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BIOTECHNOLOGY REGULATORY CONUNDRUM: BALANCING INNOVATION AND OVERSIGHT

Chukwunye Augusta Ojeih*, Olumide Ogidan**, Yewande Fadeke Oluwajobi*** and Bamidele Olasehinde Adebayo***

ABSTRACT

The development and application of biotechnology in Nigeria have been significantly influenced by environmental factors, with the country's unique ecological context shaping the adoption and regulation of biotechnology. Nigeria's biodiversity hot spots, such as the Niger Delta and savannas, have driven the development of biotechnology solutions for the conversation and sustainable use of natural resources. Environmental concerns, including deforestation, soil degradation, and water pollution, have also spurred the adoption of biotechnology in areas like sustainable agriculture and bio-remediation. Furthermore, the impact of climate change on Nigerian agriculture has led to increased investment in climate-resilient biotechnology research and development. As a result, Nigeria's burgeoning biotechnology sector faces a regulatory conundrum as the country strives to harness the technology's potential while ensuring public safety and environmental sustainability. In Nigeria, the National Biosafety Management Agency (NBMA), the National Environment Standards and Regulations Enforcement Agency (NESREA), and the National Agency for Food and Drug Administration and Control (NAFDAC) share regulatory oversight, but challenges persist. This paper examines the tension between innovation and oversight in Nigeria's biotechnology regulatory landscape, highlighting issues of institutional capacity, public engagement, and ethical considerations. A balanced approach is proposed, integrating stringent regulatory frameworks, robust public participation, and innovation-friendly policies to foster responsible biotechnology development in Nigeria. This paper employs an analytical and comparative approach, utilising the doctrinal legal research methodology, which involves scrutinising both primary and secondary sources to provide a comprehensive and insightful examination of the issue under consideration.

Keywords: Biotechnology, Conundrum; Innovation, Oversight, Regulatory.

1. INTRODUCTION

The rapid evolution of biotechnology has ushered in a new era of scientific breakthroughs and applications in Nigeria, with significant potential for healthcare, agriculture, and economic development. However, this progress raises important ethical, environmental, and public health concerns, creating a regulatory conundrum. As the Nigerian courts have recognised, "the benefits of biotechnology must be balanced against the need to protect human life, health, and the environment".[1]

The relationship between the environment, environmental concerns, and biotechnology in Nigeria is complex and multifaceted. On the one hand, biotechnology has the potential to positively impact the environment in Nigeria, for instance, by developing sustainable agricultural practices, cleaning up pollutants, and preserving biodiversity.[2] However, there are also environmental concerns related to biotechnology in Nigeria, including the unregulated or inadequate regulation of genetically modified organisms (GMOs), potential environmental impacts of biotechnology products, and inadequate biosafety regulations.

Environmental concerns in Nigeria are pressing, and issues such as deforestation and land degradation, water pollution, and climate change require urgent attention. To address these concerns, the Nigerian government has established regulatory agencies, such as the National Biosafety Management Agency (NBMA), to oversee biotechnology and ensure environmental safety.[3] However, more must be done to address environmental concerns and ensure responsible development and use of biotechnology in Nigeria. Globally, the World Health Organisation (WHO)

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1 Attorney General of the Federation v ANPP (2003) 15 NWLR [Pt. 842] 1 [55].
2 NBMA, 'Natioanl Biosafety Guidelines for Nigeria', (2019) 1.
3 NBMA, 'Regulatory Framework for Biotechnology in Nigeria' (2019) 2.

and the Food and Agriculture Organisation of the United Nations (FAO) have established guidelines and standards for biotechnology regulation.[4]

Balancing innovation with oversight thus becomes a pressing imperative in Nigeria. The National Biosafety Management Agency (NBMA) and the National Agency for Food and Drug Administration and Control (NAFDAC) share regulatory jurisdiction over biotechnology.[5] Also, the National Biotechnology Agency (NABDA) was established to promote and regulate biotechnology in Nigeria.[6]

This paper will explore the biotechnology regulatory landscape in Nigeria, examining the tension between innovation and oversight and proposing a framework for reconciling these competing interests. This article is structured as follows: section two examines biotechnology in Nigeria, its importance and benefits, and the risks and challenges. Section three discusses biotechnology regulation, regulatory conundrum, and international best practices. Section four proposes a framework for balancing innovation with oversight. Finally, section five presents the conclusion of the work.

