Mainstreaming Biodiversity Conservation and Biosafety for Sustainable Development

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Kariuki Muigua*

Abstract

Biosafety refers to secure methodologies used in managing biological materials, particularly infectious pathogens, to avoid unintended exposure to infections and poisons. It involves responsible laboratory procedures to mitigate risks of unauthorized access, loss, theft, misuse, or deliberate release. The need to integrate biodiversity into economic growth and development is recognized, but the global decline of biodiversity persists due to over-exploitation of natural resources. The Convention on Biological Diversity aims to preserve biodiversity, encourage sustainable use, and ensure equitable distribution of benefits from genetic resources. It establishes a framework for action, addressing diverse ecosystems and cross-cutting concerns. African nations and governments must be aware of the escalating biological dangers of bioterrorism and developing infectious diseases and be prepared to detect and control these agents. Biosafety and biosecurity standards aim to mitigate both deliberate and inadvertent biological hazards that could severely impact a nation's health infrastructure, security, and political and economic stability. However, biosafety and biosecurity are inadequately prioritized at national, regional, and international levels. Innovative measures, including regional approaches that can be adapted nationally, are essential. This paper discusses the linkages between biodiversity conservation and the role of promoting biosafety regulation in achieving this, focusing on mainstreaming biosafety in biodiversity conservation regulatory frameworks through adopting an integrated approach to biosafety regulation and biodiversity conservation.

1. Introduction

The World Health Organisation defines biosafety as the secure methodologies used in the management of biological materials, especially infectious pathogens.[1] It pertains to

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[1] 'WHO EMRO | Biosafety | Health Topics' (*World Health Organization - Regional Office for the Eastern Mediterranean*) <http://www.emro.who.int/health-topics/biosafety/index.html> accessed 11 November 2024.

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the ideas, methods, and practices of containment designed to avoid unintended exposure to infections and poisons, as well as their inadvertent discharge.[2] Adhering to responsible laboratory procedures, including protection, control, and responsibility for important biological resources, will mitigate the risks of unauthorized access, loss, theft, misuse, diversion, or deliberate release.[3]

The need of integrating biodiversity into economic growth and development is increasingly acknowledged and is now firmly included into the Sustainable Development Goals.[4] Notwithstanding the critical significance of biodiversity to economic, social, health, and cultural systems, the global decline of biodiversity persists as the quest for economic growth and development results in the conversion and, in numerous instances, over-exploitation of natural resources for production and consumption inputs.[5]

The decline of biodiversity is both the most significant and the least acknowledged. The prevailing consensus is that the present rate of ecosystem, species, and gene pool loss exceeds that of any period since the demise of the dinosaurs 65 million years ago.[6] The decline of biodiversity, together with the corresponding traditional knowledge, results in fewer alternatives for achieving diversified nutrition, improving food production, increasing incomes, adapting to environmental changes, and managing ecosystems.[7] The

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[2] Ibid.

[3] Ibid.

[4] OECD (2018), *Mainstreaming Biodiversity for Sustainable Development*, OECD Publishing, Paris, https://doi.org/10.1787/9789264303201-en.

[5] Ibid., p. 22.

[6] Zedan, Hamdallah. "The role of the convention on biological diversity and its protocol on biosafety in fostering the conservation and sustainable use of the world's biological wealth for socio-economic and sustainable development." *Journal of Industrial Microbiology and Biotechnology* 32, no. 11-12 (2005): 496-501.

[7] Ibid.; see also 'Dwindling Biodiversity Threatens Food Security' (*Welthungerhilfe.de - Für eine Welt ohne Hunger und Armut*) <https://www.welthungerhilfe.org/news/latest-articles/2021/the-loss-of-biodiversity-threatens-world-food-security> accessed 9 December 2024; Jones, Andrew D. "Critical review of the emerging research evidence on agricultural biodiversity, diet diversity, and nutritional status in low-and middle-income countries." *Nutrition reviews* 75, no. 10 (2017): 769-782; Benton, Tim G., Carling Bieg, Helen Harwatt, Roshan Pudasaini, and Laura Wellesley. "Food system impacts on biodiversity loss." *Three levers*

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Convention on Biological Diversity seeks to preserve biodiversity, encourage sustainable use of its elements, and guarantee equitable distribution of benefits derived from the use of genetic resources.[8] It seeks to harmonise conservation with economic growth while preserving the ecological underpinning essential for all human communities. The Convention establishes a framework for action, with Parties implementing its provisions via work programs that address diverse ecosystems and cross-cutting concerns, including traditional knowledge, access to genetic resources, biodiversity, tourism, and incentive measures.[9]

African nations and governments must now be more aware of the escalating biological danger presented by bioterrorism and developing infectious illnesses, and be prepared to detect and control these agents. The objectives of biosecurity and biosafety standards are to mitigate both deliberate and inadvertent biological hazards that might severely impact a nation's health infrastructure, security, and political and economic stability.[10] Notwithstanding the continuous efforts to enhance the health of humans and animals in these regions, biosafety and biosecurity continue to be inadequately prioritized at

for food system transformation in support of nature. Chatham House, London (2021): 02-03; Muluneh, Melese Genete. "Impact of climate change on biodiversity and food security: a global perspective—a review article." *Agriculture & Food Security* 10, no. 1 (2021): 1-25; Kennedy, Gina, Zeyuan Wang, Patrick Maundu, and Danny Hunter. "The role of traditional knowledge and food biodiversity to transform modern food systems." *Trends in Food Science & Technology* 130 (2022): 32-41; Knez, Marija, Marija Ranić, and Mirjana Gurinović. "Underutilized plants increase biodiversity, improve food and nutrition security, reduce malnutrition, and enhance human health and well-being. Let's put them back on the plate!" *Nutrition Reviews* 82, no. 8 (2024): 1111-1124; Kanter, Rebecca, Gina Kennedy, and Sofia Boza. "Local, traditional and indigenous food systems in the 21st century to combat obesity, undernutrition and climate change." *Frontiers in Sustainable Food Systems* 7 (2023): 1195741.

