Strathmore University
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INTEGRATING BIOSECURITY INTO KENYAN BIOSAFETY LEGISLATION: A PATH TOWARDS A COMPREHENSIVE ONE HEALTH LEGAL FRAMEWORK

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Declaration

I, IRUNGU SHANIEL WAITHERA, do hereby declare that this research is my original work and that, to the best of my knowledge and belief, it has not been previously, in its entirety or part, been submitted to any other university for a degree or diploma. Other works cited or referred to are accordingly acknowledged.

Signed: .....

Date: 07/04/2025

This dissertation has been submitted for examination with my approval as University Supervisor.

Signed: .....

[Supervisor's Name] Dr Melissa Muindi

Date: 7th April 2025

LIST OF ABBREVIATIONS

AU	African Union
Africa CDC	Africa Centres for Disease Control and Prevention
BBI	Biosafety and Biosecurity Initiative
BSBS	Biosafety and Biosecurity
BSL	Biosafety Level
BWC	Biological Weapons Convention
CBD	Convention on Biological Diversity
CPB	Cartagena Protocol on Biosafety
EIDs	Emerging Infectious Diseases
FAO	Food and Agriculture Organisation
GHSA Index	Global Health Security Index
GHSA	Global Health Security Agenda
GMOs	Genetically Modified Organisms
HCATs	High Consequence Animal Transboundary and Emerging Diseases
IHR	International Health Regulations
JEE	Joint External Evaluations
LMOs	Living Modified Organisms
NBA	National Biosafety Authority
NEMA	National Environment Management Authority
OHHLEP	One Health High-Level Expert Panel
OIE	World Organisation for Animal Health
OSHA	Occupational Safety and Health Act
POTA	Prevention of Terrorism Act
SARS	Severe Acute Respiratory Syndrome
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus-2
UNEP	United Nations Environment Programme
UNSCR	United Nations Security Council Resolution
VBM	Valuable Biological Materials
WHO	World Health Organisation
WOAH	World Organization for Animal Health

LIST OF LEGAL INSTRUMENTS

KENYA

1. Constitution of Kenya (2010).
2. The Biosafety Act (Act No. 2 of 2009, Amended 2018)
3. The Biosafety (Contained Use) Regulations
4. The Biosafety (Environmental Release) Regulations
5. The Biosafety (Import, Export and Transit) Regulations
6. The Biosafety (Labelling) Regulations
7. The Health Act (2017)
8. Draft Biosecurity Bill (2024)

INTERNATIONAL TREATIES AND CONVENTIONS

1. Africa CDC Biosafety and Biosecurity Legislative Framework
2. The Cartagena Protocol on Biosafety
3. Convention on Biological Diversity (1992)
4. International Health Regulations (2005)
5. The Biological and Toxins Weapons Convention
6. United Nations Security Council Resolution 1540 (2004)

ABSTRACT

The integration of biosecurity into Kenya's Biosafety Act is a critical yet overlooked dimension in addressing biological risks that threaten human, animal, and environmental health. The current Biosafety Act primarily focuses on regulating genetically modified organisms and lacks a robust biosecurity framework, leaving gaps in the prevention, control, and response to emerging biological threats. This research arises from the necessity to align Kenyan legislation with regional and international standards, particularly the Africa CDC's Biosafety and Biosecurity framework, which emphasises a One Health approach. This study analyses the Biosafety Act in comparison to the Africa CDC's framework to identify gaps and propose amendments that incorporate biosecurity measures. Using a conceptual framework based on the concept of security, the research explores how biosecurity can enhance preparedness and resilience in preventing biological threats. The methodology includes a qualitative analysis of legislative texts and comparative studies of international frameworks. The research aims to deliver actionable recommendations to integrate biosecurity into Kenya's legal framework, enhancing its threat response and prevention to meet international obligations and protect public health. The study highlights the necessity of harmonizing security principles with legal frameworks to establish a comprehensive and sustainable biosafety and biosecurity system.

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CHAPTER 1: INTRODUCTION

1.1 Background

Biosafety involves the secure management and confinement of dangerous biological agents and infectious microorganisms within laboratory settings. It uses containment strategies and risk assessments to protect lab workers from pathogens and prevent accidental releases.[1] It emphasises the importance of implementing strict microbiological practices, proper containment of biological materials, and efficient administrative measures to safeguard employees from potential exposure to infectious agents.

Biosecurity, conversely, pertains to the actions implemented to prevent the introduction or spread of detrimental biological entities affecting human, animal, or plant life.[2] Biosecurity is a multi-faceted approach that combines efforts from various sectors, including bioscience laboratories, customs agents, and agricultural officials. The main objective is to ensure human health and protect agricultural products by addressing, managing, and preventing biological hazards.[3] This includes protecting against bioterrorism and adverse biosecurity events and ensuring biological agents are not employed in harmful ways.

The possibility of a disastrous biological occurrence is escalating due to factors such as international travel, urbanisation, bioterrorism concerns, and advancements in biotechnology that could potentially enable the creation and manipulation of pandemic pathogens. Most African nations, however, do not possess the requisite capacity to effectively respond to these threats.[4] The findings from the World Health Organization (WHO) Joint External Evaluations (JEE), which took place from 2016 to 2019, along with the 2019 Global Health Security Index (GHS Index),

[1] Biosafety and Biosecurity, 6 *KEMRI Bioethics Review* 3, 2016, 3.
[2] Biosafety and Biosecurity, 6 *KEMRI Bioethics Review* 3, 2016, 3.
[3] Biosafety and Biosecurity, 6 *KEMRI Bioethics Review* 3, 2016, 3.
[4] https://africacdc.org/programme/laboratory-systems-and-networks/biosafety-and-biosecurity/

revealed significant deficiencies in biosafety and biosecurity capabilities among member states of the African Union (AU).[5]

In light of the results, the Africa Centres of Disease Control and Prevention (Africa CDC) inaugurated the Biosafety and Biosecurity Initiative (BBI). The initiative aimed at reinforcing biosafety and biosecurity frameworks across AU member states.[6] The objective is to empower AU member states to meet international standards and regulations like the International Health Regulations (IHR) 2005, Biological Weapons Convention (BWC) and the United Nations Security Council Resolution (UNSCR) 1540.[7]

The Biosafety Act establishes a comprehensive legal and administrative framework for regulating activities that involve genetically modified organisms (GMOs).[8] Its primary focus is to address and manage the potential biosafety hazards related to the use of GMOs. The Act is intended to facilitate the responsible use, development and handling of GMOs, while aiming to reduce potential dangers to environmental and human health.

The JEE report notes Kenya's establishment of a National Biosafety Authority and the enactment of the Biosafety Act of 2009, which reflect the country's dedication to biosafety and biosecurity.[9] The JEE findings underscore the critical gap in Kenya's biosafety and biosecurity legislative framework, particularly regarding legislative insufficiencies. The report identifies a gap in the existing Biosafety Act as it primarily focuses on GMOs, neglecting other essential elements of biosafety and biosecurity.[10]

According to the JEE report, a Bioscience Bill, which includes a biosafety and biosecurity component, is under parliamentary review, and if passed, the bill will strengthen national biosafety

[5] Africa Centres for Disease Control and Prevention, Development of a National Biosafety And Biosecurity Strategy, 2022, 4.

[6] The African Centres for Disease Control and Prevention Biosafety and Biosecurity Initiative 2021 - 2025 Strategic Plan, Africa CDC, 2021, 5. -<https://africacdc.org/download/biosafety-and-biosecurity-initiative-2021-2025-strategic-plan/>-

[7] The Africa CDC Biosafety and Biosecurity Initiative, 5.

[8] Section 4, *Biosafety Act* (Act No 2 of 2009).

[9] World Health Organisation, Joint External Evaluation of IHR Capacities of the Republic of Kenya, 2017,20.

[10] World Health Organisation, Joint External Evaluation of IHR Capacities of the Republic of Kenya, 21.

and biosecurity legislation.[11]A survey was conducted in Kenya to assess its biosecurity level in light of its commitment to international obligations.[12] The survey revealed a lack of formal and comprehensive set of regulations that encompasses all elements of biosecurity.[13] A need was recognized for biosecurity legislation. In alignment with international laws against the misuse of harmful biological substances, Kenya was developing a National Bioscience Bill and Policy.[14]

Additionally, Kenyan laboratories store various biological agents which can be potentially weaponised, posing a threat to human, animal and environmental life, emphasising the need for a legal framework addressing biosecurity.[15] Although some Kenyan laboratories have included biosecurity in their guidelines, and the Ministry of Health has issued policy recommendations, these guidelines remain voluntary and lack legal binding.[16] To ensure consistent and effective biosecurity practices, legislation is necessary.

The Africa CDC is a technical agency of the African Union that supports member states in strengthening their public health capacities to effectively identify, prevent, and respond to health concerns.[17] Africa CDC has initiated a Biosafety and Biosecurity Initiative (BBI) focused on establishing a comprehensive legal framework for Biosafety and Biosecurity (BSBS Legal Framework) across the Africa.[18] The BSBS Legal Framework is a tool designed to assist AU member states in evaluating and improving their legal frameworks for biosafety and biosecurity.

It serves to guide the analysis of existing legislation and identify areas for enhancement, as well as propose methods for amending or developing legislative instruments to support national biosafety and biosecurity systems.[19] To achieve a sustainable impact, a One Health approach

[11] World Health Organisation, Joint External Evaluation of IHR Capacities of the Republic of Kenya, 21

[12] Ndhine EO, Slotved HC, Osoro EM, Olsen KN, Rugutt M, Wanjohi CW, Mwanda W, Kinyagia BM, Steenhard NR, Hansen JE, 'A Biosecurity Survey in Kenya' 14 *Health Security* 4, 2016, 206.

[13] Ndhine EO, *et al*, 'A Biosecurity Survey in Kenya,' 212.

[14] Kenya Vision 2030, 'Transforming Kenya: Pathway to Devolution, Socio-economic Development, Equity and National Unity' 2013. <https://vision2030.go.ke/2013-2017/#73>

[15] Ndhine EO, *et al*, 'A Biosecurity Survey in Kenya,' 211.

[16] Ndhine EO, *et al*, 'A Biosecurity Survey in Kenya,' 211.

[17] The Africa CDC, Biosafety and Biosecurity Initiative, 4.

[18] The Africa CDC, Advocacy and Communication Strategy for the Biosafety and Biosecurity Legal Framework, 1.

[19] The Africa CDC, Advocacy and Communication Strategy for the Biosafety and Biosecurity Legal Framework, 2.

should be incorporated into the implementation of the BBI.[20] This holistic perspective recognises the interconnectedness of human, animal and plant health and the influence of environmental factors.

Kenya is a member of the African Union.[21] As a result, AU legislation is incorporated into Kenyan law, subject to the Constitution providing that any treaty or convention that Kenya ratifies becomes law.[22] Kenya, like many countries, faces challenges in managing biological risks due to gaps in its legal and policy frameworks. While the Biosafety Act provides a basis for regulating biotechnology, it lacks explicit biosecurity provisions, creating vulnerabilities in national security and public health.

1.2 Statement of the Problem

The Health Act of Kenya, 2017, mandates the government to uphold and ensure the right to health for all citizens to the highest attainable standard. The Biosafety Act of Kenya, primarily focused on GMOs, lacks a comprehensive biosecurity component for addressing threats such as bioterrorism, unauthorized access to hazardous biological materials, and emerging infectious diseases. It lacks a dedicated biosecurity oversight agency, national standards, risk assessment mechanisms, and secure protocols for handling high-consequence agents, increasing risks of accidental releases and bioterrorism. This oversight leaves a critical vulnerability in mitigating biological threats animal, plant and environmental well-being.

This research addresses these legal shortcomings by examining the Biosafety Act through the lens of the Africa CDC Biosafety and Biosecurity Initiative framework, proposing reforms to integrate biosecurity measures and embrace an extensive One Health strategy that takes environmental, animal, and human health into account.

[20] The Africa CDC, Biosafety and Biosecurity Initiative, 5.
[21] Member States | African Union
[22] Article 2 (5), *Constitution of Kenya* (2010).

1.3 Research Objectives

I. To evaluate the role of the One Health approach in strengthening Kenya's biosafety and biosecurity legal framework.

II. To explore the legal framework for biosafety and biosecurity and identify gaps in Kenya's Biosafety Act regarding biosecurity.

III. To assess the Africa CDC's Biosafety and Biosecurity framework in relation to Kenya's Biosafety Act and recommend reforms that incorporate biosecurity measures to improve alignment with the One Health approach and international standards.

1.4 Research Questions

I. What is the importance of the integration of the One Health approach into Kenya's biosafety and biosecurity legal framework?