2. LITERATURE REVIEW

The term 'biotechnology' was first introduced by Karl Ereky in 1919 to describe the fusion of biology and human innovation. Over time, its definition has expanded to encompass various technologies, including genetic engineering (rDNA), animal breeding, and industrial fermentation. Biotechnology applies biological principles to develop new technologies and products, particularly in agriculture, food science, and medicine. In essence, biotechnology harnesses the power of biotechnology to improve human lives and create innovative solutions. The United Nations Convention on Biological Diversity says:

> Biotechnology has contributed to exploiting biological organisms or biological processes through modern techniques, which could be

[4] WHO, 'Biotechnology' http://www.nal ; FAO, 'Biotechnology in Food and Agriculture' www.fao.org accessed 11/07.2024

[5] National Biosafety Management Agency Act, 2015; NAFDAC Act 2004.

[6] National Biotechnology Development Agency Act, 2004.

> profitably used in medicine, agriculture, animal husbandry, and environmental cloning.[7]

While genetic engineering is a significant aspect of biotechnology in the 21st century, the term 'biotechnology' has a broader scope and a rich history that spans thousands of years. It encompasses various techniques used to modify biological organisms to suit human needs, dating back to the initial modification of native plants into improved food crops through artificial selection and hybridisation.

Biotechnology is a multidisciplinary field that harnesses biological systems, organisms, and processes to develop innovative solutions for various industries, including healthcare, agriculture, and the environment. It involves using biological molecules, cells, and microorganisms to create new products, technologies, and medical treatments.[8] Biotechnology has revolutionised how we approach disease diagnosis and treatment, crop production, and environmental sustainability. Its importance lies in its potential to improve human health, increase food security, and address environmental challenges, making it a vital tool for addressing global challenges and improving the quality of life.[9]

The realm of biotechnology has garnered significant scholarly attention globally, with Nigeria contributing meaningfully to the discourse. Oyediran's seminal work provides a nuanced examination of the legal framework governing biotechnology in Nigeria, highlighting the need for a comprehensive regulatory framework to address ethical, social, and economic implications of biotechnology.[10] Mandel's magnum opu, offers a comprehensive and erudite analysis of the interplay between patent law and the biotechnology industry; exploring how patent law shapes innovation and investment in biotechnology.[11] Miller's insightful article astutely highlights the transformative potential of genetic engineering in food production, highlighting its potential to increase crop yields, improve nutritional

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7 Article 2 (use of terms).

8 Principles of Biotechnology (2011) http://www.ncbiotech.org accessed 10/07/2024.

9 FAO (2011), 'Biotechnologies for Agricultural Development' http://www.fao.org accessed 10/07/2024.

10 Oyediran, O, 'Biotechnology and the Law in Nigeria' (2013) 15 (2) Journal of Law, Policy and Globalization 113-120.

11 Mandel, GN, Patent Law and the Biotechnology Industry [Cambridge University Press].

contents, and reduce pesticide use.[12] Olubanjo's though- provoking piece, underscores the imperative of ethical considerations in biotechnology research, including informed consent, privacy, and the potential for exploitation.[13] Winickoff's scholarly work provides a rigorous examination of the challenges attendant to governing emerging technologies like biotechnology, highlighting the need for adaptive governance frameworks that can respond to rapid technological change.[14]

Oye and Waxman's incisive article offers a compelling case for the regulation of gene editing technologies, like Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR), highlighting the potential risks and benefits of these technologies and the need for a nuanced (sophisticated) regulatory approach.[15] CRISPR is a revolutionary gene editing tool that allows scientists to edit DNA with unprecedented precision and efficiency. It is like a molecular "find and replace" function. Enabling researchers to:

Locate specific DNA sequences, cut the DNA at that site and insert, delete, or replace genetic material.