[8] Ibid.; see also Article 1, United Nations, *Convention on Biological Diversity*. Rio de Janeiro, 5 June 1992, 1760 U.N.T.S. 79, 143; 31 I.L.M. 818 (1992).

[9] Ibid.; see also 'A Brief Introduction to the Convention on Biological Diversity' <https://enb.iisd.org/process/biodiv_wildlife-cbdintro.htm> accessed 9 December 2024.

[10] Abdi, A. M., S. A. Abdiweli, H. Sheban, A. Abdale, H. Sead, M. Hussein, Z. Mohamed, M. Dayib, and H. Kosar. "Biosafety and Biosecurity in Africa: Challenges and Future Perspectives." (2024).

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national, regional, and international tiers.[11] It has been pointed out that while biosafety and biosecurity are essential for public and animal health; nevertheless, there is an absence of standardized protocols to manage dangerous illnesses across Africa.[12] To address this issue, innovative measures, including the implementation of regional approaches that may be adapted nationally, are essential.[13]

This paper broadly discusses the linkages between biodiversity conservation and the role of promoting biosafety in achieving this. The discussion focuses on the need for mainstreaming biosafety in biodiversity conservation regulatory framework and the need for an integrated approach to biosafety regulation and biodiversity conservation.

2. Biosafety Regulation and Biodiversity Conservation: Key Issues

It has rightly been pointed out that in several sub-Saharan African nations, regulatory biosafety law has been influenced by the Cartagena Protocol and the African Model Law on Biosafety, both of which advocate for risk assessment in decision-making, but the latter adopts a notably preventive approach.[14] Nonetheless, the Protocol recognises the

[11] Ibid.; see also AL-Eitan L and Alnemri M, 'Biosafety and Biosecurity in the Era of Biotechnology: The Middle East Region' (2022) 4 Journal of Biosafety and Biosecurity 130; Maruta, Talkmore, Jaures Arnaud Noumedem Kenfack, Yenew Kebede Tebeje, Donewell Bangure, and Ahmed E. Ogwell Ouma. "Regional approach to strengthening biosafety and biosecurity systems in Africa." *Global Security: Health, Science and Policy* 8, no. 1 (2023): 2257766.

[12] Ibid.; Heckert, Robert & Reed, Craig & Gmuender, Felix & Ellis, Maureen & Tonui, Willy. (2011). International Biosafety and Biosecurity Challenges: Suggestions for Developing Sustainable Capacity in Low-resource Countries. Applied Biosafety. 16. 223-230. 10.1177/153567601101600404.

[13] Ibid.; Maruta, Talkmore, Jaures Arnaud Noumedem Kenfack, Yenew Kebede Tebeje, Donewell Bangure, and Ahmed E. Ogwell Ouma. "Regional approach to strengthening biosafety and biosecurity systems in Africa." *Global Security: Health, Science and Policy* 8, no. 1 (2023): 2257766; Ongu, Isaac, Priscilla Olayide, Erik Alexandersson, Barbara Mugwanya Zawedde, and Dennis Eriksson. "Biosafety regulatory frameworks in Kenya, Nigeria, Uganda and Sweden and their potential impact on international R&D collaborations." *GM Crops & Food* 14, no. 1 (2023): 1-17.

[14] Quinlan MM and others, 'Experiences in Engaging the Public on Biotechnology Advances and Regulation' (2016) 4 Frontiers in Bioengineering and Biotechnology <https://www.frontiersin.org/journals/bioengineering-and-biotechnology/articles/10.3389/fbioe.2016.00003/full> accessed 4 December 2024.

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conflict between the necessity to safeguard human health and the environment from the potential detrimental impacts of modern biotechnology products and the technology's capacity to enhance human welfare, especially in addressing essential requirements for food, agriculture, and healthcare.[15]

Biodiversity protection necessitates a careful equilibrium between growth and preservation, since it is inherently connected to the sustenance of its populace, with around 65% reliant on the agricultural sector.[16] The connection between biodiversity and agriculture is emphasised by international conventions and accords that tackle the hazards of invasive alien species to natural and agricultural ecosystems, as well as challenges of environmental sustainability.[17]

Numerous animal species may go extinct owing to deforestation, wildlife hunting, climate change, pollution, population increase, and various other factors.[18] If governments and communities neglect to safeguard and preserve biodiversity, several species face significant loss and extinction.[19]

It has been observed that most African countries have just initiated the establishment of national biosafety systems, and the development and enforcement of science-based legislation has proved to be a formidable challenge.[20] The Cartagena Protocol on Biosafety, approved in 2003, pertains to the environmental impacts of transboundary

[15] Ibid.
[16] Lum KengYeang, Lum KengYeang. "Preserving biodiversity, promoting biosecurity and biosafety: developing country perspectives." (2011): 27-30.
[17] Ibid.
[18] Ibid.
[19] Ibid.
[20] Abdi, A. M., S. A. Abdiweli, H. Sheban, A. Abdale, H. Sead, M. Hussein, Z. Mohamed, M. Dayib, and H. Kosar. "Biosafety and Biosecurity in Africa: Challenges and Future Perspectives." (2024).

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transport, management, and safe utilisation of genetically modified organisms (GMOs), and has laid the groundwork for the majority of these systems.[21]

3. International and Regional Legislative Framework on Biosafety

a) Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety[22] was adopted on 29 January 2000 at the Extraordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity (ExCOP) and serves as a supplemental accord to the Convention.[23] The Protocol became effective on 11 September 2003, ninety days after the receipt of the 50th ratification document.[24]

The Protocol aims to safeguard biological diversity from the possible hazards associated with living modified organisms (LMOs) arising from modern biotechnology.[25] It pertains to the transfer of Living Modified Organisms (LMOs) between countries via an Advance Informed Agreement (AIA) protocol, ensuring that nations have the necessary information to make informed choices prior to consenting to the importation of these organisms into their jurisdiction.[26] It also establishes an alternate protocol for LMO commodities (LMOs designated for direct consumption as food or feed, or for processing).[27]

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[21] Ibid.

