



Biorisk Governance in Africa: A Landscape Analysis of Policies, Challenges, and Emerging Trends

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Abstract

Africa is making strides in addressing biosafety and biosecurity challenges, as evidenced by continental and national initiatives to strengthen bio-risk management. In this report, we examine the continent's urgent need for effective bio-risk governance due to its rich biodiversity and vulnerability to emerging infectious diseases. Key initiatives, such as the Africa CDC's Biosafety and Biosecurity Initiative, aim to strengthen systems across all 55 African Union Member States, while national efforts vary significantly, with countries like Kenya, Ethiopia, South Africa, and Nigeria adopting diverse regulatory approaches ranging from restrictive to facilitative. Despite high ratification rates of international treaties, including the Biological Weapons Convention (BWC), challenges such as resource constraints, capacity gaps, regulatory inconsistencies, and limited public awareness hinder full implementation. We also identified emerging trends, including the adoption of One Health approaches, increasing interest in synthetic biology, and efforts toward regional harmonization of biosafety regulations. These developments underscore the critical importance of robust biosafety governance for Africa's sustainable development, particularly in agriculture, public health, and environmental protection. This further emphasizes the need for sustained commitment, enhanced regional cooperation, and innovative capacity-building strategies to address existing challenges and leverage opportunities in bio-risk governance.

This landscape analysis was conducted to understand the bio-risks governance efforts in Africa by examining continental and national initiatives, challenges, and emerging trends. The goal is to provide the Tech Governance Project (TGov) with a deeper understanding of biorisk governance activities in Africa, assist TGov in refining its interventions, and facilitate connections with appropriate stakeholders. This analysis also serves as a valuable resource for those interested in gaining insights into biorisk governance activities in Africa, ultimately improving understanding and decision-making.

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Tech Governance Project (TGov)

TGov is a non-profit initiative committed to improving the governance of emerging technologies in Africa through stakeholder collaboration, with a focus on Artificial Intelligence and Biotechnology.

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1. Introduction

Management of biological risks has become increasingly critical worldwide, particularly in Africa. This urgency is exacerbated by advancements in biotechnology, which could increase the propensity of biothreat. Africa's unique ecological landscapes and developmental and regulatory gaps create a complex environment for biosafety and biosecurity considerations. Effective bio-risks governance in Africa is crucial for several reasons:

1. Protection of rich biodiversity and genetic resources
2. Safe advancement of biotechnology research and development
3. Mitigation of vulnerabilities to emerging and re-emerging infectious diseases with regional or global implications
4. Optimization of limited resources and infrastructure

2. Continental Efforts Toward Governance

At the continental level, several frameworks and initiatives exist to guide and support biorisk governance in Africa, aligning with international standards such as the Biological Weapons Convention (BWC). Notable among these are efforts by the African Union (AU) and the United Nations System, though approaches and considerations vary.

2.1 Africa CDC Biosafety and Biosecurity Initiative

The Africa Centres for Disease Control and Prevention (Africa CDC) launched its Biosafety and Biosecurity Initiative in 2019, representing a landmark effort to align the continent's approach with international requirements. This initiative aims to strengthen systems across all 55 African Union Member States, focusing on compliance with:

- International Health Regulations (2005)
- Biological Weapons Convention
- United Nations Security Council Resolution 1540 (Africa CDC, 2021a)

The initiative identified five key priorities:

1. Legal Framework: Developing a continent-wide biosafety and biosecurity legal framework
2. Technical Working Groups: Establishing multi sectoral groups at regional and national levels
3. Regulatory Framework: Creating a system for certifying and regulating high-containment facilities
4. Training Program: Establishing a standardized regional training and certification program
5. Institutional Strengthening: Enhancing capabilities of National Public Health Institutes and National Reference Laboratories

As part of this initiative, five multisectoral Regional Biosafety and Biosecurity Technical Working Groups (RBB-TWGs) were created. Distributed across different regions of Africa, these groups are crucial in coordination and implementation bodies for biosafety and biosecurity initiatives. Their work is further supported by the development of a standardized Regional Training and Certification Program aimed at building a skilled workforce (Maruta et al., 2023).