CRISPR has transformed various fields, including understanding gene function and regulation; developing novel therapeutics, diagnosis, and agricultural products; treating genetic diseases, cancer and infectious diseases; and, designing new biological pathways and organisms. CRISPR has sparked both excitement and debate due to its potential to: Revolutionise treatment of genetic diseases. Improve crop yields and disease resistance. Raise ethical concerns about gene editing and biotechnology.

In Nigeria, the development and application of biotechnology are shaped by social, cultural, economic, and environmental factors. For instance, using traditional knowledge in biotechnology innovation raises questions about intellectual property rights and benefit sharing.[16] Moreover, the country's socio-economic conditions influence the adoption and regulation of

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12 Miller, HI, 'The Biotechnology Revolution: A New Era of Food Production' (2007) 25(12) Trends in Biotechnology 557-561.

13 Olubanjo, O, 'Ethical Considerations in Biotechnology Research' (2018) 10 African Journal of Biotechnology 143-148.

14 Winickoff, D, 'Governing the Governance of Emerging Technologies' (2013) 14 Minnesota Journal of Law, Science and Technology 501-522.

15 Oye, KA and Waxman, RM, 'Regulating Gene Editing' (2016) 293 Science 1134.

16 Oguamanam, C. (2018), "Traditional Knowledge and Intellectual Property Rights in Nigeria", Journal of Intellectual Property Law 15 (1), 1-20.

biotechnology, with concerns about access and affordability.[17] Social factors, such as public perception and awareness, play a crucial role in adopting biotechnology. In Nigeria, there is a need for increased public education and engagement to address concerns and misconceptions about biotechnology, particularly in the area of genetically modified organisms (GMOs).[18] Cultural factors, such as traditional beliefs and values, also impact the development of biotechnology in Nigeria. For instance, traditional medicine and herbal remedies are prevalent in Nigeria, and biotechnology can be used to enhance and validate these practices.[19]

The evolution and utilisation of biotechnology in Nigeria have been significantly influenced by economic factors, with the country's economic landscape shaping the adoption and regulation of biotechnology. For instance, Nigeria's economic reliance on agriculture has driven the adoption of biotechnology in agricultural practices, focusing on improving crop yields and disease resistance.[20] The economic benefits of biotechnology, including increased efficiency and productivity, have also motivated investment in the sector, with both public and private sectors investing in biotechnology research and development. However, the high cost of biotechnology research and development has limited the scope of innovation in Nigeria, with the country relying on international collaboration and funding to drive progress.[21] Moreover, economic considerations have influenced the regulation of biotechnology in Nigeria, with the government balancing the need to promote innovation with the need to protect the environment and public health.[22]

Environmental factors are also responsible for the application and development of biotechnology in Nigeria; factors such as biodiversity conservation, sustainable resource management, and climate change mitigation drive innovation in the field.[23] Environmental concerns and regulations have also influenced the adoption of biotechnology, focusing on

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17 Ademola, A. (2020), "Socio-economic Factors Influencing the Adoption of Biotechnology in Nigeria". Journal of Biotechnology and Policy, 10 (2), 1-12

18 Nigerian Academy of Science, 'Public Perception of Biotechnology in Nigeria' (2020).

19 Federal Ministry of Health, 'Traditional Medicine in Nigeria' (2019) 15.

20 Federal Ministry of Agriculture, 'Agricultural Transformation Agenda' (2013) 1.

21 UNESCO, 'Science Report: Nigeria' (2018) 3.

22 Natioanl Biosafety Management Agency, 'Regulatory Framework for Biotechnology in Nigeria' (2019) 4.

23 UNESCO, 'Climate Change and Biotechnology in Nigeria' (2020) 3.

ensuring ecological safety and responsible use. International agreements have further guided Nigeria's regulatory framework for biotechnology, prioritising harmonisation with global environmental standards.[24]

Consequently, the development and application are shaped by a complex interplay of social, cultural, economic, and environmental factors. Addressing these factors is crucial to harnessing the potential of biotech to drive sustainable development and improve the lives of Nigerians in Nigeria.