[22] Secretariat of the Convention on Biological Diversity (2000), *Cartagena Protocol on Biosafety to the Convention on Biological Diversity: text and annexes*. Montreal: Secretariat of the Convention on Biological Diversity, 2226 UNTS 208, UN Doc. UNEP/CBD/ExCOP/1/3, 39 ILM 1027 (2000).

[23] 'The Cartagena Protocol | Belgian Biosafety Clearing-House' <https://www.biosafetyprotocol.be/cartagena-protocol> accessed 14 November 2024.

[24] Ibid.; Unit B, 'The Cartagena Protocol on Biosafety' (*The Biosafety Clearing-House (BCH)*, 25 October 2024) <https://bch.cbd.int/protocol> accessed 14 November 2024.

[25] Ibid.

[26] Ibid.

[27] Ibid.

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It encompasses additional provisions regarding the types of information required, scientifically grounded risk assessment, streamlined procedures, information exchange, management of confidential data, public awareness and engagement, capacity building for developing nations, financial resources, and other aspects related to accompanying documentation, liability and redress, and socio-economic factors.[28]

b) The Biosafety Clearing-House of the Cartagena Protocol on Biosafety

Article 20 of the Cartagena Protocol on Biosafety establishes a Biosafety Clearing-House (BCH) as part of the Clearing-house Mechanism outlined in Article 18, paragraph 3, of the Convention on Biological Diversity.[29] This mechanism aims to facilitate the exchange of scientific, technical, environmental, and legal information regarding living modified organisms and to assist Parties in implementing the Protocol, particularly addressing the specific needs of developing country Parties, especially the least developed and small island developing States, as well as countries with transitioning economies and those that are centres of origin and genetic diversity.[30]

The Biosafety Clearing-House (BCH) is thus an information exchange system created by the Cartagena Protocol on Biosafety to assist Parties in executing its provisions and disseminating information on living modified organisms (LMOs).[31]

The BCH is crucial for the effective execution of the Protocol. It offers a comprehensive platform for users to easily access or submit pertinent biosafety information, aiding governments in making educated choices on the importation or release of LMOs.[32] The information in the BCH is owned and updated by the users, guaranteeing its timeliness

[28] Ibid.
[29] Art. 20, Cartagena Protocol on Biosafety.
[30] Ibid.
[31] 'Background to the Cartagena Protocol on Biosafety | AUDA-NEPAD' <https://www.nepad.org/content/background-cartagena-protocol-biosafety> accessed 8 December 2024.
[32] Ibid.

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and correctness. By providing accessible and transparent access to essential information, the BCH enhances the clarity of Protocol implementation and promotes active involvement of the public and civil society in the decision-making process.[33] The BCH operates as a "central information marketplace" facilitating the interaction and transparent sharing of biosafety information between suppliers and consumers.[34] The BCH has been designed to ensure that locating and disseminating information is straightforward and intuitive, use uniform formats and standardized language (controlled vocabulary).[35]

The successful execution of the Biosafety Protocol is contingent upon the effective and timely dissemination of pertinent information. Parties, governments, and other stakeholders must fully use the BCH and actively provide information to it.[36]

c) **African Regulatory and Certification Framework for Institutions Handling High Risk Pathogens**

In April 2019, the Africa Centres for Disease Control(CDC)initiated a program to enhance the biosecurity and biosafety systems of African Union Member States in accordance with the International Health Regulations (IHR) (2005), the Biological Weapons Convention (BWC), and UN Security Council Resolution (UNSCR) 1540.[37]

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[33] Ibid.

[34] Secretariat of the Convention on Biological Diversity (2004), *The Biosafety Clearing House of the Cartagena Protocol on Biosafety: A Guide to the BCH*. Montreal: Secretariat of the Convention on Biological Diversity < https://www.cbd.int/doc/publications/bch-brochure-en.pdf> accessed 8 December 2024.

[35] Environment UN, 'BCH Phase II | UNEP - UN Environment Programme' (18 October 2017) <https://www.unep.org/explore-topics/biosafety/what-we-do/developing-biosafety-frameworks/bch-phase-ii> accessed 8 December 2024.

[36] McLean, Morven, Mary-Ellen Foley, and Eija Pehu. *Status and Impact of Bio Safety Regulation in Developing Economies Since Ratification of the Cartagena Protocol*. World Bank, Washington, DC, 2012; Mackenzie, Ruth. "An Explanatory Guide to the Cartagena Protocol on Biosafety." (2003).

[37] Abdi, A. M., S. A. Abdiweli, H. Sheban, A. Abdale, H. Sead, M. Hussein, Z. Mohamed, M. Dayib, and H. Kosar. "Biosafety and Biosecurity in Africa: Challenges and Future Perspectives." (2024).

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The Africa CDC, in conjunction with Member States, has established a Regulatory and Certification Framework for Institutions Managing High-Risk Pathogens.[38] The Framework establishes the necessary requirements for facilities managing High Consequence Agents and Toxins (HCATs), directing the execution of laboratory biosafety and biosecurity protocols pertinent to the design, commissioning, and regular operation of secure biocontainment labs.[39] The Framework received endorsement after a collaborative process including the five Regional Biosafety and Biosecurity Technical Working Groups.[40]

The Africa CDC Regional Biosafety and Biosecurity Initiative facilitates the creation of standardized regional initiatives that may be adapted for national implementation.[41] Nonetheless, it has been argued that there exists a persistent deficiency in the availability of nationally approved, standardized biosafety and biosecurity training programs.[42] From November 2020 to March 2021, five multisectoral Regional Biosafety and Biosecurity Technical Working Groups (RBB-TWGs) were established and operationalized for the regions of Central, East, North, Southern, and West Africa.[43]

[38] 'African Union List of Certified Assessors for the Regulatory and Certification Framework for Institutions Handling High Risk Pathogens' (*Africa CDC*) <https://africacdc.org/download/african-union-list-of-certified-assessors-for-the-regulatory-and-certification-framework-for-institutions-handling-high-risk-pathogens/> accessed 8 December 2024.
[39] Ibid.
[40] Ibid.
[41] Abdi, A. M., S. A. Abdiweli, H. Sheban, A. Abdale, H. Sead, M. Hussein, Z. Mohamed, M. Dayib, and H. Kosar. "Biosafety and Biosecurity in Africa: Challenges and Future Perspectives." (2024).
[42] Ibid.
[43] Ibid.