II. What are the gaps in Kenya's Biosafety Act concerning biosecurity, and how do they affect the country's ability to manage biological risks effectively?

III. How does the Africa CDC's Biosafety and Biosecurity framework compare to Kenya's Biosafety Act, and what legislative reforms are necessary to integrate biosecurity and ensure alignment with international and regional standards and the One Health approach?

1.5 Hypothesis

Integrating a robust biosecurity framework into Kenya's Biosafety Act, guided by the Africa CDC's Biosafety and Biosecurity Legal framework, will enhance Kenya's capacity to address biological threats, align with international standards, and promote a comprehensive One Health approach.

1.6 Justification for the Study

By addressing the shortcomings of the current Biosafety Act, this study seeks to improve Kenya's biosafety and biosecurity legal framework. The study seeks to improve Kenya's ability to handle new biological threats like bioterrorism, dual-use research risks, and zoonotic diseases by coordinating with the Africa CDC's Biosafety and Biosecurity framework. The relevance of the study lies in its contribution to the development of a unified biosafety and biosecurity system that

incorporates a One Health approach, thereby ensuring the protection of animal, plant and environmental health.

The findings will benefit key stakeholders, including lawmakers, public health officials, regulatory agencies, and biosafety experts, by providing actionable recommendations for legislative reform. Additionally, the study will contribute to the existing knowledge on incorporating biosecurity into biosafety laws, offering a replicable framework for other nations facing similar challenges.

1.7 Conceptual Framework: Protecting bugs from people.

Security refers to the state of being secure, that is, free from danger.[23] Security against exposure to dangerous biological agents, including precautions used to maintain this security encompasses biosecurity.[24] Biosecurity is the protection against biological threats, which can harm human health, animals, the environment, food, agriculture, infrastructure, and the economy.[25] These threats range from natural occurrences to intentional misuse, including accidents and negligence. Biosecurity encompasses safeguarding humans, animals, plants, the environment, and food from such threats. Biosafety concerns are a key component of biosecurity.

Biosecurity strives to safeguard against the threats posed by diseases and organisms, focusing on preventing pathogen introduction and dissemination.[26] While biosafety and biosecurity are often used interchangeably in scientific literature, they represent different concepts. Biosafety complements biosecurity by emphasising laboratory methods, facility design, safety equipment, and operating procedures to avoid unintentional exposure to biological agents.[27] This study intends to highlight the interdependence of animal, human and environmental health as part of the One Health approach, which is essential for comprehensive biosecurity.

[23] Merriam Webster Dictionary, 4 ed.
[24] Merriam Webster Dictionary, 4 ed.
[25] Ngethe E, 'Review of Biosecurity in Kenya in the context of food security' Unpublished LLM Thesis, Murdoch University, 2013, 5.
[26] Renault V, Humblet M F, Saegerman C, 'Biosecurity Concept: Origins, Evolution and Perspectives' 12 *Animals* 63, 2021, 2.
[27] Renault V, Humblet M F, Saegerman C, 'Biosecurity Concept: Origins, Evolution and Perspectives' 2.

Biosecurity has evolved from its initial focus on biological weapons and bioterrorism to a larger awareness of the interconnectivity of animal, human, plant, and environmental health.[28] This evolution aligns with the "One Health" approach, which recognises the intersection of these domains in ensuring overall well-being. The current understanding of Biosecurity supports this perspective by protecting all these domains. This holistic approach emphasizes the importance of collaboration among various stakeholders and sectors.[29]

Biological agents and their metabolites can be utilised as weapons of mass destruction in modern society. Biosecurity is critical to ensuring that these hazardous compounds are employed for good rather than harm. Additionally, the resurgence of deadly infections like Ebola underscores the need for Kenya to be better prepared to mitigate risks and respond effectively to outbreaks, both domestic and foreign.[30] According to the National Research Council in 2009, while biosafety shields humans from bugs, biosecurity shields bugs from humans.[31] Essentially, biosafety measures protect persons and the environment against potentially damaging consequences of biological agents, whereas biosecurity measures prevent those agents from slipping into the wrong hands or being used maliciously.

The Africa CDC BSBS legal framework is the basis of this study as it provides a guide for AU member states to review existing and develop new legal instruments that strengthen national biosafety and biosecurity systems.[32] Biosecurity should be included in legislative revisions to address the dangers of deliberate misuse and guarantee the accountability, control and protection of biological agents. Failure to enforce the framework enhances the possibility of accidentally or intentionally releasing hazardous biological agents and poisons, and also the incapacity to prevent, recognise, and respond to biological crises.[33]

[28] Renault V, Humblet M F, Saegerman C, 'Biosecurity Concept: Origins, Evolution and Perspectives' 1.
[29] Renault V, Humblet M F, Saegerman C, 'Biosecurity Concept: Origins, Evolution and Perspectives' 3.
[30] Biosafety and Biosecurity, 6 *KEMRI Bioethics Review* 3, 4.
[31] Beeckman DSA and Rüdelsheim P, 'Biosafety and Biosecurity in Containment: A Regulatory Overview' 8 *Frontiers in Bioengineering and Biotechnology,* 650, 2020, 2.
[32] The Africa CDC, Advocacy and Communication Strategy for the Biosafety and Biosecurity Legal Framework, 1.
[33] The Africa CDC, Biosafety and Biosecurity Initiative, 9.

The framework provides a lens to examine how Kenya's Biosafety Act can be enhanced to address biosecurity comprehensively while maintaining its focus on biosafety. By integrating these concepts into a unified system, the study aims to ensure effective biological risk management in line with international standards and the One Health approach.

1.8 Literature Review

Advancements in biotechnology have enabled gene editing and genetic transfer techniques, which could potentially be applied to pathogens. For instance, arboviruses could be modified to enhance their virulence or transmissibility. Such engineered pathogens pose significant risks, as they could be exploited for harmful intentions, like military applications or bioterrorism.[34] Given the potential dangers associated with handling arboviruses in both field and laboratory settings, it is clear that strong guidelines are required to limit these risks. The absence of clear and coherent guidelines could pose significant challenges to biosafety.[35]

The results of a biosecurity survey carried out in Kenya revealed that Kenyan laboratories possess biological agents that pose biosecurity risks. Many of these facilities lack adequate restrictions, allowing unauthorised access by students or staff. Additionally, a widespread lack of awareness about biosecurity and biosafety was observed among laboratory personnel.[36] The survey highlighted a lack of biosecurity legislation. Whilst Kenya has assented to international treaties such as the BWC and the UNSCR 1540, as well as legislation implemented the Cartagena Protocol on Biosafety in relation to genetically modified organisms, this does not cover all aspects of biosecurity.[37]

Kenya has made attempts to comply with international rules aimed at preventing the exploitation of biological materials by developing the Kenya National Biosciences Bill and the National

[34] Biosafety and Biosecurity, 6 *KEMRI Bioethics Review* 3, 7.
[35] Biosafety and Biosecurity, 6 *KEMRI Bioethics Review* 3, 7.
[36] Otieno E N, Slotved H C, Osoro E M, Olsen K N, Rugutt M, Wanjohi C W, Mwanda W, Kinyagia B M, Steenhard N R, and Hansen J E, 'A Biosecurity Survey in Kenya, November 2014 to February 2015' 14, Health Security 4, 2016, 205.
[37] Otieno E N, *et al,* 'A Biosecurity Survey in Kenya, November 2014 to February 2015', 206.

Biosciences Policy.[38] Although a Bioscience Bill currently under parliamentary review aims to address this gap by establishing comprehensive legislation for biosafety and biosecurity across all relevant sectors, its pending approval hinders progress in clearly defining roles, responsibilities, and regulatory mechanisms.[39] The survey authors recommend enacting legislation to establish a mandatory and standardised biosecurity system in Kenya. They point to Denmark as a successful example, which, through the implementation of a single law and executive order, transformed its biosecurity landscape.[40]

Kenya's regulatory framework for GMOs is legally aligned with the Cartagena Protocol on Biosafety.[41] The Biosafety Act of 2009 mandates the evaluation of socioeconomic impacts before approving applications[42] per the Cartagena Protocol.[43] However, the specifics of the evaluation process, analysis, and incorporation into biosafety decision-making remain unclear. To guarantee an equitable and open regulatory framework, it is crucial to provide specific rules for these aspects.[44] The authors acknowledge existing gaps in public awareness and education and emphasise the importance of addressing these gaps to foster informed decision-making and enhance biosecurity.[45] They recommend raising public awareness about biosafety regulations and developing robust policies and legal frameworks to support biosafety regulations.

While international discussions on biosafety often focus on GMOs in controlled settings like laboratories, the broader scope of biosafety encompasses a wide range of biological materials, including pathogens, genetic material, biological samples, and organisms. This overlap with biosecurity highlights the need for a comprehensive approach to managing biological risks.[46] The WHO Bio risk Management Laboratory Biosecurity Guidance established the notion of Valuable

[38] Otieno E N,*et al*, 'A Biosecurity Survey in Kenya, November 2014 to February 2015', 206.
[39] World Health Organisation, Joint External Evaluation of IHR Capacities of the Republic of Kenya,21.
[40] Otieno E N,*et al*, 'A Biosecurity Survey in Kenya, November 2014 to February 2015', 206.
[41] Catherine N K, Mugiira B R and Muchiri N J, 'Public Perception of Genetically Modified Organisms and the Implementation of Biosafety Measures in Kenya' Hindawi, 2024, 2.
[42] Section 29 (1)(e), *Biosafety Act* (Act No 2 of 2009).
[43] Article 26, *The Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, 29 January 2000.
[44] Catherine N K, *et al*, 'Public Perception of Genetically Modified Organisms and the Implementation of Biosafety Measures in Kenya,' 2.
[45] Catherine N K,*et al*, 'Public Perception of Genetically Modified Organisms and the Implementation of Biosafety Measures in Kenya,' 13.
[46] Beeckman DSA and Rüdelsheim P, 'Biosafety and Biosecurity in Containment: A Regulatory Overview,' 1.

Biological Materials (VBM). VBM are biological components that require special handling and preservation because of its economic, historical, or potential danger to public health. These materials can range from pathogens and toxins to non-pathogenic organisms, GMOs, and even extraterrestrial samples.

Beyond the risk of theft or intentional misuse, there is also the concern of "dual use" research, where knowledge gained from legitimate research could be exploited for malicious purposes.[47] This shows the importance of comprehensive biosafety legislation that encompasses all aspects of biosecurity. The authors conclude by stating that biosafety and biosecurity, while serving distinct objectives, are often considered together, especially in controlled settings. This area has a lengthy past, preceding GMO-focused biosafety, and it continues to change as new ideas and methodologies emerge.[48]

To improve AU member states' ability to adhere to international norms and laws, the Africa CDC initiated the Regional Biosafety and Biosecurity Initiative in May 2019.[49] The Africa CDC's BBI aims to address national-level capacity gaps identified through consultations with AU member states. Training, legislation, policies, prioritising pathogen identification, and establishing coordinating mechanisms are among the identified capability deficiencies. The program is governed by a 5-year strategic plan, which highlights topics aimed at forming regional infrastructure and procedures to assist the national implementation of biosecurity and safety.[50]

The framework intends to provide a regionally agreed-upon scope of legislation which each nation can subsequently apply and harmonise with their own legislation.[51] The model law developed by the AU provides a guide to member states in drafting and implementing their biosafety regulations. This model law promotes the harmonization of biosafety policies across the continent, ensuring a

[47] Beeckman DSA and Rüdelsheim P, 'Biosafety and Biosecurity in Containment: A Regulatory Overview,' 3.
[48] Beeckman DSA and Rüdelsheim P, 'Biosafety and Biosecurity in Containment: A Regulatory Overview,' 6.
[49] Maruta T, Kenfack JAN, Tebeje Y K, Bangure D and Ouma AEO, 'Regional approach to strengthening biosafety and biosecurity systems in Africa' 8 *Global Security: Health, Science and Policy* 1, 2023, 2.
[50] Maruta T, Kenfack JAN, Tebeje Y K, Bangure D and Ouma AEO,'Regional approach to strengthening biosafety and biosecurity systems in Africa,' 3.
[51] Maruta T, Kenfack JAN, Tebeje Y K, Bangure D and Ouma AEO,'Regional approach to strengthening biosafety and biosecurity systems in Africa,' 4.

consistent approach to biosafety and biosecurity.[52] East African countries, including Rwanda and Uganda, have drawn on this model to inform their national legislation.[53] The Africa CDC's BBI provides a valuable model for strengthening national frameworks. By emphasizing harmonized policies and a One Health approach, this initiative can help Kenya mitigate biological risks, improve regulatory systems, and align with global standards.