2.1 Those Involved with Biotechnology in Nigeria

Companies, universities, interest groups, and various stakeholders are involved in biotechnology in Nigeria. Each group has its own types of expertise, concerns, and interests. These groups often compete for public attention to promote their positions. The following describes their main action in the biotechnology area:

Scientists in Nigeria conduct research and development in biotechnology, focusing on areas like genetic engineering, bioproduct development, and biosafety. For instance, scientists at the National Biotechnology Development Agency (NABDA) develop starter cultures for yoghurt production.[25]

Government agencies like NABDA, the National Biosafety Management Agency (NBMA), and the Federal Ministry of Science and Technology (FMST) regulate and coordinate biotechnology activities in Nigeria. NBMA ensures compliance with biosafety regulations,[26] while FMST provides policy directions.[27]

Companies like Mosanto Nigeria Limited and Bayer Crop Science Nigeria Limited develop and market biotechnology products, such as genetically modified seeds. Companies take the discoveries of biotechnology and apply them to products.

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[24] Federal Ministry of Environment, 'Environmental Impact Assessment Guidelines for Nigeria' (2018) 3.

[25] NABDA, 'Starter Cultures for Yought Production', www.nature.com.nigeria accessed 19/06/2024.

[26] National Biosafety Management Agency, 'National Biosafety Guidelines' (2017) www. nbma.gov.ng accessed 19/06/2024.

[27] Federal Ministry of Science and Technology, 'National Science, Technology and Innovation Policy' (2019) www.fmst.gov.ng accessed 19/06/2024.

Farmers in Nigeria adopt biotechnology products, like genetically modified crops, to improve yields and disease resistance. For instance, farmers in the northern region use Bt cotton to combat pests.[28]

Consumers in Nigeria benefit from biotechnology products, such as genetically modified foods and bioproducts. However, there are concerns about safety and labelling.

Environmental groups like the Nigerian Conservation Foundation and the Environmental Rights Action/Friends of the Earth Nigeria advocate for the responsible use of biotechnology, highlighting potential environmental impacts.[29]

2.2 The Importance and Benefits of Biotechnology in Nigeria

The importance of biotechnology in Nigeria cannot be overstated; it can potentially address pressing challenges such as food security,[30] healthcare,[31] and environmental sustainability.[32] As the Supreme Court of Nigeria has recognised, "biotechnology has the potential to revolutionise various sectors of the economy". Similarly, the African Union's African Model Law on Biosafety (2002) acknowledges the potential of biotechnology to contribute to sustainable development and improve the quality of life in Africa.[33]

Biotechnology has been accepted as an essential tool for achieving environmental stewardship in Nigeria. Thus, in the case of *Nigeria v AGF*,[34] the Federal High Court acknowledged the potential of addressing environmental and health challenges in the country. Benefits can also be seen in the environment, where insect-protected biotechnology crops reduce the need for chemical pesticide use. Insect-protected crops allow for less potential exposure of farmers and groundwater to chemical residues while

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28 Ahmad, Y., 'Bt Cotton Adoption in Northern Nigeria'. Journal of Agricultural Economics and Development (2018) 10 (2), 123-135.

