedly spurred scientific progress, they have concurrently generated concerns regarding potential misuse for malicious intent, such as in terrorist activities (Kalidasan, 2021; Subramaniam, 2014).

Malaysia's existing legal and institutional framework for biosecurity law requires comprehensive reform to effectively manage threats and risks, particularly those posed by COVID-19. Such reforms are crucial to safeguarding the nation's sovereignty, peace, and prosperity (Hirman et al., 2023).

The framework's scope should encompass critical issues such as cross-border biosecurity crimes, digital threats to biological security, and the effective implementation of Comprehensive Security (COMSEC) protocols (Irma et al., 2022). The framework should additionally prioritize the development of preventive countermeasures and comprehensive guidelines for small and medium-sized enterprises (SMEs) to guarantee worker safety and health (Fred, 2022). Furthermore, the framework's development should integrate research on human mobility patterns and their influence on the genetic structure of the SARS-CoV-2

virus within Southeast Asian nations, including Malaysia. This would enable a more geographically informed approach to biosecurity (Al-Shami, 2022).

The demonstrated effectiveness of digital contact tracing apps in mitigating outbreak spread warrants their inclusion within the framework (Singh, 2022). Hence, to effectively navigate the challenges posed by COVID-19, Malaysia requires a comprehensive and current legal and institutional framework for biosecurity law, aligned with international best practices.

This research underscores the critical need for a comprehensive and up-to-date Malaysian legal and institutional framework for biosecurity law. Such a framework is essential to effectively mitigate risks associated with modern biotechnology applications, ensure compliance with international regulations, and foster responsible scientific advances. By strengthening regulatory mechanisms, promoting robust biosafety practices, and addressing bioethical concerns through public engagement and stakeholder collaboration, Malaysia can significantly enhance its biosecurity governance capabilities, enabling effective management of the threats posed by modern biotechnology.

## 2. Biosecurity Regulatory Strategy in Conserving Biodiversity and Human Health

Effective regulatory strategies for biosecurity are essential for protecting biodiversity and public health. These strategies help manage the risks stemming from advancements in contemporary biotechnology. National biosecurity laws, such as China's Biosecurity Law, highlight the importance of enhancing biosecurity governance to attain these objectives. This involves employing a comprehensive strategy that encompasses safeguarding biodiversity, preventing the introduction of invasive species, controlling the emergence of antimicrobial resistance, and mitigating the threats posed by bioterrorism (Wang, 2021).

This comprehensive biosecurity law is designed to achieve a multifaceted mandate: safeguarding human health, bolstering national security, and strengthening biosecurity governance capabilities. The implementation of such laws is essential for fostering the responsible development of biotechnology, protecting genetic resources, preventing the introduction of invasive alien species, and ultimately promoting harmonious human-nature coexistence (Wang, 2021).

A global trend in biosecurity initiatives emphasizes a strategic, integrated approach to managing risks encompassing human, animal, and plant health. These initiatives prioritize analysing and mitigating risks associated with infectious diseases, invasive species, and biological threats. Collaborative efforts involving public and private stakeholders are crucial for achieving this goal. Strengthening biosecurity regulations and frameworks is essential, as it enables the effective management of emerging biological threats and the promotion of sustainable biosecurity systems. Ultimately, such systems safeguard biodiversity and ecological environments while fostering responsible advances in biotechnology (Militzer et al., 2023).

Findings related to RQ2 what was the optimal biosecurity regulatory strategy that can achieve a balance between biodiversity conservation and safeguarding human health? Optimal biosecurity law strategies necessitate a three-pronged approach: thorough analysis of key components and their subsequent adoption to address global challenges. Three themes presented below to answer the research questions. (1) Global Cooperation and Collaboration in implementing Biosafety/Biosecurity; and (2) The “One Biosecurity” Approach; and (3) Regulating modern Biotechnology in Malaysia as a necessity.

### Theme 1: Global Cooperation and Collaboration in implementing Biosafety/ Biosecurity

Confronting the challenges and risks posed by emerging technologies such as gene editing and bioprinting, alongside the persistent threat of infectious disease outbreaks, necessitates robust international cooperation and collaboration in the implementation of biosafety and biosecurity measures within Malaysia. The absence of a comprehensive legal framework for

gene editing in Malaysia underscores the urgency of establishing clear guidelines, legal policies, and standards to effectively manage this rapidly evolving field (Marina, 2020).

To further bolster biosecurity measures, Malaysia could explore the implementation of DNA sequence screening within gene synthesis companies. This approach has the potential to mitigate the misuse of genetic material for bioterrorism purposes (Kalidasan, 2021). Malaysia's participation in strategic multilateral dialogues with Southeast Asian nations and the United States could significantly contribute to enhanced regional and global biosecurity. These collaborative platforms would facilitate the exchange of critical information and promote Malaysia's active engagement in international biosecurity forums (Anita et al., 2019). For Malaysia, striking a balance between promoting the advancements of biotechnology and safeguarding against potential environmental and human health risks necessitates a focus on strengthening its existing biosafety regulations (Fred, 2022). Through the execution of these strategies and fostering partnerships with international entities, Malaysia can effectively utilize contemporary biotechnological advancements while upholding the safety and protection of its population (Vilasini, 2020).