2.2 Other Notable Continental Governance Initiatives

- Signature Initiative to Mitigate Biological Threats in Africa (SIMBA): A Global Partnership initiative aimed at reducing bio-threats through coordinated activities between member countries and African organizations.
- African Biosafety Network of Expertise (ABNE): A biosafety resource network for African regulators and policymakers focused on enhancing the capacity for functional biosafety regulatory systems.
- African Union Biosafety Regulators Forum: A platform for biosafety regulators to share best practices and harmonize approaches (African Union, 2023).
- African Biosciences Initiative (ABI): Strengthens Africa's capacity in biosciences, focusing on health, agriculture, and environmental management (NEPAD, 2022).
- African Society for Laboratory Medicine (ASLM): A scientific and capacity-building group aiming to strengthen laboratory systems, combat diseases, and improve African public health outcomes through stakeholder collaborations.
- WHO Africa: Provides guidance on health-related aspects of biotechnology and supports regulatory framework development for new health technologies (WHO Africa, 2024).
- African Union Model Law on Biosafety: Provides a template for member states to develop national biosafety legislation (Glover et al., 2018).
- COMESA Biotechnology Policy Harmonization: Efforts to align biotechnology regulations among member states (Waithaka et al., 2015).
- East African Community (EAC) Bioeconomy Strategy: Aims to promote sustainable utilization of biological resources through biotechnology (Mugiira, 2021).

3. National Efforts Toward Biorisks Governance

While continental initiatives provide an overarching framework and support capacity development, governance implementation largely occurs at the national level. There is significant variability across African nations in their approach to biosafety and biosecurity regulation due to the lack of a continent-wide governing body; African CDC serves as an advisory body, not a governing body. However, substantial progress has been made at the national level in developing biosafety and biosecurity frameworks, largely in response to international agreements like the Cartagena Protocol on Biosafety (Mugiira, 2021). The implementation and effectiveness of these frameworks vary considerably across countries.

3.1 Examples of Biosafety Regulatory Frameworks and Policies in Select African Countries

- Kenya: Kenya has established a robust system through its Biosafety Act of 2009, which created the National Biosafety Authority that oversaw GMO regulations. The country's Prevention of Terrorism Act prohibits biological weapons-related activities, while the Science, Technology, and Innovation Act of 2013 requires licensing for scientific research. Kenya's National Commission for Science, Technology, and Innovation (NACOSTI) serves as the national focal point for the Biological Weapons Convention (BWC).
- Ethiopia: Ethiopia recently amended its Biosafety Proclamation (No. 655/2009) to facilitate biotechnology research while maintaining safety standards. The country has developed Biosafety and Biosecurity Guidelines for Health Laboratories (2022) and established the Ethiopian Biosafety and Biosecurity Association (EBBA) in 2023. Ethiopia's Criminal Code addresses biological weapons offenses, with penalties including imprisonment for up to 15 years.
- South Africa: South Africa's Non-Proliferation of Weapons of Mass Destruction Act provides a comprehensive framework for biosecurity. The country's Regulations for Hazardous Biological Agents (No. R. 1390 of 2001) and Genetically Modified Organisms Act (No. 15 of 1997) address biosafety concerns. South Africa has established a National Community of Practice for Biosafety and Biosecurity and a National Biosecurity Technical Working Group.
- Nigeria: Nigeria incorporates biosafety and biosecurity measures in its Criminal Code and the Terrorism Prevention Act of 2011. The National Biosafety Management Agency Act of 2015 regulates GMOs, with significant penalties for non-compliance. Nigeria has established a National Authority on Chemical and Biological Weapons Convention (NAC&BWC) and an Inter-Ministerial Council to implement the BWC.

3.2 Policy Approaches to Biosafety and Biosecurity

African countries have adopted a spectrum of policy approaches to biosafety and biosecurity, ranging from restrictive to facilitative. These policies have evolved in response to scientific advancements, economic considerations, and international obligations.