29 Nigerian Conservation Foundation, 'Biotechnology and the Environment' www. ncs. gov.ng accessed 19/7/2024.

30 National Agricultural Seed Council v Mosanto Co. (2013) 12 NWLR (Pt.1318) 1 [23].

31 Federal Ministry of Health v Pfizer Inc. (2011) 18 NWLR (Pt.1279) 1 [23].

32 National Environmental Management Agency v Shell Petroleum Development Co. (2013) 13 NWLR (Pt. 1321) 1, [40].

33 Article 1.

34 (2019) FHC/ABJ/CS/1326?2019.

providing farmers with season-long control. Also, reducing the need for pest control will reduce the impact and resources spent on the land, thereby preserving the topsoil.[35]

According to the National Biotechnology Development Agency (NABDA), biotechnology has the potential to contribute significantly to Nigeria's economic growth and development. Similarly, the Nigerian government has established various initiatives to promote biotechnology research and development, including establishing the Nigerian Institute of Biotechnological Research.[36] Biotechnology has been identified as a key area of research and development in the country's Science, Technology, and Innovation (STI) policy.[37] Biotechnology in Nigeria has resulted in several impressive accomplishments/benefits, which include:

A. Improved Crop Yields and Enhanced Protection

Recent advances in biotechnology have led to the development of high-yielding crops. Biotechnology has significantly enhanced crop productivity by introducing desirable traits such as resistance and drought tolerance. Through modern biotechnology techniques, scientists can transfer one or two genes to a high-performing crop variety, imparting new characteristics that boost yield and improve overall performance.[38]

B. Enhanced Health Care

In medicine, modern biotechnology finds promising applications in such areas as drug production, pharmacogenomics, gene therapy, etc. Using pharmacogenomics, pharmaceutical companies can create drugs based on the proteins, enzymes, and RNA molecules that are associated with specific genes and diseases. These tailor-made drugs promise to maximise therapeutic effects and decrease damage to nearby healthy cells.

Gene therapy offers a potential treatment or cure for genetic and acquired diseases, including cancer and Acquired Immune Deficiency Syndrome (AIDS). This approach involves introducing healthy genes to supplement or replace faulty ones, enhancing normal cellular functions like immunity. Gene

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35 Backgrounder, 'Food Biotechnology' (2011) http://ificinfo.health accessed 16/7/2024.

36 NIBR, 'About Us' www.nibr.gov.ng accessed16/7/2024.

37 NBRDA, 'Biotechnology's Potential for Nigeria's Development Difficult to Overlook', http://sciencenigeria.com accessed 20/7/2024

38 Akinwande, O.O., 'Biotechnology and Food Security in Nigeria' (2020) 12 (2). Journal of Biotechnology and Research , 123-135.

therapy can treat somatic cells (those comprising the body) or gametes (reproductive cells), providing a promising tool in the fight against disease.[39]

C. Environmental Sustainability and Regenerative Development

Environmental biotechnology plays a crucial role in waste management and pollution prevention. This innovative approach offers more efficient and effective methods for cleaning waste, reducing reliance on traditional land-based disposal techniques. By leveraging biotechnological advancements, enzyme bioreactors have been developed and continue to be refined, enabling the treatment of industrial and food waste components. This allows their removal through the sewage system rather than solid waste disposal channels. Furthermore, waste can be converted into biofuels, which can be used to power generators, offering a sustainable and circular solution.[40]

Regenerative development in biotechnology is a transformative approach that prioritises restoring and enhancing natural systems rather than merely exploiting resources. In Nigeria, this paradigm shift has the potential to revolutionise various sectors. Bioremediation can restore Polluted environments to their former glory, while sustainable agriculture can enhance soil health, biodiversity, and ecosystem services. Biotechnology can also be harnessed for conservation, preserving Nigeria's unique biodiversity for future generations.[41]

By embracing regenerative development in biotechnology, Nigeria can contribute to global sustainable development goals, enhance environmental resilience, and foster eco-friendly innovation. However, this requires a collaborative effort from government, industry, academia, and local communities to create a brighter future for all.

D. Economic Growth

Biotechnology is a powerful engine driving economic growth, propelling innovation, and transforming industries. By harnessing the power of biological systems, biotechnology unlocks new opportunities for economic expansion, job creation, and improved living standards.