1.9 Methodology

This study employs a doctrinal research methodology, focusing on a detailed analysis of Kenya's Biosafety Act and related guidelines and regulations to identify critical gaps in biosecurity It places this analysis in the context of international legal documents that Kenya has accepted, including the Cartagena Protocol on Biosafety, the United Nations Security Council Resolution 1540 (UNSCR 1540), and the Biological Weapons Convention (BWC), and evaluates their applicability to domestic duties.

A comparative study utilizing Africa CDC's Biosafety and Biosecurity legislative framework benchmarks best practices to address the identified gaps. This framework serves as a regional model for enhancing biosafety systems and serves as a critical lens for assessing legislative shortcomings in Kenya. The study also reviews various reports, journal articles, and expert commentaries to provide insight into global standards and their application in Kenya's context.
This multifaceted approach facilitates a thorough examination of the biosecurity legal gap in Kenya, offering actionable recommendations aligned with international and regional standards, thus laying the groundwork for effective legislative reform.

1.10 Limitations

The research, while grounded in a comprehensive analysis of legislative texts and international frameworks, is subject to time constraints. To address this, the study prioritizes critical areas and leverages available resources efficiently. While it provides a comprehensive doctrinal and

[52] Niyonzima K B, 'Regulatory Frameworks and Policies in Synthetic Biology: Biosafety and Biosecurity in East Africa' 5 *Newport International Journal Of Scientific And Experimental Sciences* 3, 2024, 49.
[53] Niyonzima K B, 'Regulatory Frameworks and Policies in Synthetic Biology: Biosafety and Biosecurity in East Africa,' 49.

comparative analysis, it may not fully capture practical implementation challenges and institutional capacity. The absence of fieldwork and limited access to recent data may restrict the depth of analysis. Nonetheless, the research offers actionable recommendations aligned with international and regional frameworks to address legislative gaps.

1.11 Chapter Breakdown

Chapter1:Introduction

This chapter begins the analysis by emphasising the crucial role of biosafety and biosecurity in tackling biological threats. It explains the distinction between biosafety and biosecurity. It outlines Kenya's legislative framework, particularly the Biosafety Act, emphasizing its narrow focus on GMOs and the absence of robust biosecurity measures. It lays out the aims and research issues and the justification of the research. It outlines a conceptual framework rooted in the concept of security and the One Health approach used to analyse the problem and understand the literature review.

Chapter 2: The One Health Approach and its Role in Strengthening Biosecurity Legislation in Kenya

This chapter explores the One Health approach as an essential guide for enhancing Kenya's biosafety and biosecurity laws. It stresses the interconnectivity of individual, animal, and ecological health as well as its role in preventing and managing biological threats. The chapter highlights real-world cases where gaps in biosecurity policies led to global health catastrophes, including COVID-19 pandemic, the West Africa Ebola outbreak, and the 2003 SARS lab escapes, demonstrating the risks posed by weak biosecurity systems.

Chapter 3: Examining Kenya's Legislative Framework for Biosafety and Biosecurity

This chapter examines the existing laws for biosafety and biosecurity in Kenya, focusing on the Biosafety Act. It analyses its provisions and limitations, identifying gaps that hinder effective biosecurity, such as the absence of a dedicated oversight agency, risk assessment mechanisms, and comprehensive national standards. The chapter also evaluates how these gaps impact Kenya's ability to manage biological risks and align with global biosecurity requirements.

Chapter 4: The Africa CDC Biosafety and Biosecurity Model Legal Framework

This chapter analyses the Africa CDC's legislative framework on biosafety and biosecurity (BSBS framework) as a regional framework designed to guide AU member states in enhancing their biosafety and biosecurity systems. It compares the BSBS framework to Kenya's Biosafety Act, evaluating whether the Act meets the regional and international standards outlined in the legal framework. The analysis focuses on the seven domains of the BSBS framework and assess its applicability as a model for addressing Kenya's legislative shortcomings.

Chapter 5: Conclusion, Recommendations and Proposed Legal Reforms

The final chapter summarises key findings and present actionable recommendations for legislative and operational reforms. It will propose strategies to enhance Kenya's biosafety and biosecurity systems, ensuring alignment with regional and global standards. The chapter will conclude by emphasising the significance of adopting a comprehensive and integrated framework to safeguard public health, national security, and the environment.

CHAPTER 2: THE ONE HEALTH CONCEPT AND ITS IMPORTANCE IN STRENGTHENING BIOSECURITY LEGISLATION

2.1: Introduction

The One Health Approach is a multidisciplinary technique that acknowledges the interdependence of the health of people, animals, and the environment in preventing and controlling biological risks. Given the rise of zoonotic diseases, laboratory biosafety breaches, and the increasing risk of bioterrorism, an integrated approach to biosecurity is essential to safeguarding national and global health security. This chapter explores the One Health Approach as a basis for strengthening Kenya's biosecurity legislation. It highlights real-world cases where the failure to integrate biosecurity considerations led to global public health crises, emphasizing the urgency of comprehensive legal reforms.

2.2: Understanding the One Health Concept

Since the phrase One Health first appeared in the early 2000s, initiatives to implement a One Health strategy at national, regional and global level are on the rise.[54] Global health organisations, notably the World Health Organisation (WHO), the World Organisation for Animal Health (WOAH), and the Food and Agriculture Organisation (FAO), have all accepted this approach for combating biological threats holistically. The tripartite cooperation marked the start of the One Health strategy's implementation; nonetheless, the One Health framework's traditional focus has been on controlling zoonotic illnesses and high-impact threats with potential to cause regional and global security crises.[55]

One Health entails involvement of the welfare of people, animals, and the environmental sectors, alongside other pertinent stakeholders, in the layout and execution of programs, policies, laws, and

[54] Mwatondo A, Rahman-Shepherd A, Hollmann L, Chiossi S, Maina J, Kurup KK, Hassan OA, Coates B, Khan M, Spencer J, Mutono N, Thumbi SM, Muturi M, Mutunga M, Arruda LB, Akhbari M, Ettehad D, Ntoumi F, Scott TP, Nel LH, Ellis-Iversen J, Sönksen UW, Onyango D, Ismail Z, Simachew K, Wolking D, Kazwala R, Sijali Z, Bett B, Heymann D, Kock R, Zumla A, Dar O, 'A global analysis of One Health Networks and the proliferation of One Health collaborations' 401 *The Lancet* 10376, 2023, 605.

[55] Mwatondo A *et al, '*A global analysis of One Health Networks and the proliferation of One Health collaborations' 605.

research aimed at improving health outcomes for all.[56] Implementing a One Health approach entails cross-sectoral collaboration in animal, human, and environmental health to address common health threats. The modern era's bio-fare is an intentional societal threat that, like natural epidemics, has the potential to jeopardise human livelihood by attacking food supply networks across geographic boundaries.[57] New infections are constantly appearing all over the world, most of which are zoonotic to mean transmittable from animals to humans and have an animal origin.[58]

On January 18, 2021, WHO Director-General Dr. Tedros Adhamon Ghebreyesus remarked that the COVID-19 pandemic has demonstrated that One Health must be not simply a concept, and it must be turned into mechanisms to keep people safe.[59] The Tripartite and the United Nations Environment Programme (UNEP) founded the One Health High-Level Expert Panel (OHHLEP) to advance the One Health concept. OHHLEP defines One Health as an interpolated, unified approach that attempts to reconcile and promote individual well-being, animal health, and ecosystems, and calls for rallying diverse sectors, various fields, and communities to combat risks.[60]

In summary, One Health dismantles the disciplinary silos that have frequently divided the social and biological sciences into distinct fields of study and promotes cooperation between specialists from different disciplines, stressing the importance of an interdisciplinary approach for research

[56] Alimi Y and Wabacha J, 'Strengthening coordination and collaboration of one health approach for zoonotic diseases in Africa' 5 *One Health Outlook* 10, 2023, 3.
[57] Jimale H A, Dr. O.Ochieng and Dr. Ouman M, 'Effectiveness of the Existing Regulatory Framework for Biosecurity Preparedness Atgarissa Level Five Hospital Garissa County Kenya' 9 *International Journal of Science and Research* 12, 2020, 840.
[58] Alimi Y and Wabacha J, 'Strengthening coordination and collaboration of one health approach for zoonotic diseases in Africa' 5 *One Health Outlook* 10, 2023, 2.
[59] Mwatondo A *et al, '*A global analysis of One Health Networks and the proliferation of One Health collaborations' 605.
[60] Mwatondo A *et al, '*A global analysis of One Health Networks and the proliferation of One Health collaborations' 606.

and creating solutions to health issues at the local, national, and international levels.[61] The foundation of One Health is the interdependence of environmental, animal, and human health.[62]

2.3: One Health Approach in Biosecurity Legislation

One of the key elements of the One Health philosophy is biosecurity.[63] Despite the fact that biosecurity is sometimes used interchangeably with biodefense or biosafety, it frequently refers to studies, practices, and regulations that address the prevention, elimination, or efficient control of threats brought about by the introduction of invasive alien species and genotypes, zoonoses, GMOs, and pests of plants and animals.[64] Because it seeks to stop spread of infections to domesticated animals, people, and the environment (including wildlife and plant species), biosecurity is crucial in this context. By protecting people's health and well-being, it also aims to lessen the negative effects of infectious illnesses on the environment, economy, and society at large.[65]

Globalisation and recent developments in life science technology have increased society's susceptibility to bio risks without increasing the interdisciplinary connections between bioscience and military security.[66] Evidence suggests that changes like wildlife biodiversity, population growth, urbanisation, increasing agricultural practices, wildlife encroachment, and climate change are major contributors to the emergence of illness.[67] In relation to the One Health concept, biosecurity, comprising all measures to prevent the entrance of diseases and control their spread

[61] Degeling C, Johnson J,Kerridge I, Wilson A, Ward M, Stewart C and Gilbert G, 'Implementing a One Health approach to emerging infectious disease: reflections on the socio-political, ethical and legal dimensions' 15 *BMC Public Health* 1307, 2015, 2.

[62] Degeling C *et al,* 'Implementing a One Health approach to emerging infectious disease: reflections on the socio-political, ethical and legal dimensions' 2.

[63] Huber N, Andraud M, Sassu EL, Prigge C, Zoche-Golob V, Käsbohrer A, D'Angelantonio D, Viltrop A, Żmudzki J, Jones H, Smith RP, Tobias T, Burow E, 'What is a biosecurity measure? A definition proposal for animal production and linked processing operations' 15 *One Health* 100433, 2022, 1.

[64] Hulme P, 'One Biosecurity: a unified concept to integrate human, animal, plant, and environmental health' 4 *Emerging Topics in Life Sciences* 5, 2020, 539.

[65] Huber N *et al,* What is a biosecurity measure? A definition proposal for animal production and linked processing operations' 1.

[66] Jimale H A, Dr. O.Ochieng and Dr. Ouman M, 'Effectiveness of the Existing Regulatory Framework for Biosecurity Preparedness Atgarissa Level Five Hospital Garissa County Kenya' 840.

[67] Alimi Y and Wabacha J, 'Strengthening coordination and collaboration of one health approach for zoonotic diseases in Africa' 5 *One Health Outlook* 10, 2023, 2.

(biocontainment), provides an integrative coordinated strategy that addresses the connections between diverse players and areas.[68]

The WHO, the International Plant Protection Convention (IPPC), and WOAH define worldwide standards for human, plant, and animal health, while the CBD establishes non-binding criteria for managing alien species that endanger biodiversity.[69] The sectorial divisions overlook the shared biological processes behind all invasions regardless of the affected species, reflecting a lack of cross-disciplinary thinking. The global passage of viruses, parasites, plants, and animals, all of which represent biological invasions, necessitates a more fused approach to biosecurity.[70]

2.4: Real-world cases and their implications on the need for biosecurity legislation.