- Restrictive Policies: Some countries have taken cautious approaches. Kenya, for instance, imposed a ban on GM food imports in 2012, which has only recently been partially lifted for specific crops (Mugiira, 2021). Similarly, Rwanda has a policy that officially does not allow GM imports, including for emergency food aid (Mugiira, 2021).
- Facilitative Policies: Other nations have adopted more permissive approaches. Sudan, for example, became one of the first African nations to commercialize GM crops (Bt cotton) through a collaborative project with the Chinese government (Mugiira, 2021). Ethiopia has

also amended its Biosafety Proclamation to facilitate biotechnology research and development while maintaining safety standards.

3.3 Institutional Arrangements for Biosafety and Biosecurity

African countries have established various institutional structures to govern biosafety and biosecurity:

- **Dedicated Authorities:** Some countries have established specialized agencies. Kenya's National Biosafety Authority, created by the Biosafety Act of 2009, oversees GMO regulation (Mugiira, 2021).
- **Integrated Approaches:** Other nations integrate biosafety oversight into broader environmental or agricultural agencies. In Tanzania, for instance, the National Biosafety Focal Point operates within the broader environmental management framework (Mugiira, 2021).
- **Multi-Agency Coordination:** Countries like South Africa have adopted multi-agency approaches, establishing a National Community of Practice for Biosafety and Biosecurity and a National Biosecurity Technical Working Group.
- **Scientific Advisory Bodies:** Some countries have incorporated scientific expertise into their institutional arrangements. South Africa, for example, has established a Standing Committee on Biosafety and Biosecurity at the Academy of Science of South Africa.

These institutional arrangements reflect the diverse approaches African countries are taking to address biosafety and biosecurity challenges, ranging from comprehensive legislative frameworks to the establishment of specialized agencies and working groups.

4. Africa in Global Conversations on Biothreats Governance

4.1 International Treaty Participation

1. **Biological Weapons Convention (BWC):** The BWC, opened for signature in 1972 and entered into force in 1975, is an international treaty that limits the stockpiling, development, and production of biological weapons. A majority of African countries have ratified or acceded to this treaty; as of July 2024, only four countries in the region have neither signed nor ratified the convention. This high level of participation reflects a strong continental commitment to preventing the development, production, and stockpiling of biological weapons.

Notable points include:

- Most African countries ratified or acceded to the BWC in the 1970s and 1980s, with early adopters including Kenya (1976) and Nigeria (1973).

- Some countries joined more recently, such as Central African Republic (2018), Cameroon and Malawi (2013), and Mozambique (2011).
 - Two African countries (Egypt and Somalia) have signed but not yet ratified the convention.
2. Cartagena Protocol on Biosafety: 48 out of 55 African countries are parties to the Cartagena Protocol, demonstrating a high level of commitment to ensuring the safe handling, transport, and use of living-modified organisms.
 3. International Health Regulations (IHR): All 47 WHO African Region Member States have agreed to be bound by the IHR, showing a region-wide commitment to preventing and responding to acute public health risks.
 4. United Nations Security Council Resolution 1540: This resolution is binding on all UN member states, including those in Africa, and requires all states to adopt legislation to prevent the proliferation of weapons of mass destruction, including biological weapons.
 5. WHO Joint External Evaluation (WHO-JEE): All 47 countries in the WHO African region have participated in this voluntary, collaborative, multisectoral process to assess country capacities to prevent, detect, and rapidly respond to public health risks.

The high rate of participation in these international frameworks demonstrates Africa's strong commitment to global biosafety and biosecurity efforts. However, it's important to note that ratification does not always translate to full implementation, and many countries face challenges in effectively operationalizing these commitments due to resource constraints and competing priorities.

4.2 Adoption of International Standards

- Incorporation of global biosafety and biosecurity standards into national frameworks, often with support from international organizations (Nyakairu, 2024).
- Utilization of the Biosafety Clearing-House (BCH) mechanism for information sharing on GMOs and biosafety decisions (Nyakairu, 2024).

4.3 Collaboration with International Organizations

- Partnerships with WHO, FAO, and OIE on One Health approaches to address zoonotic diseases and antimicrobial resistance (Abdi et al., 2024).
- Engagement with initiatives like the Global Health Security Agenda to strengthen national capacities for preventing, detecting, and responding to infectious disease threats.