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4. Biosafety Legislation and Policy in Kenya: Challenges and Prospects

a) Biosafety Act (Cap. 320)

The Kenya Biosafety Act (Cap. 320)[44] is an Act of Parliament to regulate activities in genetically modified organisms, establish the National Biosafety Authority, and for connected purposes.[45] The Act was published in the Kenya Gazette Vol. CXI—No. 16 on 20 February 2009 and amended by the Biosafety Act Commencement on 1 July 2011 by Biosafety Act.

The Act aims to avoid risks to human health and safety and the conservation of the environment as a result of the use of genetically modified organisms. The Biosafety Act defines "biosafety" to mean the avoidance of risk to human health and safety, and the conservation of the environment, as a result of the use of genetically modified organisms.[46] It also defines "environment" to includes the physical factors of the surroundings of human beings, including land, water, atmosphere, soil, vegetation, climate, sound, odour, aesthetics, fish and wildlife.[47] "Genetically modified organism" is used in the Statute to mean any organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology techniques.[48] "Modern biotechnology" as used in the Act includes the application of—(a) in-vitro nucleic acid techniques including the use of recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or (b) fusion of cells beyond the taxonomic family, that overcome natural physiological, reproductive and recombination barriers and which are not techniques used in traditional breeding and selection.[49]

[44] Biosafety ACT, Cap. 320, No. 2 of 2009, Laws of Kenya.
[45] Ibid., Preamble.
[46] S. 2, Biosafety ACT, Cap. 320, Laws of Kenya.
[47] Ibid.
[48] Ibid.
[49] Ibid.

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The Act covers various aspects, including the scope of the Act, its objectives, establishment, powers, and functions of the Authority, the Board of the Authority, the conduct of business and affairs, delegation by the Board, remuneration of members of the Board, the Chief Executive Officer, staff of the Authority, protection from personal liability, and liability for damages.[50]

Part III focuses on applications for approval and risk assessment, including applications for contained use activity, introduction into the environment, importation, placing on the market, genetically modified organisms in transit, export, withdrawal of application, confidentiality information, acknowledgment of application, risk assessment and risk management, non-assessment of risks, determination of an application, communication of decision, suspension or revocation of an approval, register, review and appeals, establishment of the Appeals Board, regulatory agencies, restoration and cessation orders, inspection and monitoring, appointment of biosafety inspectors, financial provisions, handling, packaging, regulations, offenses and penalties, restriction on institution of proceedings, public awareness and participation, and the expiry date of the Act.[51]

The Act also includes provisions for the handling, packaging, handling, and disposal of genetically modified organisms,[52] as well as provisions for the establishment of the National Biosafety Authority[53]. In summary, the Kenya Biosafety Act (Cap. 320) is a comprehensive legislation that aims to protect human health and safety, conserve the environment, and regulate activities in genetically modified organisms[54].

[50] Part I (sections 1-4) & Part II (Sections 5-17).
[51] Part III (Sections 18-32).
[52] Biosafety Act, s. 50.
[53] Ibid., s.5.
[54] See s. 4.

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b) National Biosafety Authority

The National Biosafety Authority is a body corporate established to facilitate responsible research into genetically modified organisms, minimize risks, ensure adequate protection for safe transfer, handling, and use of these organisms, and establish a transparent, science-based, and predictable process for reviewing and making decisions on their transfer, handling, and use.[55] The Authority is managed by a Board consisting of nine members, including an eminent scientist Chairperson, Principal Secretary in the Ministry for Science and Technology or a representative, two experts in biological, environmental, and social sciences, one member with financial expertise, and the Chief Executive Officer who is an ex officio member.[56]

The Authority's objectives include exercising general supervision and control over the transfer, handling, and use of genetically modified organisms to ensure human and animal health safety and adequate environmental protection.[57] It considers and determines applications for approval for the transfer, handling, and use of genetically modified organisms, coordinates research and surveys related to the safe development, transfer, handling, and use of genetically modified organisms, identifies national requirements for manpower development and capacity building in biosafety, advises the Government on legislative and other measures relating to the safe transfer, handling, and use of genetically modified organisms, promotes awareness and education among the general public in matters relating to biosafety, establishes and maintains a biosafety clearing house, and performs any other function incidental to the performance of these functions.[58]

[55] Biosafety Act, s.7.
[56] Ibid., s. 6.
[57] Ibid., s.7(1).
[58] Ibid., s. 7(2).

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Approval and risk assessment applications for contained use activity and introduction into the environment must be submitted in the prescribed manner and contain information set out in the Third Schedule and the Fourth Schedule.[59] The Authority must publish notice concerning any application for release into the environment of a genetically modified organism for public information.[60]

The Biosafety Act (Cap. 320) Kenya allows individuals to make representations to the Authority regarding their application for genetically modified organisms. The Authority must address any concerns raised by the person within thirty days of publication of the notice.[61] A person cannot import or place a genetically modified organism into Kenya without written approval, including information from the Fourth Schedule and other relevant information.[62] When transporting genetically modified organisms through Kenya, the applicant must apply for written approval and ensure proper packaging and transportation in accordance with regulations and international standards.[63]

For exporting genetically modified organisms from Kenya, the applicant must provide an advance written consent granted by a relevant authority of the country to which the organism is destined.[64] However, the Authority may withdraw an application at any time before issuance of a final decision. Confidential information provided to the Authority must be treated as confidential and not used for any purpose not authorized under this Act.[65] Upon receipt of an application, the Authority screens the application for completeness and acknowledges receipt in writing within thirty days. If an application is not complete, the Authority requests additional information. The time taken before

[59] Ibid., s.18; s.19.
[60] Ibid., s. 19(4).
[61] Ibid., s. 19(5).
[62] Ibid., s. 20.
[63] Ibid., s. 22.
[64] Ibid., s. 23.
[65] Ibid., s. 25.