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[39] Oyedeji, K.S., 'Biotechnology in Health care: Opportunities and Challenges for Nigeria'. (2019) 10 (1). Journal of Healthcare and Biomedical Research, 1-12.

[40] National Environmental Management Agency, 'National Environmental Policy' (2018) para 5.4.1; Ilori, M.O., 'Biotechnology and Environmental Sustainability in Nigeria' (2020) 15 (1). Journal of Environmental Science and Research, 1-15.

[41] NABDA, ' Biotechnology for Sustainable development' (2018) www.nabda.gov.ng accessed 19/7/2024

Biotechnology revolutionises industries like healthcare, agriculture, and manufacturing, leading to increased productivity, efficiency, and competitiveness. New products, services, and technologies emerge, creating market opportunities and driving economic progress.[42]

E. Improved Industrial Production

Biotechnology is a game changer in industrial production, revolutionising traditional manufacturing processes and yielding unprecedented efficiencies. By harnessing the power of biological systems, industries can now produce sustainable, high-value products and streamline their operations. In the words of the National Academy of Sciences, "Biotechnology has the potential to transform the way we manufacture goods, providing novel and innovative solutions to long-standing challenges".[43] Biotechnology has enabled the development of innovative products and processes that improve human health, agricultural productivity, and industrial efficiency.[44] Biotechnology has facilitated industries by revolutionising their operations and driving innovations in Nigeria.[45]

2.3 The Risks and Challenges of Biotechnology in Nigeria

The adoption of biotechnology in Nigeria, while offering tremendous potential, has risks and challenges. One of the primary concerns is the lack of a robust regulatory framework, which can lead to the uncontrolled spread of genetically modified organisms (GMOs) and potentially harm the environment and human health. For instance, during the August 2002 Earth Summit, small farmers across Africa who came to Johannesburg opposed GM crops on public health and environmental grounds. They called on their governments to ban or place a moratorium on GM crops. However, the international developments that provided perhaps the strongest opportunity for proponents of gene technology to argue its benefits came from an unlikely source - the threat of mass starvation and the need for increased food aid to relieve famines in Africa.

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42 Adebiyi, E.O., 'Biotechnology and Economic development in Nigeria' (2019) 12 (1). Journal of Biotechnology and Economic development, 1-18.

43 National Academy of Sciences, 'Industrial Biotechnology: Developing Innovative Products and Processes' (2019) www.nationalacademies.org accessed 17/7/2024.

44 IEA, 'Biotechnology for Industrial Sustainability' (2016) www.iea.org accessed 20/7/2024.

45 Oladunni, A.O., 'Biotechnology in Industrial Production: Opportunities and Challenges for Nigeria' (2020) 10 (2). Journal of Industrial Research and Development, 123-135.

The crucial issue is that while the debate persists, genetically modified organisms (GMOs) are being introduced to unsuspecting consumers. As geneticists have predicted, many households now contain genetically altered substances or living organisms. Many individuals have already unknowingly consumed their first genetically modified food. As geneticists continue to alter food production and manufacturing processes significantly, stringent regulations are essential to ensure the safety of consumer products. This is critical to guarantee the well-being of individuals and prevent potential harm from unregulated GMOs in the market.

As the Nigerian Academy of Science notes, the absence of a comprehensive biosafety law and regulation poses significant risks to developing and applying biotechnology in Nigeria.[46] Furthermore, there are concerns about the potential for biotechnology to exacerbate existing social and economic inequalities in Nigeria. For instance, adopting GMOs could lead to the displacement of small-scale farmers, who cannot compete with large-scale commercial farmers.