5. Challenges to Biorisk Governance in Africa

5.1 Resource Constraints and Competing Priorities

- Limited financial resources for implementing comprehensive biosafety measures in low-income countries (Abdi et al., 2024).

- Inadequate laboratory infrastructure and equipment hinder the implementation of biosafety and biosecurity practices (Heckert et al., 2011).
- Difficulty prioritizing biosecurity amid other pressing health, economic, and security challenges often leads to limited resources being directed to more immediate crises rather than long-term biosecurity capacity building (Wakefield, 2022).

5.2 Capacity Gaps and Weak Institutional Capacity

- Shortage of trained personnel in biosafety and biosecurity, particularly in specialized areas, including biorisk management and high-containment facility operations (Rutebemberwa et al., 2020).
- Limited expertise in risk assessment and management, which is crucial for effective decision-making in biotechnology regulation (Abdi et al., 2024).
- Additionally, limited institutional capacity to enforce and monitor compliance with biosafety regulations poses challenges in building sustainable capabilities for managing biosafety and biosecurity in low-resource settings (Wakefield, 2022).

5.3 Regulatory Harmonization and Gaps in Legal Frameworks

- Inconsistent regulatory approaches across countries, creating challenges for regional collaboration and trade in biotechnology products (Masehela & Barros, 2023).
- Difficulties in aligning national policies with international standards due to varying national priorities and capacities (Komen et al., 2020).
- There is also a lack of comprehensive national biosafety laws and difficulties in translating international biosecurity requirements into national legislation (Wakefield, 2022).

5.4 Public Awareness and Engagement

- Misconceptions and resistance to new technologies due to limited public understanding of biotechnology and biosafety issues.(Gastrow et al., 2018).
- Challenges in effective risk communication, especially in translating complex scientific concepts for diverse audiences (Nyakairu, 2024).
- Furthermore, there is a lack of awareness among policymakers and scientists about key biosecurity frameworks, which hampers effective risk communication and engagement with international biosecurity initiatives (Wakefield, 2022).

5.5 Political Will and Commitment

- Varying levels of political support for biosafety initiatives, often influenced by competing national priorities.

- Challenges in sustaining long-term commitment to biosafety and biosecurity programs amid changing political landscapes (Mugiira, 2021).

5.6 Lack of Coordination and Limited Regional Approaches

- Difficulty coordinating biosecurity efforts across different sectors (health, agriculture, security) and between national and regional levels (Wakefield, 2022).
- This lack of coordination can lead to duplication of work or missed opportunities for collaboration, highlighting the need for greater harmonization of biosecurity efforts at the regional level across Africa (Wakefield, 2022).

6. Emerging Trends and Sectoral Focus

6.1 One Health Approach

- Growing recognition of the interconnectedness of human, animal, and environmental health in biosafety and biosecurity strategies (Abdi et al., 2024).
- Increased efforts to integrate One Health principles into national and regional bio-risks governance frameworks (Rutebemberwa et al., 2020).

6.2 Synthetic Biology and Gene Editing

- Rising interest in emerging biotechnologies like CRISPR/Cas9, presenting new opportunities and challenges for regulators (Masehela & Barros, 2023).
- Need for updated regulatory frameworks to address the unique considerations of gene editing and synthetic biology applications.

6.3 Digital Biosurveillance

- Adoption of digital tools and platforms for disease surveillance and reporting, enhancing early warning capabilities (Maruta et al., 2023).
- Emerging challenges in data privacy, security, and cross-border information sharing (Abdi et al., 2024).

6.4 Regional Harmonization Efforts

- Initiatives by regional bodies like the East African Community (EAC) to harmonize biosafety approaches, facilitating research collaboration and trade (Mugiira, 2021).
- Development of regional centers of excellence for biosafety and biosecurity training and capacity building (Maruta et al., 2023).