Drawing on the work of Rutjes (2023), this study offers a comprehensive analysis of how the COVID-19 pandemic exposed vulnerabilities in biosafety and biosecurity. The authors pinpoint the pandemic's detrimental impact on training opportunities, resource availability, and laboratory testing capacity, particularly within low- and lower-middle-income countries (LMICs). Crucially, the study emphasizes the importance of global cooperation and collaboration in sharing resources, best practices, and information to strengthen the implementation of biosafety and biosecurity regulations. The authors advocate for international legislation alongside robust enforcement of existing biosafety and biosecurity policies to effectively address global health and security concerns. Overall, the study provides valuable insights, practical resources, and recommendations to improve biosafety and biosecurity preparedness for future global health emergencies.

**Theme 2: The “One Biosecurity” Approach**

This study explores the "One Biosecurity" concept (Hulme, 2020) as a potential approach to biosecurity regulation. This framework prioritizes the interconnectedness of human, animal, plant, and environmental health, advocating for a holistic system that transcends traditional sector-specific regulations. The analysis assesses the paper's contribution to biosecurity law by examining its compatibility with existing legal frameworks and summaries. Notably, the article champions a move away from organism-centric perspectives towards a unified biosecurity policy that acknowledges these inherent linkages. This aligns perfectly with the established goals of biosecurity law (lex lata) which are to protect human, animal, and plant health, as well as the environment, from biological threats. Furthermore, "One Biosecurity" emphasizes multidisciplinary collaboration, reflecting the need for taxonomists, population biologists, social scientists, and other experts to work synergistically. This interdisciplinary approach mirrors the multifaceted nature of biosecurity law, which frequently navigates legal, scientific, ethical, and policy considerations when addressing biosecurity challenges.

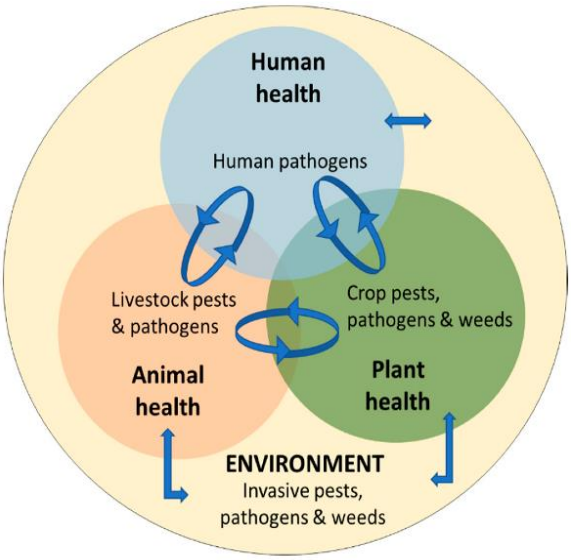


Figure 1: The One Biosecurity principle is visually represented in the diagram provided, elucidating the interconnections among environmental, animal, and human well-being stemming from the impacts of introduced non-native plants, animals, and pathogens. (adopted from Hulme, 2020)

The author also commends the article's emphasis on interconnected health, a potential shortcoming lies in the limited exploration of legal implementation mechanisms for the "One Biosecurity" approach within existing frameworks. A deeper analysis of how this concept aligns with diverse national legal and regulatory landscapes could strengthen the article's appeal. Critics may raise concerns about the feasibility of integrating "One Biosecurity" into current legislation and policies. They might call for more concrete examples of how the approach could be applied within various legal and policy contexts. Additionally, the article could benefit from a more thorough discussion of the ethical and societal implications surrounding the application of "One Biosecurity" within legal and policy boundaries.

The potential shortcomings identified, such as the limited exploration of legal implementation and ethical considerations, highlight the need for a more comprehensive investigation into the practical, moral, and legal ramifications of incorporating "One Biosecurity" into existing biosecurity legislation. Addressing these weaknesses could significantly enhance the value of the research as a conceptual framework and summary for biosecurity law.

Debates persist regarding the sufficiency of Malaysia's biosecurity legal framework. The Biosafety Act (2007) serves as the cornerstone, regulating genetically modified organisms (GMOs) and living modified organisms (LMOs). To address evolving biosecurity concerns, a revision of the National Biosafety Policy was implemented in 2020. This revision emphasizes risk-based decision-making, capacity building, and stakeholder engagement

**Theme 3: Regulating Modern Biotechnology in Malaysia as A Necessity**

Effective governance is essential for ensuring the responsible and safe application of gene editing technologies within Malaysia's modern biotechnology sector. The Biosafety Act (2007) and its accompanying regulations (Biosafety [Approval and Notification] 2010) play a central role in regulating gene editing activities, upholding biosafety standards, and ensuring biosecurity within the Malaysian context. While advancements have been spurred by the promotion of modern biotechnology in Malaysia, concerns regarding potential misuse for malicious intent, such as in terrorist activities, have also emerged (Kalidasan, 2021).