Following the Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) epidemic, many people around the world have realised the significance of biosecurity in safeguarding global health.[71] The epidemic of SARS, the first fatal highly transmissible new disease to appear, prompted the realisation that, an unknown pathogen can emerge unexpectedly from wildlife posing a global threat to health and economies; that countries need to have the capability to quickly detect and respond to outbreaks and that international collaboration and a One Health approach are necessary for dealing with major multi-country epidemics.[72]

The zoonotic genesis and a spillover pathway from animal farming and wildlife trading are the most likely explanations of the growing body of scientific information about the origins of SARS-CoV-2.[73] The involvement of humans in reverse zoonosis is highlighted by new agricultural methods like mink farming, where SARS-CoV-2 epidemics were caused by a "spill-over" from

[68] Renault V, Humblet M F, Saegerman C, 'Biosecurity Concept: Origins, Evolution and Perspectives' 3.
[69] Hulme P, 'One Biosecurity: a unified concept to integrate human, animal, plant, and environmental health' 540.
[70] Hulme P, 'One Biosecurity: a unified concept to integrate human, animal, plant, and environmental health' 541.
[71] Hulme P, 'One Biosecurity: a unified concept to integrate human, animal, plant, and environmental health' 539.
[72] Mackenzie J S, Jeggo M, 'The One Health Approach-Why Is It So Important?' 4 *Tropical Medicine and Infectious Disease* 88, 2019, 1.
[73] Keusch G T, Amuasi J H, Anderson D E, Daszak P, Eckerle I, Field H, Koopmans M, Lam S K, Das Neves C G, Peiris M, Perlman S, Wacharapluesadee S, Yadana S, and Saif L, 'Pandemic origins and a One Health approach to preparedness and prevention: Solutions based on SARS-CoV-2 and other RNA viruses' 119 *Proc Natl Acad Sci* 42, 2022, 1.

people who worked on the farms.[74] In light of the incident, the major priorities for pandemic prevention and preparation are increased monitoring and risk analysis at the intersection of livestock, wildlife and human health (One Health); research to accelerate vaccine and treatment development and strategies to lessen the causes of disease spread. Integrating biosafety and biosecurity within a One Health framework is crucial for all three targets.[75]

The outbreak of Ebolavirus in the West Africa region, as well as ongoing infection rates with a new H7N9 virus influenza A strain in mainland China, serve as stark reminders of the inextricable relationship between human and animal health.[76] Emerging and re-emerging infections (EIDs) pose concerns because viruses can modify behaviour over time, either due to genetic modification or changes in transmission patterns. The increased prevalence of EIDs caused by many variables is best handled with a complete One Health strategy.[77] A One Health technique is gradually being recognised as the most effective method of controlling EID threats because it acknowledges certain realities about the character of the pathogen.[78]

WHO investigations linked inadequate biosecurity preparedness capabilities and subpar Biosafety Level (BSL) BSL-3 laboratory techniques to the 2003 acquired SARS illness.[79] COVID-19, which is suspected to have originated from zoonotic transmission, underscored the risks associated with poor biosecurity in animal markets and research facilities.[80] As a result of Kenya's institutional

[74] Alimi Y and Wabacha J, 'Strengthening coordination and collaboration of one health approach for zoonotic diseases in Africa' 5 One Health Outlook 10, 2023, 2.
[75] Keusch G T *et al,* 'Pandemic origins and a One Health approach to preparedness and prevention: Solutions based on SARS-CoV-2 and other RNA viruses'1.
[76] Degeling C *et al,* 'Implementing a One Health approach to emerging infectious disease: reflections on the socio-political, ethical and legal dimensions' 2.
[77] Keusch G T *et al,* 'Pandemic origins and a One Health approach to preparedness and prevention: Solutions based on SARS-CoV-2 and other RNA viruses' 1.
[78] Degeling C *et al,* 'Implementing a One Health approach to emerging infectious disease: reflections on the socio-political, ethical and legal dimensions' 2.
[79] Jimale H A, Dr. O.Ochieng and Dr. Ouman M, 'Effectiveness of the Existing Regulatory Framework for Biosecurity Preparedness Atgarissa Level Five Hospital Garissa County Kenya' 840.
[80] Keusch G T *et al,* 'Pandemic origins and a One Health approach to preparedness and prevention: Solutions based on SARS-CoV-2 and other RNA viruses' 5.

inadequacy, the 2006/7 wave of Rift Valley fever hit six out of eight regions, with documented individual cases totalling 717 and 162 deaths.[81]

Because of the endemic burden of disease and the numerous environmental and host factors that promote the establishment of biological threats, Africa faces numerous health-related difficulties.[82] Anthrax, Ebola, zoonotic influenza, monkeypox, Lassa fever, and Rift Valley fever outbreaks keep on causing fatalities and serious illness in humans and animals throughout the continent. They also affect livelihoods, disrupt the flow of people and goods, cause food insecurity, put a strain on national health systems, and cause enormous financial losses for the public and private sectors.[83]

The development and characterisation of zoonotic organisms require fully equipped laboratories, better biosafety and biosecurity framework to safeguard investigators, specialised reagents, and highly educated laboratory personnel, which may be challenging to sustain in resource-poor environments.[84] In Africa and other low-resource countries, numerous obstacles significantly impede the establishment of sustainable capability in biosafety and biosecurity management.[85] Through the Africa CDC, the AU supports the One Health approach to combat zoonotic diseases in the human, animal, and environmental domains. A framework for One Health Practice at National Public Health Institutes (NPHIs) has been developed under the leadership of the Africa CDC in an effort to strengthen the One Health approach.[86] The Africa CDC Regional Biosafety and Biosecurity Initiative enables standard regional initiatives that may be employed at national level.[87]

[81] Jimale H A, Dr. O.Ochieng and Dr. Ouman M, 'Effectiveness of the Existing Regulatory Framework for Biosecurity Preparedness Atgarissa Level Five Hospital Garissa County Kenya' 840.
[82] Abdi M A, *et al,* 'Biosafety and Biosecurity in Africa: Challenges and Future Perspectives' 3.
[83] Alimi Y and Wabacha J, 'Strengthening coordination and collaboration of one health approach for zoonotic diseases in Africa' 5 *One Health Outlook* 10, 2023, 2.
[84] Bird B H and Mazet JAK, 'Detection of Emerging Zoonotic Pathogens: An Integrated One Health Approach' 6 *Annual Review of Animal Biosciences,* 2017, 132.
[85] Abdi M A, *et al,* 'Biosafety and Biosecurity in Africa: Challenges and Future Perspectives' 2.
[86] Alimi Y and Wabacha J, 'Strengthening coordination and collaboration of one health approach for zoonotic diseases in Africa' 5 *One Health Outlook* 10, 2023, 3.
[87] Abdi M A, *et al,* 'Biosafety and Biosecurity in Africa: Challenges and Future Perspectives' 2.

In order for biosecurity policies to be successful, they must leverage a more unified, universal strategy that looks for national and international synergies between the environmental, agricultural, and health sectors. They should also try to move away from the conventional emphasis on regulating specific sectors in order to guarantee trust in the overall risk management.[88] Since One Health initiatives are being conducted in silos, operationalising One Health is still difficult and has not been able to establish a solid institutional base.[89] The AU spearheaded the creation of the African Union One Health initiative in an attempt to do away with the compartmentalised approach.

A single framework for addressing biosecurity threats that go beyond the conventional divisions of animal, plant, human, and environmental health is offered by the One Biosecurity concept.[90] One Biosecurity is a multifaceted approach to biosecurity research and policy that draws on the interconnection between human, animal, and environmental health to reduce the implications of pervasive alien species more effectively.[91] Clear legal frameworks for dealing with emerging infectious diseases are essential to provide the necessary structure to support and coordinate a One Health approach.[92]

In order to successfully implement a One Health strategy to developing infectious diseases, sociopolitical, ethical, and legal problems must be addressed, including aligning policies with public values and preferences through public engagement, developing an ethical framework, and integrating these into decision-making processes.[93]

[88] Hulme P, 'One Biosecurity: a unified concept to integrate human, animal, plant, and environmental health' 540.
[89] Alimi Y and Wabacha J, 'Strengthening coordination and collaboration of one health approach for zoonotic diseases in Africa' 5 *One Health Outlook* 10, 2023, 4.
[90] Hulme P, 'One Biosecurity: a unified concept to integrate human, animal, plant, and environmental health' 541.
[91] Hulme P, 'One Biosecurity: a unified concept to integrate human, animal, plant, and environmental health' 541.
[92] Degeling C *et al,* 'Implementing a One Health approach to emerging infectious disease: reflections on the socio-political, ethical and legal dimensions' 5.
[93] Degeling C *et al,* 'Implementing a One Health approach to emerging infectious disease: reflections on the socio-political, ethical and legal dimensions' 9.

CHAPTER 3: LEGAL FRAMEWORK FOR BIOSAFETY AND BIOSECURITY IN KENYA.

3.1 Introduction

This chapter focuses on the legal framework governing biosafety and biosecurity. This will be done by analysing the Biosafety Act, biosafety regulations and guidelines, and international conventions ratified by Kenya. This chapter evaluates Kenya's legislative framework for biosafety and biosecurity, identifies gaps, and explores the implications of these deficiencies.

3.2 Background To The Development Of Biosafety Legislation

By controlling the handling, disposal, use, and transfer of biological agents and genetically modified organisms (GMOs), biosafety laws form a fundamental framework for safeguarding public health, the environment, and global security. Laboratory research on pathogens is essential for developing tools to combat infectious diseases. Researching infectious agents contributes to the development of public health and medical instruments for outbreak detection, diagnosis, and response. Expanding facilities and resources for handling infectious agents, however, calls for strict biosafety and biosecurity policies to safeguard researchers and society.[94] Biosafety aims to safeguard personnel, while biosecurity focuses on securing infectious agents from misuse.[95]

Kenya recognises the significance of agriculture and has been actively engaged in advancing biotechnology research and development. Genetically modified sorghum, maize, cotton, sweet potatoes, and cassava have all undergone authorised trials in the nation.[96] Appreciating the significance of biosafety, it ratified the Cartagena Protocol on Biosafety (CPB) and signed the Convention on Biological Diversity (CBD), which required the creation of a thorough legislative framework for biosafety (Biotechnology Policy, Biosafety Act, and implementing regulations).[97] Biological agents can be abused as terrorist weapons in the modern era. To guarantee that such

[94] World Health Organisation, Joint External Evaluation of IHR Capacities of the Republic of Kenya, 20.
[95] The Africa CDC, Biosafety and Biosecurity Initiative, 2021, 5.
[96] Kingiri A and Ayele S, 'Towards a smart biosafety regulation: The case of Kenya' Environ. Biosafety Res.8, 2009, 133-134. -<https://doi.org/10.1051/ebr/2009014>-
[97] Kingiri A and Ayele S, 'Towards a smart biosafety regulation: The case of Kenya,' 134.

substances are used for beneficial purposes, biosecurity is crucial. The necessity for robust biosecurity measures to safeguard public health is underscored by the resurgence of lethal viruses such as Ebola.[98]

Biosafety frameworks and the urgency to enact biosafety regulations may be traced back to the 1992 Convention on Biological Diversity (CBD), an international agreement established under the direction of the United Nations Environment Programme (UNEP).[99] Its primary objectives were biodiversity conservation, sustainable utilisation of its components, and a fair allocation of benefits from the usage of genetic resources.[100] While formulating the agreement, governments observed that recent biotechnology could contribute to sustainable growth if developed and applied properly and responsibly.[101]

On January 29, 2000, the Conference of Parties to the CBD adopted the Cartagena Protocol on Biosafety, a supplementary accord to the Convention. In May 2000, Kenya became the first state in the world to ratify the Cartagena Protocol, which aimed to secure the secure transport, storage, and utilisation of living-modified organisms produced by new biotechnology.[102] The Protocol was ratified in 2003, hence Kenya was bound by its rules.[103] Kenya's implementation of the Biosafety Law in February 2009 fulfilled its international commitment as a signatory to the Protocol.

Beyond Kenya's international obligations, a Biosafety Law was urgently needed to guide ongoing research and facilitate the commercialization of products like transgenic cotton and maize.[104] The existing Science and Technology Act (1980) lacked the necessary provisions, making a new law crucial for responsible and safe biotechnology use. A comprehensive biosafety law was required

[98] Biosafety and Biosecurity, 6 *KEMRI Bioethics Review* 3, 2016, 4.
[99] Karembu M, Otunge D, and Wafula D, 'Developing a Biosafety Law: Lessons from the Kenyan Experience' *ISAAA AfriCenter*, Nairobi, Kenya, 2010, 3.
[100] Article 1, *Convention on Biological Diversity*, 22 May 1992.
[101] 'Developing a Biosafety Law: Lessons from the Kenyan Experience' 3.
[102] 'Developing a Biosafety Law: Lessons from the Kenyan Experience' 4.
[103] https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXVII-8-a&chapter=27&clang=_en
[104] 'Developing a Biosafety Law: Lessons from the Kenyan Experience' 4.

to support the appropriate use of modern biotechnology, address possible threats to the ecosystem and human life, and promote the technology's benefits.[105]

3.3 Overview of Kenya's Legislative Framework

Rules and guidelines were developed in 1998 as a result of the early genetic engineering research conducted in the 1990s. The 2006 National Biotechnology Development Policy, on the contrary, took a more thorough approach and provided an outline for Kenya's biotechnology development.[106] This policy created an administrative and legal framework for the production and use of biotechnology goods and laid the path for a legislative framework to regulate them. This legislative framework was further strengthened and adherence to the Cartagena Protocol was guaranteed by the Biosafety Act of 2009 and its implementing rules.