7. Importance of Development

Advancements in bioscience are only sustainable when developed and used responsibly. Effective biosafety and biosecurity governance are crucial for harnessing the benefits of bioscience advancement in Africa, especially in key sectors such as:

7.1 Agricultural Development and Food Security

- Biotechnology offers potential solutions to agricultural challenges, such as pest resistance and drought tolerance (Juma & Serageldin, 2007).
- Proper governance can facilitate the safe adoption of productivity-enhancing technologies while protecting biodiversity (Mugiira, 2021).

7.2 Economic Growth and Trade

- Harmonized biosafety regulations can reduce non-tariff barriers to trade within Africa and globally, supporting the objectives of the African Continental Free Trade Area (AfCFTA) (African Union, 2018).
- A robust regulatory environment can attract investment in biotechnology and related industries, fostering innovation and economic diversification (Bediako, 2022).

7.3 Public Health

- Strong biosecurity measures are crucial for preventing and responding to disease outbreaks, as demonstrated during recent epidemics (Maruta et al., 2023).
- Advances in biotechnology can contribute to improved healthcare and pharmaceutical development, addressing Africa's unique health challenges (Sammut, 2021).

7.4 Environmental Protection

- Biosafety measures are essential for protecting biodiversity and preventing ecological disruptions from the introduction of genetically modified organisms (Komen et al., 2020).
- Biotechnology can contribute to sustainable environmental management practices, such as bioremediation and pollution control (Wambugu, 1999).

7.5 Scientific and Technological Advancement

- A balanced regulatory approach can foster innovation while ensuring safety, supporting Africa's aspirations for knowledge-based economies (Bediako, 2022).
- Capacity building in biosafety and biosecurity can have spillover effects, enhancing overall scientific and technological capabilities across various sectors (Rutebemberwa et al., 2020).

8. Conclusion

While Africa has made significant progress in developing biosafety and biosecurity frameworks, several critical issues emerge from this landscape analysis:

1. **Implementation Gap:** Despite the existence of continental initiatives, national frameworks, and active participation in international initiatives, there remains a significant gap between policy formulation and effective implementation, particularly in countries with limited resources and institutional capacities.
2. **Regulatory Inconsistency:** The variance in regulatory approaches across countries, ranging from highly restrictive to more permissive, creates challenges for regional collaboration and trade, potentially hindering the continent's ability to fully leverage biotechnology for development.
3. **Capacity Building Needs:** The persistent shortage of trained personnel and adequate infrastructure underscores the urgent need for sustained investment in capacity building. Without addressing these fundamental gaps, even well-designed policies may fail to achieve their intended outcomes.
4. **Balancing Innovation and Precaution:** Many African countries struggle to strike the right balance between fostering innovation in biotechnology and maintaining appropriate precautionary measures. This tension is reflected in ongoing debates surrounding GMO regulations and emerging technologies like gene editing.
5. **Public Engagement Challenges:** The limited public understanding of biotechnology and biosafety issues highlights the need for more effective science communication and stakeholder engagement strategies. Without public trust and support, the development of the bioeconomy may face significant obstacles.
6. **Regional Harmonization Efforts:** While initiatives for regional harmonization are promising, progress has been slow. Accelerating these efforts could significantly enhance Africa's collective capacity to manage bio-risks and participate in the global bioeconomy.
7. **Sustainable Financing:** The reliance on external funding for many biosafety and biosecurity initiatives raises questions about the long-term sustainability of these efforts. Developing sustainable, domestically-driven financing mechanisms will be crucial for ensuring continuity and ownership of bio-risks governance.

In conclusion, while Africa has laid important groundwork in bio-risks governance, addressing these critical issues will require sustained commitment, enhanced regional cooperation, and innovative approaches to capacity building and resource mobilization. By strengthening its biosafety and biosecurity systems, Africa can better protect public health, support sustainable development, and position itself as a key player in the global bioeconomy.

Note: This literature review report offers a broad overview of biosafety and biosecurity governance in Africa, based on select publications identified during the initial literature search. It aims to provide a high-level landscape analysis rather than an exhaustive examination of individual policies or research papers. The breadth of this summary allows for a comprehensive understanding of key trends and challenges.

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