Malaysia's commitment to strengthening biosecurity governance and adhering to international regulations is exemplified by the drafting of its Biological Weapons Convention (BWC) implementation bill in 2012 (Kalidasan, 2021).

Upon implementation, the institutional biorisk management mandates outlined in the Malaysian BTWC Bill will play a vital role for entities dealing with infectious agents in effectively mitigating associated risks (Subramaniam, 2014).

Recent advancements underscore the imperative nature of regulating modern biotechnology in Malaysia. This necessitates a delicate balance between fostering innovation and mitigating the potential risks associated with gene editing technologies. Establishing comprehensive regulatory frameworks and ensuring adherence to biosafety and biosecurity protocols are crucial steps towards achieving responsible development and application of modern biotechnology within the Malaysian context.

**RESULTS**

Previous studies in biosecurity law have predominantly concentrated on formulating fresh regulations and guidelines to manage the evolving risks linked with advancements in biotechnology. This strategy is geared towards recognizing and evaluating potential dangers, followed by the establishment of efficient regulatory structures to mitigate these risks. However, a critical equilibrium must be achieved between promoting economic advantages derived from biotechnology research and development and safeguarding biodiversity.

Additionally, this research examines the role of Malaysia's National Biotechnology Policy (NBP) 2.0 (DBN 2.0) 2022 in shaping the country's biotechnology sector. It elucidates the fundamental principles of the policy intended to foster growth across various segments of the biotechnology industry. While Malaysia possesses a legislative framework for various biosecurity aspects, a dedicated and comprehensive biosecurity law is currently absent. Existing regulations are scattered across diverse legal instruments, underscoring the need for a consolidated and specific biosecurity act (Marina, 2020; Kalidasan, 2021). In summary, these studies emphasise the pivotal role of comprehensive and well-defined biosecurity legislation spanning diverse domains in Malaysia's capacity to address emerging challenges effectively.

**DISCUSSION**

The “One Biosecurity” approach also plays the vital part in Biosecurity areas. The notion of One Biosecurity extends past conventional biosecurity protocols, advocating for a comprehensive and interconnected strategy in mitigating threats to human, animal, plant, and ecosystem well-being. This entails the establishment of worldwide surveillance networks, the standardization of risk evaluation methods, the advancement of novel management strategies such as gene editing, and the activation of international knowledge pools during periods of crises (Hulme, 2021).

Notably, the current scope of Malaysian biosecurity law seems restricted, primarily addressing weaponry, flora, and fauna. The lack of robust protocols and procedures undermines its efficacy in addressing emerging threats. Hence, a dynamic and autonomous legal framework is imperative. Through the adoption of suitable strategies, Malaysia has the potential to implement and enhance its biosecurity legislation to tackle contemporary challenges effectively.

The Biosecurity Law constitutes a pivotal and comprehensive legislation concerning biosecurity matters. Its implementation and enforcement yield advantageous outcomes in protecting human well-being, ensuring national security, and bolstering the nation's ability to govern biosecurity effectively. This law underscores the significance of biosecurity in national defense and aims to mitigate and manage biosecurity risks (Robertson,2020), preserve ecological diversity (Wang et. al,2020), and the natural environment (Zheng et. al,2019), encourage the sustainable advancement of biotechnology (Wittich,2016),

encourage the establishment of a global community aimed at mutual prosperity and strive for a balanced relationship between humanity and the environment.

**LIMITATION**

This study examines recent developments and trends shaping biosecurity law in Malaysia, with a particular focus on analysing the concept through both domestic and international legal lenses. It delves into the provisions of the proposed Biosecurity Law, specifically scrutinizing aspects and applications related to reclamation requirements and identifying potential deficiencies arising from their limitations. This analysis addresses a gap in existing research, which has not yet comprehensively explored the need for improvements in security and biosecurity legislation. Notably, Malaysia currently lacks a comprehensive biosecurity law, with existing legislation solely focused on biological weapons. To address this critical gap, the study employs a holistic legal framework to assess the proposed Biosecurity Law's efficacy in safeguarding human, animal, and environmental health from biosecurity threats associated with biotechnology activities. This approach aims to not only recommend comprehensive legal amendments but also consider the broader social, economic, and health implications, ensuring that proposed changes not only improve biosecurity but also prioritize the well-being of individuals, society, and the environment. However, limitations exist within Malaysia's current biosecurity law. Its scope appears limited to weapons, plants, and animals, lacking standardized procedures and protocols to address broader biosecurity threats. To strengthen the legal framework, a dynamic and independent approach is necessary. This could involve implementing improvements based on established frameworks like the" One Biosecurity" approach.

**CONCLUSION**

In conclusion, it can be seen that the reason for conducting this study is very reasonable and necessary. This is because the need for improvements to biosecurity laws is a major issue that affects the health of the community and negatively impacts the public economically, emotionally, and socially. A systematic and comprehensive approach is seen as important to ensure that the proposed legal improvements are not only focused on human health but also on biological diversity. Indirectly, a more comprehensive and systematic implementation of the law can be implemented to address issues related to viruses and pathogens. While the implementation of this approach may involve challenges and require intensive cooperation with various parties, it is an important step in ensuring the health and welfare of the Malaysian community.

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