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receiving the information is not considered in calculating the time taken prior to making a final decision on the application.[66]

Risk assessment and risk management are conducted when the application for approval under this Act has been screened and found to be complete. The Authority will make a report of its findings and indicate measures to ensure the safe use of a genetically modified organism. The Authority may opt not to undertake a risk assessment if sufficient experience or information exists to conclude that the organism or contained use activity does not pose a significant risk.[67]

In determining an application, the Authority takes into account the information submitted by the applicant, information and conditions submitted by the relevant regulatory agency, the risk assessment report, public representations, and socio-economic considerations arising from the impact of the genetically modified organism on the environment. The Authority must communicate its final decision of approval or rejection to the applicant within one hundred and fifty days of receipt.[68]

The Biosafety Act (Cap. 320) Kenya allows the Authority to suspend or revoke approvals for certain activities, such as genetically modified organisms or contained use activities.[69] The Authority must give written notice of its intention to suspend or revoke an approval and invite the person to make representations within thirty days. If the authority suspends or revokes an approval, it must publish the order in the Gazette, newspapers with nationwide circulation, and electronic media.[70]

The Authority maintains a register that contains information about every application received, risk assessment report, decision document, approval, and any other necessary

[66] Ibid., s. 26.
[67] Ibid., s. 27 & 28.
[68] Ibid., s. 29 & 30.
[69] Ibid., s. 31.
[70] Ibid.

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information.[71] It can review a decision made under section 29 upon obtaining significant new scientific information relating to biosafety of the organism or contained use activity involved.[72] A regulatory agency or applicant may request the Authority to review its decision with respect to an activity conducted by the applicant if they believe a change in circumstances has occurred that may have a material effect on the outcome of the risk assessment.[73] If the Authority is satisfied that a change is warranted, the Authority shall substitute its earlier approval with another approval taking into account the changed circumstances.[74]

The Authority gives special consideration for review requests from regulatory agencies.[75] If a person upon whom approval has been granted withholds information that could reasonably be expected to change the evaluation of the risk posed by the person's intended activity, they commit an offence and are liable on conviction to a fine not exceeding two million shillings or imprisonment for a term not exceeding ten years, or both.[76]

The Appeals Board is established, consisting of a Chairperson appointed by the Cabinet Secretary and four other persons appointed by the Cabinet Secretary. The Chairperson is an advocate of the High Court qualified for appointment as a judge of the High Court of Kenya, and the members hold office for three years. The Appeals Board has the powers of a court to summon witnesses, take evidence upon oath or affirmation, and call for the production of books and other documents. It may also consider any evidence relevant to the subject of an appeal before it.[77]

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[71] Ibid., s. 32.
[72] Ibid., s. 33.
[73] Ibid.
[74] Ibid.
[75] Ibid., s. 33(6).
[76] Ibid., s. 34.
[77] Ibid., 35.

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The Biosafety Act (Cap. 320) Kenya outlines the Authority's role in coordinating activities involving genetically modified organisms and advising regulatory agencies on compliance with conditions imposed on approvals.[78] The Authority may consult with regulatory agencies to ensure that approved activities comply with these conditions.[79] If a regulatory agency becomes aware of new scientific information indicating potential biosafety risks, it must inform the Authority and propose measures to ensure continued safe use of the organism.[80] The Authority may issue restoration orders for unintentional or unapproved introductions into the environment, requiring the person to restore the environment as close as possible to its pre-release state. These orders specify the activity, person, time, action to remedy harm, and penalties if not undertaken. The Authority may also issue cessation orders if there is an imminent danger posed to the conservation and sustainable use of biological diversity, taking into account human health risks.[81]

Biosafety inspectors are appointed by the Cabinet Secretary on the recommendation of the Authority and by notice in the Gazette. They perform functions such as monitoring compliance, conducting inspections, and submitting reports. A biosafety inspector may enter premises, facilities, vessels, or property to verify compliance with requirements or approvals, take appropriate samples, dismantle or subject organisms to tests, and require records to be produced.[82]

Notably, the Authority is also obligated to promote public awareness and education of the public and those conducting the activities subject to the Act, concerning biosafety matters, through the publication of guidance documents and other materials aimed at improving the understanding of biosafety.[83] This is important considering that public

[78] Ibid., s. 38.
[79] Ibid.
[80] Ibid., s. 38(3).
[81] Ibid., s. 40, 41 & 42.
[82] Ibid., s. 43,44 & 45.
[83] Ibid., s. 54.

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feedback is often solicited throughout the biosafety decision-making process and dissemination and communication of advancements in biotechnology constitute the first phase of involvement.[84] Public engagement is essential for the creation, assessment, and adoption of any novel technology.[85] This aspect is deemed particularly significant within the biosafety decision-making framework and is included in Article 23 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (2000).[86]

In conclusion, and as outlined above, the Biosafety Act of Kenya outlines the Authority's responsibilities in coordinating activities involving genetically modified organisms, implementing restoration orders, and appointing biosafety inspectors.

Under First Schedule to the Act, the National Biosafety Authority is required to work closely with the following regulatory agencies: Department of Public Health; Department of Veterinary Services; Kenya Bureau of Standards; Kenya Plant Health Inspectorate Services; Kenya Industrial Property Institute; Kenya Wildlife Service; Pest Control Products Board; and the National Environment Management Authority.

Despite have these legal and institutional safeguards, there have been key public concerns as to their adequacy in not only engineering progress in this area in Kenya but also in safeguarding public health and the environment, the key objects of the Biosafety Act, Cap 320.[87] The National Biosafety Authority is pursuing a revision of the Biosafety

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[84] Quinlan MM and others, 'Experiences in Engaging the Public on Biotechnology Advances and Regulation' (2016) 4 Frontiers in Bioengineering and Biotechnology <https://www.frontiersin.org/journals/bioengineering-and-biotechnology/articles/10.3389/fbioe.2016.00003/full> accessed 4 December 2024.

[85] Ibid.

[86] Ibid.