3.3.1 The Biosafety Act 2009 (Cap 320, Laws of Kenya)

The Biosafety Act of Kenya purposes to regulate the use and handling of genetically modified organisms (GMOs) to ensure animal, human and environmental protection. It is the primary legal instrument regulating biotechnology and GMOs in Kenya. The Act establishes a robust regulatory framework which oversees the transfer, handling, and use of GMOs.[107] It applies to all activities involving GMOs except pharmaceuticals for human use.[108] The Act establishes the National Biosafety Authority (NBA) as the primary regulatory body.[109] The NBA is governed by a nine-member Board responsible for overseeing its operations and implementing the Act's provisions. The composition of the Board reflects a multi-sectoral approach, including representation from relevant ministries and experts in biological, environmental, and social sciences.[110]

The NBA oversees compliance, conducts risk assessments, and issues approvals for GMO activities.[111] In the First Schedule, the Act recognizes the role of various regulatory agencies, such as the Department of Public Health, the Department of Veterinary Services, Kenya Plant Health

[105] 'Developing a Biosafety Law: Lessons from the Kenyan Experience' 4.
[106] Kingiri A and Ayele S, 'Towards a smart biosafety regulation: The case of Kenya,' 134.
[107] Section 4, Biosafety Act (No 2 of 2009).
[108] Section 3, Biosafety Act (No 2 of 2009).
[109] Section 5, Biosafety Act (No 2 of 2009).
[110] Section 6, Biosafety Act (No 2 of 2009).
[111] Section 7, Biosafety Act (No 2 of 2009).

Inspectorate Services, and the National Environment Management Authority. In order to provide a coordinated and thorough regulatory framework for GMOs, the NBA is required to liaise with these agencies.

While the Biosafety Act establishes a strong framework for managing GMOs in Kenya, it falls short in addressing broader biosecurity issues. Although the Act aligns with the Cartagena Protocol, emphasising precautionary principles and socio-economic considerations, its focus remains primarily on the activities surrounding GMOs. This limitation creates a gap in the regulation of other biological risks, such as high-consequence pathogens and dual-use research. As a result, the Act lacks specific provisions for managing these risks, potentially leaving the country exposed to biological threats. Dual-use research defines technologies and knowledge generated from biomedical research for non-combative uses that could be abused to endanger national security or public health.[112]

The Biosafety Act defines a genetically modified organism (GMO) as any creature with a new combination of genetic material generated using modern biotechnology techniques.[113] Biosafety is the aversion of hazards to human health as well as environmental preservation due to the usage of GMOs.[114] There is no definition of biosecurity in the Act nor the complementing biosafety regulations of the Act. Kenya must adopt an extensive legal foundation for biosecurity to guarantee efficient oversight over biological agents and protection against biological hazards.[115]

Subject to the provisions of the Biosafety Act, some regulations govern various aspects of biosafety and biosecurity, including procedures for contained use, environmental release, importation, exportation, transit, handling, packaging, transportation, and labelling of genetically modified organisms.[116]

[112] Kenya Biosafety Guidelines, 121.
[113] Section 2, Biosafety Act (No 2 of 2009).
[114] Section 2, Biosafety Act (No 2 of 2009).
[115] Otieno E N, *et al*, 'A Biosecurity Survey in Kenya, 211.
[116] Section 51, Biosafety Act (No 2 of 2009).

3.3.2 The Biosafety (Contained Use) Regulations

These regulations govern activities involving GMOs in controlled facilities. They seek to lessen possible negative impacts on the environment and human health.[117] The NBA classifies containment levels and, in collaboration with regulatory agencies, evaluates the suitability of premises based on GMO risk.[118] These levels apply to laboratory, greenhouse, and screen house activities, with separate procedures for confined field trials. An Institutional Biosafety Committee (IBC) must be established by research institutions engaging in contained use activities responsible for preparing and submitting applications to the Authority, advising on biosafety matters, and monitoring compliance.[119] The regulations place a central task on the NBA to assess applications for contained use, ensuring that proposed activities adhere to the prescribed safety protocols, containment levels and emergency response plans, ultimately safeguarding human and environmental well-being.[120]

3.3.3 The Biosafety (Environmental Release) Regulations

The regulations offer a framework for assessing and managing hazards connected with the environmental release and commercialisation of GMOs in Kenya. Their primary objective is to mitigate potential adverse effects on human health and the environment associated with these activities.[121] These laws were created in anticipation of the commercial introduction of GMOs in the country. A robust risk assessment process is mandated for all applications involving environmental release[122] or placing on the market of GMOs.[123] The NBA has the discretion to exempt certain applications based on existing knowledge and experience.[124] The regulations emphasize public awareness and engagement, requiring the NBA to publicize applications and invite public comments.[125] Post-release monitoring is mandatory, with the NBA and relevant regulatory agencies collaborating to ensure compliance and mitigate potential risks.

[117] Section 3, Biosafety (Contained Use) Regulations 2011.
[118] Section 5, Biosafety (Contained Use) Regulations 2011.
[119] Section 6, Biosafety (Contained Use) Regulations 2011.
[120] Section 8, Biosafety (Contained Use) Regulations 2011.
[121] Section 3, Biosafety (Environmental Release) Regulations 2011.
[122] Section 5, Biosafety (Environmental Release) Regulations 2011.
[123] Section 6, Biosafety (Environmental Release) Regulations 2011.
[124] Section 8, Biosafety (Environmental Release) Regulations 2011.
[125] Section 12, Biosafety (Environmental Release) Regulations 2011.

3.3.4 The Biosafety (Import, Export and Transit) Regulations

The rules aim to secure the safe transit of GMOs into, across, and out of Kenya while safeguarding human well-being and the environment.[126] It outlines application procedures and requirements for importing, exporting, and transiting GMOs, specifying necessary approvals, fees, and documentation. The regulations also address issues such as unauthorised movement and accidental releases.[127] Applications for importing, exporting, or transporting GMOs must be submitted in a prescribed format, along with supporting documents, fees, and detailed information about the GMO, its intended use, and the safety measures in place.[128] The National Biosafety Authority (NBA) reviews these applications, potentially conducting risk assessments before granting approvals.

3.3.5 The Biosafety (Labelling) Regulations

These regulations aim to ensure consumer transparency regarding genetically modified foods, feeds, and products, enabling informed choices.[129] They facilitate product traceability to implement necessary risk management measures. The rules encourage proper labelling, the tracking of health and environmental impacts, and the application of suitable risk management strategies, such as product discontinuation.[130] However, they exclude foods, feeds, or ingredients with minimal inadvertent genetically modified material, highly refined foods, processing aids or food additives with negligible novel DNA or protein, and food made and sold directly from eateries and suppliers.[131]

3.3.6 Laboratory Biosafety and Biosecurity Guidelines

Kenya has developed and distributed biosafety and biosecurity policy guidelines that have been used in developing laboratory-specific safety manuals.[132] In relation to biosafety and biosecurity, the guidelines highlight the importance of protecting valuable biological materials and preventing

[126] Section 3, Biosafety (Import, Export and Transit) Regulations 2011.
[127] Section 10, Biosafety (Import, Export and Transit) Regulations 2011.
[128] Section 4-9, Biosafety (Import, Export and Transit) Regulations 2011.
[129] Section 3, Biosafety (Labelling) Regulations 2011.
[130] Section 6-10, Biosafety (Labelling) Regulations 2011.
[131] Section 5, Biosafety (Labelling) Regulations 2011.
[132] World Health Organisation, Joint External Evaluation of IHR Capacities of the Republic of Kenya, 20.

their misuse.[133] The guidelines' intent is to offer Kenyan laboratories with safe practices, guidelines, and minimum requirements that they may utilise to establish and improve their own occupational health and safety program, as well as their coworkers, environment, and community.[134] The standards establish minimal requirements, policies, and procedures to reduce hazards to persons, facilities, and the environment associated with the handling of biological and chemical agents.

Based on the Occupational Safety and Health Act of 2007, the guide serves as a resource for new hire orientation and follow-up training on occupational safety and health (OSHA 2007).[135] All persons dealing with chemical and biological agents and any activities involving them are subject to the guidelines. These consist of dual-use research, biosecurity, bioethics, and workplace safety and health. It touches on biosecurity as it provides for biorisk management, which encompasses both biosafety and biosecurity. The aim is to reduce the risk of both accidental and intentional harm and provide assurance that measures are in place to mitigate such risks.[136] Biosecurity is better addressed in the guidelines; however, a survey conducted in Kenya illustrates that they are merely voluntary and need to be backed up by legislation to be more effective.

3.4 Kenya's International Obligations

3.4.1 The Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety strives to offer adequate protection in regard to of safe transport, managing, and usage of living-modified organisms (LMOs) that may harm biodiversity and human health, particularly focusing on transboundary movements. The Protocol places a strong emphasis on handling, packing, and transporting LMOs safely during deliberate cross-border travels in accordance with international regulations and norms.[137] However, the Cartagena Protocol mainly focuses on GMOs and does not encompass broader biosecurity concerns. Kenya passed the Cartagena Protocol on Biosafety in order to protect the environment and ensure human

[133] Laboratory Biosafety and Biosecurity Policy Guidelines, 13.
[134] Laboratory Biosafety and Biosecurity Policy Guidelines, 12.
[135] Laboratory Biosafety and Biosecurity Policy Guidelines, 12.
[136] Laboratory Biosafety and Biosecurity Policy Guidelines, 12.
[137] Article 18, *The Cartagena Protocol on Biosafety to the Convention on Biological Diversity,* 29 January 2000.

safety when using GMOs. However, biosafety requirements addressing the risks of exposure to biological agents cannot be implemented due to framework challenges and the capacity of authorised institutions in occupational health and safety.[138]

3.4.2 The Biological Weapons Convention

Biological weapons, using disease-causing organisms or toxins, pose significant threat to global health and security. These weapons can spread rapidly and have devastating consequences if deliberately released by state or non-state actors.[139] In 1976, Kenya acceded to the BWC, which criminalises the creation and abuse of biological weapons.[140] The Convention barred the creation, manufacture, acquisition, stockpiling, or transfer of biological weapons in addition to their use in combat.[141] Incorporating biosecurity in the current legislation will align Kenya's framework with global standards such as the BWC, ensuring compliance and fostering international collaboration.

3.4.3 The United Nations Security Council Resolution 1540

Kenya signed the Resolution in 2004, requiring member states to prevent the spread of weapons of mass destruction, including biological toxins. The UNSCR 1540 legally compels every state participant to enforce effective steps to institute domestic controls to prevent the dissemination of biological, chemical, and nuclear arms and their methods of delivery, including imposing sufficient controls over associated materials.[142] Integrating biosecurity will enhance Kenya's ability to prevent bioterrorism and unauthorized use of biological agents, safeguarding public health and national security.