[87] Macharia, F., 'National Biosafety Agency Moves to Enhance GMO Foods Oversight Role – People Daily' 4 December 2024 <https://peopledaily.digital/national-biosafety-agency-moves-to-enhance-gmo-foods-oversight-role/> accessed 4 December 2024; Makokha, Kibaba, and Winfred Kyalo. "Ethical Objections to Commercial Farming and Consumption of Genetically Modified Foods in Kenya." *Thought and Practice* 7, no. 1 (2015): 51-76; Khamala, Charles A. "Green crimes: the impact of genetically modified organisms on promoting food security in Kenya." *African Human Rights Yearbook* 6 (2022): 291-320.

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Act to include developing technologies, including genome editing, gene-drive technologies, synthetic biology, and biosecurity applications. These changes seek to maintain Kenya's leadership in global biosafety standards while addressing widespread concerns.[88]

c) Seeds and Plant Varieties Act, Cap 326

The Seeds and Plant Varieties Act, is an Act of Parliament to confer power to regulate transactions in seeds, including provision for the testing and certification of seeds; for the establishment of an index of names of plant varieties; to empower the imposition of restriction on the introduction of new varieties; to control the importation of seeds; to authorize measures to prevent injurious cross-pollination; to provide for the grant of proprietary rights to persons breeding or discovering and developing new varieties; to establish a centre for plant genetic resources for food and agriculture, including indigenous seeds and plant varieties; to establish a Tribunal to hear appeals and other proceedings; and for connected purposes.[89]

The Act empowers the Cabinet Secretary, after consultation with representatives of such organizations as he deems to have a substantial interest in the matter to be regulated and of such other interests as appear to him to be concerned, to make regulations for the production, processing, testing, certification and marketing of seeds, and without prejudice to the generality of this power, such regulations may, in particular, be made for any or all of the following purposes— (a) for ensuring that reliable and adequate information is afforded as to the nature, condition and quality of seeds intended for sale; (b) for preventing the sale of seeds which are deleterious, or which have not been produced in specified conditions, or which have not been tested for purity or germination, or which are of a plant variety of which the performance has not been

[88] Ibid.

[89] Seeds and Plant Varieties Act, Cap 326, Preamble.

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subjected to trials; (c) for requiring the registration of persons growing any specified crop for the main purpose of seed production, or of persons selling any seed; (d) for preventing the spread of plant disease by the sale of seeds; (e) for requiring the treatment of seed, by any specified means, for the control of plant disease and regulating the importation, quality, testing and sale of any material used in such treatment; (f) for regulating the descriptions under which seed is sold; (g) for regulating, controlling or prohibiting the export of seeds; (h) for prescribing anything which, under this Part, is to be prescribed or which, under any other provision of this Act, is to be prescribed by seeds regulations.[90]

5. Mainstreaming Biosafety in Legislation and Policy: Way Forward

To attain genuine development, it is imperative to prioritize biodiversity in development paradigms and poverty alleviation strategies, incorporate biodiversity considerations into sectoral policies, eradicate detrimental incentives in agriculture, offer constructive incentives for conservation and sustainable utilisation, and guarantee that biodiversity and biosafety issues are addressed in all pertinent forums.[91]

It has been observed that biosafety and biosecurity in Africa encounter several issues owing to the proliferation of biosafety organisations striving to improve public health inside their countries.[92] Numerous African nations, characterized by limited resources, have challenges that hinder their potential to establish or enhance sustainable biosafety

[90] Cap 326, s. 3(1).

[91] Zedan, Hamdallah. "The role of the convention on biological diversity and its protocol on biosafety in fostering the conservation and sustainable use of the world's biological wealth for socio-economic and sustainable development." *Journal of Industrial Microbiology and Biotechnology* 32, no. 11-12 (2005): 496-501.

[92] Abdi, A. M., S. A. Abdiweli, H. Sheban, A. Abdale, H. Sead, M. Hussein, Z. Mohamed, M. Dayib, and H. Kosar. "Biosafety and Biosecurity in Africa: Challenges and Future Perspectives." (2024) < https://www.researchgate.net/profile/Abas-Abdi/publication/377264685_Biosafety_and_Biosecurity_in_Africa_Challenges_and_Future_Perspectives/links/659d98873c472d2e8ec1d727/Biosafety-and-Biosecurity-in-Africa-Challenges-and-Future-Perspectives.pdf> accessed 4 December 2024.

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and biosecurity management.[93] The objectives of biosecurity and biosafety procedures are to mitigate both deliberate and inadvertent biological threats that might adversely impact a nation's health system, agriculture, security, and political and economic stability. Unfortunately, these policies often get inadequate emphasis at national, regional, and international levels.[94]

5.1. Enhanced Public Participation and Awareness Creation

There is a need for enhanced and continued public participation even as the Government agencies seek to win the support of the general public in adopting safe biotechnological developments.[95] Effective involvement encompasses all relevant stakeholders, including product creators, consumers, and regulators—essentially any individuals or institutions that may be directly impacted by the new technology. This interaction must be prompt, honest, and reliable to be successful.[96]

Engaging with the public enhances awareness and fosters community participation. The fundamental aim of this approach is to enhance decision-making by incorporating the insights and expertise of a broader array of "experts" beyond those involved in the official

[93] Ibid.; Rutebemberwa E, Aku FY, Zein EIKA, Bellali H. Reasons for and barriers to biosafety and biosecurity training in health-related organizations in Africa, Middle East and Central Asia: findings from GIBACHT training needs assessments 2018-2019. Pan Afr Med J. 2020 Sep 16; 37:64. doi: 10.11604/pamj.2020.37.64.23390. PMID: 33244327; PMCID: PMC7680230; 'Biosafety and Biosecurity' (*Africa CDC*) <https://africacdc.org/programme/laboratory-systems-and-networks/biosafety-and-biosecurity/> accessed 9 December 2024.

[94] Ibid.; Hulme PE, 'Advancing One Biosecurity to Address the Pandemic Risks of Biological Invasions' (2021) 71 BioScience 708; Sciences B on L and others, 'Potential Risks: Biosafety and Biosecurity', *Potential Risks and Benefits of Gain-of-Function Research: Summary of a Workshop* (National Academies Press (US) 2015) <https://www.ncbi.nlm.nih.gov/books/NBK285575/> accessed 9 December 2024.