3.5 Oversight of the Draft Biosecurity Bill 2024

Following the JEE report made in 2017 about the drafting of the Bioscience Bill, which was yet to be passed in parliament, efforts were made to include biosecurity in the Kenyan legislative

[138] Otieno E N, *et al*, 'A Biosecurity Survey in Kenya, 211.
[139] https://disarmament.unoda.org/biological-weapons/
[140] Otieno E N, Slotved H C, Osoro E M, Olsen K N, Rugutt M,. Wanjohi C W, Mwanda W, Kinyagia B M, Steenhard N R, and Hansen J E, 'A Biosecurity Survey in Kenya, 211.
[141] Article 1, *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction,* 26 March 1975.
[142] Article 2, *UN Security Council Resolution 1540,* 28 April 2004.

framework.[143] The draft Biosecurity Bill 2024, which is still in the process of formation, represents a significant legislative effort to address biosecurity gaps in Kenya's legal framework, particularly those identified in the Biosafety Act. The Bill aims to prohibit and prevent biological weapons. It establishes regulations to prevent the development, production, stockpiling, acquisition, transfer and misuse of biological agents and toxins.[144] It establishes an institutional framework, the National Biosecurity Authority (NBA), to oversee biosecurity measures and coordinate with regulatory agencies.[145]

The Bill provides for the coordination of the NBA with regulatory agencies over matters related to activities involving controlled biological agents and toxins.[146]It mandates approvals for the handling, transfer, storage and disposal of controlled biological agents and toxins.[147]The Bill strengthens risk assessment and incident management by introducing provisions for risk assessments,[148]incident reporting,[149]and maintaining registers of controlled agents.[150]

The Bill mandates the establishment of an Institutional Biosecurity Committee within facilities handling controlled biological agents and toxins.[151] The functions of the committee include preparing applications for using controlled agents, advising on biosecurity matters, assisting in risk assessment and managing, ensuring compliance with approvals and reviewing containment procedures. By requiring the Authority to inform the public and those carrying out activities covered by the Bill, it also raises public awareness.[152]

Nevertheless, there are gaps yet to be addressed by the Bill. The Bill lacks detailed protocols for laboratory safety, including biosafety level containment requirements for high-consequence pathogens. Insufficient containment guidelines may lead to inconsistent safety practices across

[143] World Health Organisation, Joint External Evaluation of IHR Capacities of the Republic of Kenya, 21.
[144] Section 21, Draft Biosecurity Bill, 2024.
[145] Section 6, Draft Biosecurity Bill, 2024.
[146] Section 19, Draft Biosecurity Bill, 2024.
[147] Section 23-33, Draft Biosecurity Bill, 2024.
[148] Section 34, Draft Biosecurity Bill, 2024.
[149] Section 35, Draft Biosecurity Bill, 2024.
[150] Section 36, Draft Biosecurity Bill, 2024.
[151] Section 37, Draft Biosecurity Bill, 2024.
[152] Section 38, Draft Biosecurity Bill, 2024.

laboratories, increasing the risk of accidental releases. Although public awareness is emphasized, the Bill does not mandate comprehensive biosecurity training for personnel handling biological agents. Inadequate training undermines preparedness and the ability to effectively manage biological risks effectively. Despite the Bill mentioning the secure handling of biological agents, it lacks detailed protocols for material tracking, secure storage, and disposal. Poor oversight of biological material increases the risks of unauthorized access and improper disposal.

Provisions for dual-use research oversight are not comprehensive and lack clear mechanisms for risk assessment and compliance monitoring. Dual-use research without strict oversight poses a significant biosecurity risk if misused for harmful purposes. The Bill does not explicitly adopt a One Health approach, which integrates human, animal, and environmental health in biosecurity management. The lack of an integrated approach limits comprehensive biosecurity solutions, particularly for zoonotic disease threats.

The Draft Biosecurity Bill is a significant step toward improving Kenya's biosecurity framework, yet it requires crucial refinements to address existing gaps and align with the Africa CDC Biosafety and Biosecurity Model Framework. Key improvements include comprehensive laboratory containment protocols, mandatory biosecurity training, dual-use research oversight, and the integration of a One Health approach. Strengthening these areas will better equip Kenya to manage biological risks, safeguard public health, and comply with international standards.

It is worth noting that Uganda established a National Biotechnology and Biosafety Act in 2010, which is significantly biassed towards the Cartagena Protocol on GMO crops, as observed by Kirunda and Otimonapa.[153] Mtui criticised Uganda's National Biotechnology and Biosafety Act for not adequately addressing biosecurity legislation challenges.[154] Uganda's biosafety law in the areas of GMO risk management is an imitation of many African countries including South Africa

[153] Jimale H A, Dr. O.Ochieng and Dr. Ouman M, 'Effectiveness of the Existing Regulatory Framework for Biosecurity Preparedness Atgarissa Level Five Hospital Garissa County Kenya,' 842.
[154] Mtui G, 'Biosafety systems in Eastern and Central Africa' 6 *African Journal of Environmental Science and Technology* 2, 2012, 80-93.

and Kenya, which have a comparable absence of biosecurity rules.[155] Biosecurity guidelines and manuals in Kenya are only available at accredited laboratories and are not known to many due to a lack of dissemination.[156] This calls for a need for integration of biosecurity in the existing biosafety laws.

While biosecurity aims to prevent the deliberate or careless release of biological materials or the acquisition of information, instruments, or methods that could be used to harm others, biosafety aims to prevent the unintentional or accidental release of specific biological agents and toxins. Therefore, biosafety measures by themselves cannot completely address biosecurity issues, even while they offer a basis for developing biosecurity competence.[157]

[155]Jimale H A, Dr. O.Ochieng and Dr. Ouman M, 'Effectiveness of the Existing Regulatory Framework for Biosecurity Preparedness Atgarissa Level Five Hospital Garissa County Kenya' 842.

[156] Jimale H A, Dr. O.Ochieng and Dr. Ouman M, 'Effectiveness of the Existing Regulatory Framework for Biosecurity Preparedness Atgarissa Level Five Hospital Garissa County Kenya' 847.

[157] The National Academies Press, *Potential Risks and Benefits of Gain-of-Function Research: Summary of a Workshop,* April 13, 2015, 59.

CHAPTER 4: COMPARISON BETWEEN THE AFRICA CDC BIOSAFETY AND BIOSECURITY MODEL FRAMEWORK, THE KENYAN BIOSAFETY ACT AND THE DRAFT BIOSECURITY BILL

4.1 Introduction

This chapter compares the Africa CDC regional framework on Biosafety and Biosecurity with the Kenyan Biosafety Act and the draft Biosecurity Bill (2024) to identify critical gaps in the legal framework. The Biosafety Act primarily focuses on regulating genetically modified organisms (GMOs), leaving significant omissions in addressing broader biosecurity concerns, such as preventing the misuse of biological agents, dual-use research risks, and bioterrorism.

In contrast, the Africa CDC Model Framework provides a holistic approach to biosafety and biosecurity, with seven domains that guide AU Member States in strengthening national systems. The objective is to identify how well Kenya's legislative instruments address biosafety and biosecurity challenges, highlight persistent legal gaps, and evaluate whether the Draft Biosecurity Bill sufficiently bridges those gaps in alignment with the Africa CDC framework.

4.2 Overview of the Africa CDC Biosafety and Biosecurity Model Legal Framework

Biosafety and biosecurity capacity shortfalls among the AU Member States were brought to light following the WHO JEE report, which was carried out between 2016 and 2019, the GHSI Index, and regional forums organised by Africa CDC.[158] Africa CDC, Pan African Veterinary Vaccine Centre of the African Union (AUPANVAC), and African Union Inter-African Bureau for Animal Resources (AU-IBAR) in partnership with AU Member States and its Regional Collaborating Centres (RCC) launched the Regional Biosafety and Biosecurity Initiative (BBI) to fill these gaps and help member states develop capacity and adhere to international biosafety and biosecurity requirements and regulations.[159] One of the initiative's primary goals is to create a regional

[158] Africa Centres for Disease Control and Prevention, Development of a National Biosafety And Biosecurity Strategy, 2022, 4.

[159] Maruta T, Kenfack JAN, Tebeje Y K, Bangure D and Ouma AEO,'Regional approach to strengthening biosafety and biosecurity systems in Africa,' 2.

biosafety and biosecurity legislative framework (BSBS) that may be adopted and then integrated into national legislation.[160]

The AU bodies have accepted the BSBS legislative framework, and domestication has commenced in several countries.[161] The regional BSBS legal framework stipulates the regionally agreed-upon extent of legislation needed for successful execution which individual nations would then domesticate and fit with national laws.[162] It authorises the formation (or mandate of an existing) agency to manage and supervise biosafety and biosecurity regulatory systems. It is founded on international and regional requirements for biosafety and biosecurity derived from: International Health Regulations (IHR) 2005, Cartagena Protocol on Biosafety, The OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, the BWC and UNSCR 1540, among others.[163]

This BSBS framework establishes the operational foundation for the country's biosafety and biosecurity systems. It directs how training facilities and regulatory bodies establish and fortify these systems in human, animal, plant, environmental, and biotechnology laboratories, as well as how laboratories and institutions manage High Consequence Animal Transboundary and Emerging Diseases (HCATs). The framework also establishes standards for biosafety and biosecurity specialists' training and capacity building, and it specifies technical requirements for facilities that handle or store HCATs.[164]

The framework's six categories are important topics that should be covered in laws, decrees, and regulations that affect biosafety and biosecurity operations. Each of these domains consists of a list of attributes characterising it and providing more detail about how legal instruments address important aspects of it. The domains will guide the comparative study to identify the legal gaps in

[160] The African Union Centres for Disease Control and Prevention, Regional Biosafety and Biosecurity Legal Framework for the African Union Member States, 2023, ii.

[161] Maruta T, Kenfack JAN, Tebeje Y K, Bangure D and Ouma AEO,'Regional approach to strengthening biosafety and biosecurity systems in Africa,' 1.

[162] Maruta T, Kenfack JAN, Tebeje Y K, Bangure D and Ouma AEO,'Regional approach to strengthening biosafety and biosecurity systems in Africa,' 4.

[163] The African Union Centres for Disease Control and Prevention, Regional Biosafety and Biosecurity Legal Framework for the African Union Member States, 3.

[164] The African Union Centres for Disease Control and Prevention, Regional Biosafety and Biosecurity Legal Framework for the African Union Member States, 5.

the Biosafety Act of Kenya and the Draft Biosecurity Bill against the model legal framework by Africa CDC that ought to provide guidance to countries developing national biosafety and biosecurity legal instruments.[165]

The domains include: (i) authorising the creation of a lead entity or agency to oversee and manage biosafety and biosecurity systems; (ii) creating national biosafety and biosecurity standards; (iii) establishing authority for biological risk assessment; (iv) regulating laboratory and facility requirements for handling HCATs; (v) providing education, training, and human resource development to all staff members who possess, use, manipulate, store, transfer, or destroy/incinerate HCATs; and (vi) transferring, storing, and disposing of HCATs.[166]

4.3 Comparative Analysis of Kenya's Biosafety Act, Draft Biosecurity Bill and Africa CDC BSBS Framework

The analysis provides an in-depth domain-by-domain comparison with the Kenyan Biosafety Act, highlighting specific gaps in the legislation and reviewing whether the draft Biosecurity Bill addresses the gaps.

Domain 1: Authorization of the establishment of a lead entity or agency responsible for regulating and managing biosafety and biosecurity systems.

The BSBS legal framework provides for the creation of a lead agency or institution responsible for regulating, managing, and coordinating biosafety and biosecurity on a national scale.[167] The agency or institution shall be responsible for establishing, implementing, monitoring, and managing national biosafety and biosecurity systems, including incident investigation. Its regulatory role shall include overseeing legal instruments, establishing legally constituted authorities, and designing the national biosafety and biosecurity management program.

[165] The Africa CDC, Advocacy and Communication Strategy for the Biosafety and Biosecurity Legal Framework, 6.
[166] The African Union Centres for Disease Control and Prevention, Regional Biosafety and Biosecurity Legal Framework for the African Union Member States, 7.
[167] The African Union Centres for Disease Control and Prevention, Regional Biosafety and Biosecurity Legal Framework for the African Union Member States, 9.

The Biosafety Act establishes a National Biosafety Authority (NBA), which has limited oversight of GMO-related activities, creating a fragmented approach to biological risk management.[168] This shows a lack of a single dedicated biosecurity oversight body. The NBA's jurisdiction is limited to GMOs, leaving biosecurity issues such as pathogen control, dual-use oversight and laboratory security unaddressed. This institutional weakness may result in inadequate responses to biosecurity threats.

The draft Biosecurity Bill addresses this gap by proposing the establishment of a National Biosecurity Authority, fulfilling a key recommendation from the Africa CDC framework.[169] The proposed authority has a wider oversight. Its object and purpose are exercise general supervision and control over activities involving controlled biological agents or toxins, within the context a whole of-government approach in collaboration with other regulatory agencies and institution.[170] The Authority's role and coordination with other existing agencies such as the Ministry of Health and agricultural organisations, remain ambiguous, which risks overlapping mandates and enforcement gaps.

Domain 2: Development of national standards for biosafety and biosecurity

The framework gives the principal agency or institution power to create biosafety and biosecurity minimal criteria as compliance benchmarks.[171] International guidelines and evidence-based best practices should serve as the foundation for the essentials, including recent versions of the WHO Laboratory Biosafety Manual and OIE International Standards on Biosafety and Biosecurity and others. It recommends uniform, enforceable national standards for biosafety and biosecurity across laboratories, research facilities, and institutions.

[168] Section 7, Biosafety Act (No 2 of 2009).
[169] Section 6, Draft Biosecurity Bill, 2024.
[170] Section 8, Draft Biosecurity Bill, 2024.
[171] The African Union Centres for Disease Control and Prevention, Regional Biosafety and Biosecurity Legal Framework for the African Union Member States, 11.