[95] Rowe, Gene, and Lynn J. Frewer. "Public participation methods: a framework for evaluation." *Science, technology, & human values* 25, no. 1 (2000): 3-29.

[96] Quinlan MM and others, 'Experiences in Engaging the Public on Biotechnology Advances and Regulation' (2016) 4 Frontiers in Bioengineering and Biotechnology <https://www.frontiersin.org/journals/bioengineering-and biotechnology/articles/10.3389/fbioe.2016.00003/full> accessed 4 December 2024.

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decision-making process.[97] There exists optimism that enhanced public comprehension will lead to greater acceptance of new technologies after they have been assessed and approved as safe by national biosafety authorities, contingent upon a foundational confidence in the system.[98]

5.2. Investing in Biosecurity for Biodiversity Conservation

Invasive species provide a significant hazard to the ecosystem by altering habitats, displacing or supplanting native species, and undermining human activities such as fisheries. Invasive species are the second most significant threat after habitat degradation.[99] Addressing invasive species requires addressing prevalent paths by which invaders access coasts to mitigate or prevent their invasion.[100] A contemporary strategy for controlling invasive species is ecosystem management, which involves systematic treatment of the whole ecosystem to promote the dominance of adapted native species over most foreign intruders.[101]

The Food and Agriculture Organisation of the United Nations (FAO) describes biosecurity as a strategic and integrated methodology for assessing and mitigating threats to human, animal, and plant health, together with related environmental hazards.[102] Biosecurity includes policies and regulations designed to mitigate hazards related to agricultural and food production.[103] This encompasses the introduction and

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[97] Ibid.
[98] Ibid.
[99] Lum KengYeang, Lum KengYeang. "Preserving biodiversity, promoting biosecurity and biosafety: developing country perspectives." *Op. cit.*
[100] Ibid.
[101] Ibid.
[102] Sathyapala S, 'A Global Framework to Enhance National Forest Biosecurity Strategies' <https://proceedings.science/secondiufrowpmeeting/papers/a-global-framework-to-enhance-national-forest-biosecurity-strategies?lang=en> accessed 8 December 2024.
[103] Lum KengYeang, Lum KengYeang. "Preserving biodiversity, promoting biosecurity and biosafety: developing country perspectives." *Op. cit.*

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dissemination of living modified organisms (LMOs) and genetically modified organisms (GMOs), the entrance and proliferation of invasive alien species, alien genotypes, as well as plant and animal pests, illnesses, and zoonoses.[104] A favourable result for biosecurity equates to a favourable result for biodiversity.[105]

There is thus a need for the relevant state agencies to enforce the national and international frameworks and standards to regulate, manage, and oversee biosecurity.[106] Integrating biodiversity, biosecurity, and sustainable development goals is essential for mitigating these risks and safeguarding the health and welfare of the human race and the environment.[107]

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[104] Ibid.; Vitor II, Rodel Jonathan S., and Fedelyn P. Estrella. "4 Principles of Biosecurity and Concepts." *Biosafety and Biosecurity: Practical Insights and Applications for Low and Middle-Income Countries* (2024): 65; Velasco, John Mark. "Principles of Biosafety in Resource Limited Settings." In *Biosafety and Biosecurity*, pp. 49-64. CRC Press.

[105] Ibid.; 'Biodiversity Is Biosecurity' (*Kosmos Journal*) <https://www.kosmosjournal.org/kj_article/biodiversity-biosecurity/> accessed 9 December 2024; Council NR, 'Biodiversity and Biosecurity on Land - Northland Regional Council' <https://www.nrc.govt.nz/resource-library-archive/environmental-monitoring-archive2/state-of-the-environment-report-archive/2011/state-of-the-environment-monitoring/our-land-our-air/biodiversity-and-biosecurity-on-land/> accessed 9 December 2024; Ekardt F and others, 'Legally Binding and Ambitious Biodiversity Protection under the CBD, the Global Biodiversity Framework, and Human Rights Law' (2023) 35 Environmental Sciences Europe 80; Reid CH and others, 'The State of Canada's Biosecurity Efforts to Protect Biodiversity from Species Invasions' (2021) 6 FACETS 1922.

[106] Ibid.; Sture J, Whitby S and Perkins D, 'Biosafety, Biosecurity and Internationally Mandated Regulatory Regimes: Compliance Mechanisms for Education and Global Health Security' (2013) 29 Medicine, conflict, and survival 289; 'Biosecurity In Food and Agriculture' (*International Plant Protection Convention*) <https://www.ippc.int/en/biosecurity-in-food-and-agriculture/> accessed 9 December 2024; Khalil AT and others, 'Chapter 3 - Preemptive and Proactive Strategies for Food Control and Biosecurity' in Alexandru Mihai Grumezescu and Alina Maria Holban (eds), *Food Safety and Preservation* (Academic Press 2018) <https://www.sciencedirect.com/science/article/pii/B9780128149560000032> accessed 9 December 2024; Burnette RN and Connell ND, '11 - Biosecurity Challenges for the IBC: An Exploration of the Roles and Responsibilities of Institutional Biosafety Committees in the Age of Terrorism and Biosecurity, Now and for the Future' in Carole R Baskin and Alan P Zelicoff (eds), *Ensuring National Biosecurity* (Academic Press 2016) <https://www.sciencedirect.com/science/article/pii/B9780128018859000111> accessed 9 December 2024; see also 'Implementation of the Biosecurity Legislative Framework | Australian National Audit Office (ANAO)' <https://www.anao.gov.au/work/performance-audit/implementation-the-biosecurity-legislative-framework> accessed 9 December 2024.