The Biosafety Act provides standards exclusively for GMOs such as their import,[172] export,[173] labelling and containment.[174] The Act lacks specific biosecurity standards for laboratory safety, dual-use research and the handling of high-risk biological agents and toxins.[175]The absence of detailed national standards for biosecurity increases the risk of accidental exposure, release or unauthorised access, thus leaving vulnerabilities in laboratory practices and the management of biological materials. The draft Bill mandates the established authority to develop and continuously benchmark national biosecurity standards based on prevailing national priorities and international best standards.[176] The framework authorises the agency established to set facility standards guided by the current WHO Laboratory Biosafety Manual and to monitor compliance and enforcement.

The draft Bill empowers the Cabinet Secretary, in consultation with the relevant authority, to issue regulations allowing for the collaborative development, publication, and enforcement of minimum biocontainment and safety standards for facilities handling controlled biological agents or toxins.[177] These regulations will encompass risk assessments and the establishment of control lists. While the draft Biosecurity Bill includes provisions for risk management[178] and containment protocols, it lacks specificity with regards to containment classifications, such as biosafety level (BSL) designations, which are crucial for laboratories handling high-risk agents.

Domain 3: Authority for biological risk assessment

The framework authorises the introduction of measures to prevent the proliferation of biological and toxin weapons by controlling activities involving hazardous biological agents and toxins (HCATs).[179] It includes preventing both intentional and unintentional releases of pathogens, particularly those resulting from unauthorized fusion or possession of agents with epidemic potential. The framework emphasises the importance of safeguarding animal, human, plant, and

[172] Section 20, Biosafety Act (No 2 of 2009).
[173] Section 22, Biosafety Act (No 2 of 2009).
[174] Section 18, Biosafety Act (No 2 of 2009).
[175] Laboratory biosafety manual, 4 ed, World Health Organization, Geneva, 2020, 69.
[176] Section 8, Draft Biosecurity Bill, 2024.
[177] Section 48, Draft Biosecurity Bill, 2024.
[178] Section 34, Draft Biosecurity Bill, 2024.
[179] The African Union Centres for Disease Control and Prevention, Regional Biosafety and Biosecurity Legal Framework for the African Union Member States, 12.

environmental health. It further underscores that measures taken should not hinder international cooperation and should align with UNSCR 1540, which addresses the non-proliferation of weapons of mass destruction.[180]

The Biosafety Act provides for biological risk assessment and management.[181] It limits the scope of risk assessment to GMO-related activities, excluding broader biological risks. The Act mandates that the Authority conduct a risk assessment for applications involving GMOs, considering potential risks posed by GMOs. The Authority is then required to issue a report detailing its findings and outlining measures to ensure safe GMO use. There is an absence of protocols for assessing biosecurity risks, especially for dual-use research and high-consequence biological agents. Inadequate identification of potential biological risks increases the likelihood of dual-use misuse and accidental or intentional biological threats.

The draft Bill makes significant steps by broadening the scope of risk assessment to include pathogens and toxins beyond GMOs. It provides restrictions on the use of controlled biological agents and toxins unless such activity is carried out within a collaboration or facility.[182] It prohibits the conduction of such activities or the operation of such facilities without written approval from the Authority.[183] With these provisions, the draft Bill aligns with the BSBS framework, which provides for the prohibition of all activities involving the generation or creation, storage or stockpiling, retention, acquisition or possession, transportation, and use of biological agents or associated materials for developing biological weapons of mass destruction.[184]This provision aligns with the BWC, which bans the production and development of biological weapons.[185]

[180] The African Union Centres for Disease Control and Prevention, Regional Biosafety and Biosecurity Legal Framework for the African Union Member States, 12.
[181] Section 27, Biosafety Act (No 2 of 2009).
[182] Section 23, Draft Biosecurity Bill, 2024.
[183] Section 25, Draft Biosecurity Bill, 2024.
[184] The African Union Centres for Disease Control and Prevention, Regional Biosafety and Biosecurity Legal Framework for the African Union Member States, 12.
[185] Article 1, *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction.*

However, the draft Bill lacks clear criteria for evaluating dual-use research risks and ongoing monitoring of compliance. The framework authorises the risk assessment evaluation of agents and toxins, which includes developing a list of prohibited biological agents and toxins, agents of concern and categorising them based on their ability to be weaponised, potential for infection, means of transmission, severity of harm and communicability within a population, among others.[186] The law should provide comprehensive risk assessment and require institutions to submit evaluation reports and risk management for review by the National Biosecurity Authority.

Domain 4: Regulation of laboratory and facility level requirements handling agents and toxins of concern

The model empowers the national agency or institution to control centres and facilities that operate, manipulate, utilise, keep, or transfer HCATs, which include hospitals and scholarly institutions' laboratories for plant, animal, and environmental research.[187] To ensure adherence to biosafety and biosecurity requirements, the institution or agency should establish an accreditation and certification program that meets the minimal biosafety and biosecurity standards for humans, animals, plants, and the environment. The HCAT list, which details hazardous biological agents and toxins, will be maintained as a separate appendix to the BSBS legal framework to allow for the flexible amendment of the list without necessitating a complete review of the entire document.[188]

The Biosafety Act does not have any provisions regulating laboratories handling pathogens or other hazardous biological agents. This shows an absence of national standards for biosafety levels (BSL), laboratory containment design and pathogen accountability. It increases the risk of breaches where laboratories handling dangerous biological agents operate without secure facilities. The draft Biosecurity Bill also does not mention a certification and accreditation program, and neither does it provide biosafety and biosecurity standards. It lacks specific laboratory containment

[186] The African Union Centres for Disease Control and Prevention, Regional Biosafety and Biosecurity Legal Framework for the African Union Member States, 13.

[187] The African Union Centres for Disease Control and Prevention, Regional Biosafety and Biosecurity Legal Framework for the African Union Member States, 13.

[188] The African Union Centres for Disease Control and Prevention, Regional Biosafety and Biosecurity Legal Framework for the African Union Member States, 12.

protocols, such as biosafety levels and safety measures. This shows there is limited integration of a One Health approach and insufficient monitoring and evaluation systems.

Domain 5: Education, Training, and Human Resource Requirements for Personnel who Possess, Use, Store, Manipulate, Transfer or Destroy/Incinerate HCATs

The appointed agency is empowered by the BSBS legal framework to control the necessary education, training, and human resource development for those who handle HCATs. The framework emphasizes tailored training for both technical and administrative staff. The national legal instruments should provide a broad framework for a biosafety and biosecurity training curriculum, allowing for regular reviews to ensure continued relevance and promote the recognition of biosafety and biosecurity as a distinct profession.[189]

The training provisions in the Biosafety Act focus exclusively on GMO-related activities, with no mandatory biosecurity training. The Act emphasises education and public awareness of those conducting activities relating to biosafety to improve their understanding of biosafety.[190] There is no systematic biosecurity training for laboratory workers, researchers, or public health personnel. Public awareness initiatives and education of the public and those involved in activities of biosecurity concern are emphasised by the draft Bill however, there is an absence of structured biosecurity training and certification for laboratory personnel.[191] Limited awareness and preparedness to handle biological risks undermine Kenya's biosecurity capacity and create preparedness challenges.

Domain 6: Transfer, Storage, and Disposal of HCATs

Toxins and biological agents must be transferred, stored, and disposed of using secure mechanisms in order to avoid misuse or illegal access. All laboratories and institutions that transmit, store, and dispose of biological agents and toxins, including pathogens of concern, are subject to fines for

[189] The African Union Centres for Disease Control and Prevention, Regional Biosafety and Biosecurity Legal Framework for the African Union Member States, 14.
[190] Section 54, Biosafety Act (No 2 of 2009).
[191] Section 38 (1), Draft Biosecurity Bill, 2024.

noncompliance.[192] It also sets regulatory and implementation procedures, such as certification, licensing, and registration. It facilitates the regulation of HCAT storage, including the preservation of current inventories of HCATs in storage and mandates that they be reported to the appropriate agency. Lastly, the framework places a strong emphasis on the secure, safe and environmentally conscious disposal of all harmful waste generated from the handling of biological substances and toxins, including the disposal of animal excrement and carcasses.

The Biosafety Act focuses on the movement and containment of GMOs but excludes high-risk pathogens and toxins. The Act provides for the basis of the regulations for procedures for importation and exportation of genetically modified organisms.[193] The Biosafety (Import, Export and Transit) Regulations aim to ensure the safe movement of GMOs into, across, and out of Kenya.[194] Under the Biosafety Act, there are also regulations establishing a framework for assessing and managing risks associated with the environmental release of GMOs. A robust risk assessment process is mandated for all applications involving environmental release or placing of GMOs on the market.[195] There are no protocols for handling and managing other dangerous biological materials such as pathogens of concern, hence insufficient oversight of storage and disposal.

The draft Biosecurity Bill provides restrictions on the direct or indirect transfer of biological agents and toxins without written approval from the Authority.[196] It mandates applications for an approval to handle, engage in or operate a facility involving controlled biological agents and penalises any person who contravenes.[197] It provides for the importation, transit, export and transportation of biological agents. It requires the approval of licenses for the peaceful purpose create, obtain, produce, own, store, move, transfer, utilise, or disposal of listed biological agents or toxins.[198] This shows significant steps in encompassing the provisions of the BSBS framework.

[192] The African Union Centres for Disease Control and Prevention, Regional Biosafety and Biosecurity Legal Framework for the African Union Member States, 16.
[193] Section 54, Biosafety Act (No 2 of 2009).
[194] Section 3, Biosafety (Import, Export and Transit) Regulations 2011.
[195] Section 3, Biosafety (Environmental Release) Regulations 2011.
[196] Section 24, Draft Biosecurity Bill, 2024.
[197] Section 26, Draft Biosecurity Bill, 2024.
[198] Section 32, Draft Biosecurity Bill, 2024.

4.4 Persistent Legal Gaps and their Implications

Biological threats, whether natural or human-caused, can have devastating global consequences that may overwhelm the response capabilities of both individual nations and international organizations. Outbreaks of infectious diseases can result in mass casualties, severe economic damage, and significant threats to national security and stability.[199] The term "biosecurity" was first used in relation to bioterrorism and biological weapons, but it is now used to refer to a variety of topics, including infectious disease control for human and animal health as well as biological laboratory risks.[200] Reducing both deliberate and inadvertent biological risks that could have disastrous outcomes is the aim of biosafety and biosecurity procedures.[201]

Unfortunately, despite the considerable risks posed by biological threats, biosafety and biosecurity are frequently under-prioritised at the national, regional, and international levels. Security officials often overlook the seriousness of accidental and deliberate biological threats in relation to other security concerns.[202] However, considering the growing biological risks, including those stemming from rapid technological advancements and the potential for their use as weapons of mass destruction by both state and non-state actors, a stronger emphasis on biosecurity within both health and security forums is urgently needed.

Kenya, as a resource-limited developing nation, faces significant challenges in addressing biosecurity. Research and data on the effectiveness of existing biosecurity legislation and regulatory frameworks, particularly within level five public hospitals, are limited. Kenya lacks a comprehensive national program dedicated to biosecurity. Despite implementing various counter-

[199] Brizee S, *et al*, 'Accelerating Action in Global Health Security: Global Biosecurity Dialogue as a Model for Advancing the Global Health Security Agenda' 17 *Health Security* 6, 2019, 496.
[200] Abdi M A, Abdiweli S A, Sheban H, Abdale A, Sead A, Hussein M, Mohamed Z , Dayib M and Kosa H, 'Biosafety and Biosecurity in Africa: Challenges and Future Perspectives' *Preprints,* 2024, -<https://doi.org/10.20944/preprints202401.0722.v1>- on 9 January 2024.
[201] Abdi M A, *et al,* 'Biosafety and Biosecurity in Africa: Challenges and Future Perspectives,'1.
[202] Brizee S, *et al*, 'Accelerating Action in Global Health Security: Global Biosecurity Dialogue as a Model for Advancing the Global Health Security Agenda,' 495.

terrorism strategies since 2011, it has not prioritized the development and implementation of specific laws and regulations to effectively control and regulate biosecurity risks.[203]

While laws like the Kenya Health Act 2017 and the Kenya Medical Laboratory Technicians and Technologist Act (Cap 253A) provide some relevant provisions, they do not explicitly address biosecurity and bioterrorism. The Public Health Act (Cap 242) and the Health Amendment Act of 2019, while regulating healthcare providers and products, primarily focus on the professional conduct of healthcare workers and do not specifically address biosecurity concerns.[204] The Security Laws (Amendment) Act 2014 and the Prevention of Terrorism Act (POTA) do not explicitly mention the possession of biological agents as a potential act of terrorism.[205]This omission creates a legal loophole that may hinder effective prevention and response to bioterrorism threats.

Biosafety laboratories are specialised facilities for handling infectious bacteria and biological materials. They prioritise the safety of laboratory personnel, the surrounding community, and the environment from biological hazards.[206] These laboratories are classed into biosafety levels (BSL-1 to BSL-4) that reflect the danger connected with handled materials. Higher BSL values imply more dangerous compounds, necessitating stricter safety and protection measures.[207] Biosafety labs are essential for addressing public health issues, promoting scientific research, protecting people and the environment, and maintaining national security.[208]

The Biosafety Act and the draft Biosecurity Bill 2024 lack specific and enforceable protocols for laboratory biosafety levels (BSLs) as required by the Africa CDC Framework. A survey

[203] Jimale H A, Dr. O.Ochieng and Dr. Ouman M, 'Effectiveness of the Existing Regulatory Framework for Biosecurity Preparedness Atgarissa Level Five Hospital Garissa County Kenya' 843.
[204] Jimale H A, *et al*, 'Effectiveness of the Existing Regulatory Framework for Biosecurity Preparedness Atgarissa Level Five Hospital Garissa County Kenya' 843.
[205] Jimale H A, *et al*, 'Effectiveness of the Existing Regulatory Framework for Biosecurity Preparedness Atgarissa Level Five Hospital Garissa County Kenya' 843.
[206] Gao W, Wu Z, Zuo K, Xiang Q, Zhang L, Chen X, Tan F, Liu H, 'From Biosafety to National Security: The Evolution and Challenges of Biosafety Laboratories' *Laboratories* 1, 2024. -<https://doi.org/10.3390/laboratories1030013>- on 23 December 2024.
[207] Laboratory biosafety manual, 4 ed, World Health Organization, 59.
[208] Gao W, *et al*, 'From Biosafety to National Security: The Evolution and Challenges of Biosafety Laboratories,' 158.

highlighted potential gaps in biosafety practices within Kenyan research and healthcare facilities, particularly concerning the handling and storage of high-risk biological agents. The results showed a significant proportion of facilities (37%) stored agents of high biosecurity concern, listed on the Australia Group, including 16 types of bacteria and viruses.[209]

The Australia Group is an informal group of countries that, through export control harmonisation, strives to ensure that exports do not lead to the development of weaponised chemicals or biological weapons.[210] With a growing focus on the intentional abuse of biological agents around the world, Kenya has to gauge its biosecurity level and knowledge.[211] The study advocated that Kenya adopt legislative frameworks for efficient oversight, such as biosecurity legislation and procedures, to lessen the possibility of laboratories being a source for prospective biological harm.[212]

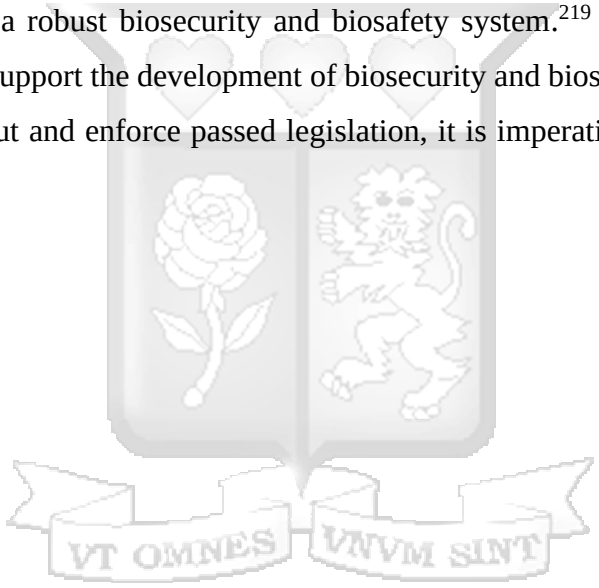
The increasing role of synthetic biology in biotechnology, agriculture, and medical research highlights the urgent need for comprehensive biosecurity legislation in Kenya.[213] The current framework, which solely focuses on GMOs, does not adequately address emerging biosecurity risks such as synthetic biology innovations. East African countries such as Tanzania, Uganda, Ethiopia and Rwanda have regulatory frameworks and policies governing biosafety and biosecurity, but the scope and coverage is limited to GMO oversight.[214] The AU model law is aimed at guiding member states in drafting and implementing their biosafety regulation. The BSBS model law on biosafety promotes the harmonisation of biosafety policies across the continent, ensuring a coherent approach to biosafety and biosecurity.[215]

Laboratory accidents in Uganda and Tanzania also highlight the importance of rigorous lab safety protocols, regular training for lab personnel, and the implementation of biosafety levels

[209] Ndhine EO, *et al*, 'A Biosecurity Survey in Kenya,' 208.
[210] https://www.dfat.gov.au/publications/minisite/theaustraliagroupnet/site/en/introduction.html
[211] Ndhine EO, *et al*, 'A Biosecurity Survey in Kenya,' 211.
[212] Ndhine EO, *et al*, 'A Biosecurity Survey in Kenya,' 212.
[213] Nyakairu Doreen G,. 'Regulatory Frameworks and Policies in Synthetic Biology: Biosafety and Biosecurity in East Africa' 5 *Eurasian Experiment Journal Of Scientific And Applied Research* 2, 2024, 12.
[214] Nyakairu Doreen G,. 'Regulatory Frameworks and Policies in Synthetic Biology: Biosafety and Biosecurity in East Africa' 13.
[215] Nyakairu Doreen G,. 'Regulatory Frameworks and Policies in Synthetic Biology: Biosafety and Biosecurity in East Africa' 13.

appropriate for the type of research being conducted.[216] With potential applications in agriculture, medicine, environmental management, and more, the benefits of synthetic biology are substantial. However, these advancements must be balanced with stringent biosafety and biosecurity measures to mitigate potential risks.[217]

The rapid pace of biotechnology advancements outstrips governmental oversight, leaving potential biological risks inadequately addressed. While these advances offer societal and economic benefits, the lack of robust institutional, national, and global mechanisms for identifying and mitigating emerging risks creates a significant vulnerability.[218] Legislation, rules, guidelines, and a compliance plan aimed at lowering the risks of both purposeful and unintentional biological events are necessary for a robust biosecurity and biosafety system.[219] In order to generate the political will required to support the development of biosecurity and biosafety laws, as well as the money needed to carry out and enforce passed legislation, it is imperative to engage lawmakers and other officials.[220]



[216] Nyakairu Doreen G,. 'Regulatory Frameworks and Policies in Synthetic Biology: Biosafety and Biosecurity in East Africa' 14.
[217] Nyakairu Doreen G,. 'Regulatory Frameworks and Policies in Synthetic Biology: Biosafety and Biosecurity in East Africa' 14.
[218] Brizee S, *et al*, 'Accelerating Action in Global Health Security: Global Biosecurity Dialogue as a Model for Advancing the Global Health Security Agenda,' 498.
[219] Brizee S, *et al*, 'Accelerating Action in Global Health Security: Global Biosecurity Dialogue as a Model for Advancing the Global Health Security Agenda,' 497.
[220] Brizee S, *et al*, 'Accelerating Action in Global Health Security: Global Biosecurity Dialogue as a Model for Advancing the Global Health Security Agenda,' 498.

CHAPTER 5: CONCLUSION, RECOMMENDATIONS AND PROPOSED LEGAL REFORMS

5.1 Introduction

This study has examined the gaps in Kenya's biosafety and biosecurity framework, focusing on the limitations of the Biosafety Act 2009 (Amended 2018) and evaluating the Draft Biosecurity Bill 2024. It highlights how Kenya's legislation remains primarily centred on genetically modified organisms (GMOs), leaving significant vulnerabilities in biosecurity governance, emergency preparedness, laboratory containment, and dual-use research oversight.

This study has identified the need for a comprehensive legal approach that integrates One Health principles to promote collaboration between human, animal, and environmental health agencies. By benchmarking Kenya's biosecurity framework against the Africa CDC Biosafety and Biosecurity Model Framework, it has identified the need for a comprehensive legal approach that aligns the country's legislation with international best practices. This chapter consolidates the key findings, presents recommendations for strengthening Kenya's biosecurity framework, and proposes legal reforms to align the country's legislation with international best practices.

5.2 Summary of Key Findings

The research highlights the lack of biosecurity regulation in Kenya's current biosafety framework. There is an absence of a dedicated biosecurity authority, weak laboratory safety regulations, lack of dual-use research oversight, and insufficient emergency preparedness measures. Additionally, the limited integration of the One Health approach has hindered cross-sectoral collaboration in managing biological risks.

Laboratory biosafety standards in Kenya are weak, with no clear biosafety level (BSL) classifications for high-risk biological research. Laboratories lack mandatory accreditation and containment measures, increasing the risks of pathogen leaks and biosafety breaches. Additionally, dual-use research lacks regulatory oversight, leaving a gap that could enable scientific studies to be misused for harmful purposes. The current biosafety and biosecurity policy guidelines intended to be used by individual laboratories in the country are merely voluntary and thus do not give rise

to legal obligations. Furthermore, Kenya's emergency response framework for biological threats is inadequate, with no clear national biosecurity response plan or structured mechanisms to manage outbreaks, bioterrorism, or accidental pathogen releases.

5.3 Recommendations

To address the gaps, the study recommends that Kenya's biosafety legislative framework formally adopt the Africa CDC Biosafety and Biosecurity model framework as a guiding instrument to inform policy and legislative reforms. The study recommends expanding the mandate of the National Biosafety Authority (NBA) or establishing a separate National Biosecurity Authority with jurisdiction over high-risk biological agents, laboratory safety, and biosecurity governance. The establishment of a National Biosecurity Advisory Committee is essential to facilitate multi-sectoral coordination among public health, veterinary, environmental, and security agencies.

Kenya must develop biosafety level standards and enforce mandatory accreditation of laboratories handling high-risk biological materials. Regular compliance audits and risk assessments for dual-use research should be introduced, with an Ethics Committee established to evaluate research proposals with potential security risks. This is to provide guidance for dual-use research and prevent the misuse of knowledge gained for malicious purposes. The Africa CDC BSBS framework provides clear guidelines on laboratory safety, risk management, and dual-use oversight, which should be incorporated into Kenya's regulatory system.

The study also emphasizes the need for a National Biosecurity Emergency Response Plan, which includes structured bioterrorism and outbreak response protocols. Regular simulation exercises and inter-agency collaboration, as recommended by the Africa CDC BSBS framework, will enhance preparedness and coordination among relevant stakeholders. Furthermore, biosecurity training and certification programs must be introduced for all personnel handling biological materials to strengthen capacity and compliance.

5.4 Proposed Legal Reforms

The study proposed key amendments to the Biosafety Act 2009 (Amended 2018) to redefine biosafety to include biosecurity governance, pathogen research oversight, and emergency preparedness. A legal provision should be introduced to establish a National Biosecurity Authority, which will have direct oversight over high-risk biological research and laboratory safety regulations. The Act should introduce regulation for dual-use research oversight, ensuring all high-risk biological research undergoes mandatory risk assessments before approval. Strict laboratory containment regulations, including biosafety level (BSL) classifications, must be incorporated into law, alongside legally binding guidelines for laboratory accreditation and inspections. The Africa CDC Model Framework should serve as a benchmark in developing these legal provisions.

While the Draft Biosecurity Bill (2024) provides a foundation for strengthening biosecurity in Kenya, it requires additional provisions to ensure comprehensive governance. The study recommends enhancing enforcement mechanisms by introducing criminal penalties for non-compliance with biosecurity laws and establishing a national monitoring system for compliance. The Africa CDC framework outlines enforcement mechanisms that could be adapted into Kenya's biosecurity laws to ensure better compliance and accountability.

The One Health approach should be explicitly integrated into the Biosecurity Bill, legally mandating collaboration between human, animal, and environmental health sectors. Additionally, the Bill should establish a National Biosecurity Training Program, requiring mandatory certification for professionals handling biological materials and ensuring ongoing education in biosafety and biosecurity principles. The Africa CDC's guidelines on workforce training should be used to develop Kenya's national training and capacity-building programs.

5.5 Conclusion

By implementing these recommendations and aligning Kenya's legal framework with the Africa CDC Biosafety and Biosecurity Model Framework, the country can develop a comprehensive, internationally compliant biosecurity system that safeguards public health, national security, and environmental safety. The proposed reforms will not only enhance laboratory safety and research

oversight but also strengthen Kenya's preparedness for future biological threats, ensuring a proactive rather than reactive approach to biosecurity governance.

This chapter serves as a call to action for policymakers to take urgent steps toward ensuring Kenya's preparedness for emerging biological risks and global health threats. Establishing a strong biosecurity governance framework is critical in protecting Kenya's scientific research, public health, and national security in an era of increasing biological threats.

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