[107] Ibid.; de Queiroz-Stein G and Siegel KM, 'Possibilities for Mainstreaming Biodiversity? Two Perspectives on the Concept of Bioeconomy' (2023) 17 Earth System Governance 100181; 'Integrating Socio-Economic

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5.3. Capacity Building in Taxonomic Expertise

It has rightly been pointed out that a prevalent theme in biodiversity and biosecurity goals is the apprehension over the proliferation of invasive alien species (IAS).[108] However, developing nations lack the capability to detect invasive alien species and compile inventories of their indigenous biodiversity to implement effective conservation strategies.[109] Thus, taxonomic expertise is essential for comprehending which aspects of biodiversity need conservation and protection, as well as for identifying invasive threats and biosecurity priorities, hence enhancing preparation levels.[110]

This would not only be important but also in line with the provisions of regulation 6 of the *Environmental Management and Co-ordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006*[111], which requires that "Within twenty-four months from commencement of these Regulations, the (National Environment Management) Authority shall, in consultation with the relevant lead agencies, identity and prepare an inventory of biological diversity of Kenya"[112]. The

Considerations into Biosafety Decisions: The Role of Public Participation | World Resources Institute' <https://www.wri.org/research/integrating-socio-economic-considerations-biosafety-decisions-0> accessed 9 December 2024; Marselle MR and others, 'Pathways Linking Biodiversity to Human Health: A Conceptual Framework' (2021) 150 Environment International 106420; Gupta, Himangana, and Pramod Singh. "Integrative and Adaptive Governance of Nature-Based Solutions to Achieve Triple Wins—Paris Agreement, Gbf and Un Agenda 2030." *Gbf and Un Agenda* 2030.

[108] Lum KengYeang, Lum KengYeang. "Preserving biodiversity, promoting biosecurity and biosafety: developing country perspectives." *Op. cit.*

[109] Ibid.

[110] Ibid.

[111] Environmental Management and Co-ordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006, Legal Notice No. 160 of 2006, Laws of Kenya.

[112] Ibid., Reg. 6(1).

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inventory should include threatened, endangered, or rare species.[113] The inventory should be maintained and updated every year thereafter by the Authority.[114]

Arguably, while these Regulations state that they shall not apply to-(a) the exchange of genetic resources, their derivative products, or the intangible components associated with them, carried out by members of any local Kenyan community amongst themselves and for their own consumption; (b) access to genetic resources derived from plant breeders in accordance with the Seeds and Plant Varieties Act, Cap. 326; (c) human genetic resources; and (d) approved research activities intended for educational purposes within recognized Kenyan academic and research institutions, which are governed by relevant intellectual property laws, the envisaged inventory would be very important as far as biodiversity conservation activities and maintaining their biosafety standards is concerned as well as taking stock of the indigenous biological diversity species.[115]

It is also important to note that regulation 4 thereof requires that no person should engage in any activity that may-(a) have an adverse impact on any ecosystem; (b) lead to the introduction of any exotic species; (c) lead to unsustainable use of natural resources, without an Environmental Impact Assessment Licence issued by the Authority under the Environmental Management and Co-ordination Act, 1999.

5.4. **Integrated and Multisectoral Approaches**

It has rightly been observed that biosecurity, in conjunction with biosafety, advocates for a strategic and comprehensive methodology that includes legislative and regulatory frameworks for assessing and mitigating pertinent hazards to human, animal, and plant

[113] Ibid., Reg. 6(2).
[114] Ibid., Reg. 6(3).
[115] See Reg. 3.

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health, as well as related environmental threats.[116] Nonetheless, the notion of addressing these hazards comprehensively has not been completely adopted by developing nations, where biosecurity is controlled on a sectoral basis, often with distinct policy and regulatory frameworks.[117]

As the government agencies responsible for biosafety as well as those responsible for biodiversity conservation and agricultural sector, they must consider developing frameworks that create synergies that ensure that biotechnology is adopted and utilised in a way that promotes biodiversity conservation. This will ensure that the indigenous knowledge is protected, food security and environmental conservation achieved. Communities, who are considered the main custodians of traditional and indigenous ecological knowledge must also be meaningfully included.

6. Conclusion

As discussed in this paper, biosafety involves handling biological materials, particularly germs, safely to avoid illness or poisoning. Biodiversity is essential to economic prosperity, yet overuse of natural resources is causing global biodiversity loss. The Convention on Biological Diversity protects biodiversity, promotes sustainable usage, and ensures genetic resource equality.

The paper also highlights the fact that African governments and nations must be prepared to discover and respond to bioterrorism and novel viral illnesses. Biosafety and biosecurity rules work to reduce biological dangers to a nation's health, security, and political and economic stability, whether intended or not. However, national, regional, and international biosafety and biosecurity are neglected.

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[116] Lum KengYeang, Lum KengYeang. "Preserving biodiversity, promoting biosecurity and biosafety: developing country perspectives." *Op.cit.*
[117] Ibid.

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As seen, the 2003 Cartagena Protocol on Biosafety addresses how GMOs harm the environment when transported, handled, and utilised responsibly. Living modified organisms (LMOs), made feasible by current biotechnology, pose hazards to biological variability. The Protocol has more rules about the types of information needed, how to assess risks using science, how to simplify the process, how to share information, how to keep private data safe, how to involve and inform the public, how to help developing countries get the skills they need, how to get money, and other paperwork, liability, remedies, and social and economic issues.

Finally, combining biosafety regulation with biodiversity conservation makes biosafety part of biodiversity conservation regulatory frameworks, which promotes sustainable development.

The National Biosafety Authority must educate the public about biosafety. Informational literature and other resources assist people understand biosafety. More opinions and information may improve decision-making. This may help consumers embrace new technology when national biosafety regulators have deemed them safe.

For true development and poverty reduction, laws and policies must safeguard biodiversity. It is also crucial to integrate biodiversity concerns in many policies, eliminate negative agricultural incentives, promote appropriate conservation and long-term usage incentives, and discuss biodiversity and biosafety problems in the correct forums.

It is thus important for government agencies responsible for biosafety, biodiversity, and agriculture to collaborate to ensure that biotechnology's use and acceptance safeguard biodiversity. This will safeguard traditional knowledge, food supplies, and the environment.

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Mainstreaming biodiversity conservation and biosafety for sustainable development is an imperative whose time is now.

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