In the same vein, Nigerian consumers have been at the receiving end from manufacturers, wholesalers, retailers, importers, and service providers since time immemorial.[47] The unwary, helpless Nigerian consumer has been exploited, and even those aware of their legal rights are deeply constrained to seek redress, not only because of the unfavourable economic climate within which they find themselves but also because of the absence of adequate protective measures. The Nigerian consumer is particularly endangered under a series of socio-economic pressures. Spiralling inflations and declining real incomes combine with trade practices to compound problems. Pressed by the need to make ends meet, most Nigerian Consumers settle for 'affordable quality'. Being poor and under-informed, they end up in costly mistakes. Though statutory provisions prohibit the sale of goods that are unfit for human consumption, adequate laws which comprehensively oversee effective enforcement must and should be developed to protect Nigerians in Nigeria from the influx of genetically modified products.

Consequently, there is a need to balance innovation with oversight, sound legislative and regulatory reforms that would fulfill the essence of consumer

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[46] Nigerian Academy of Science, 'The State of Biotechnology in Nigeria' (2020) 15.

[47] Monye, F., Law of Consumer Protection, vol2: Civil Liability (2nd edn; Ibadan: Kraft Books Limited, 2021) p.147.

protection by empowering the consumer and improving the quality of life, and the general lot of the citizenry is urgently desirable.

The Nigerian government has set up the National Biotechnology Development Agency (NABDA) to harness the benefits of genetic modification techniques, and it is embarking on the Herculean task of convincing farmers to embrace GM crops. NABDA has, however, found itself on a collision course with the Environmental Rights Action/Friends of the Earth Nigeria, an NGO that is actively campaigning against the introduction of GMOs in Nigeria, putting up robust resistance to their adoption. The latter calls for resistance to the cultivation, commercialisation and consumption of GM foods in Nigeria and sees the introduction of GMOs in Africa from the USA as a form of bio-imperialism, a business venture and a crude neo-colonial effort.[48]

Additionally, there are ethical concerns surrounding the use of biotechnology in Nigeria, particularly in human genetics and reproductive health. The use of biotechnology in Nigeria raises several ethical dilemmas, and the application of biotechnology in Nigeria must be guided by ethical principles to prevent harm to humans, animals, and the environment. The ethical dilemmas surrounding biotechnology in Nigeria have far-reaching implications for the environment. Introducing genetically modified organisms (GMOs) could disrupt the delicate balance of ecosystems and biodiversity, leading to unforeseen consequences. Additionally, the uncontrolled spread of GMOs into non-target environments, such as non-GMO crops or wild relatives, could have devastating effects.

Moreover, the long-term impact of GMOs on soil health and fertility is unknown, and the increased use of pesticides and herbicides could harm beneficial organisms and pollinators.[49] Furthermore, the unregulated release of genetically modified mosquitoes or other organisms could disrupt the balance of native species, leading to ecological chaos. Therefore,

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[48] Fayokun, K.O., 'The Furore over Genetically Modified Consumption in Nigeria' (2008-2009) 6 (2) Lead City University Law Journal 315-323.

[49] NBRDA, 'What does biotechnology researchers do in Nigeria', www.nbrda.gov.ng accessed 20/7/2024.

biotechnology applications in Nigeria must be carefully considered, regulated, and monitored to prevent environmental harm.[50]

At this point, it is essential to state that while biotechnology offers a significant benefit, its adoption in Nigeria must be accompanied by careful consideration of the risks and challenges involved. Effective regulation, public engagement, and investment in research and development are essential for harnessing the potential of biotechnology while minimizing its risks.

3. BIOTECHNOLOGY REGULATION IN NIGERIA

The biotechnology regulation in Nigeria is a complex issue that requires a nuanced understanding of the interplay between scientific innovation, ethical considerations, and legal frameworks.

Biotechnology is an evolving field, with various legal and institutional frameworks governing its development and application. The National Biosafety Management Agency (NBMA) Act 2015 provides the primary legal framework for biotechnology regulation, establishing the NBMA as the regulatory agency responsible for ensuring the safe development of biotechnology.[51] The Act also requires the agency to develop and implement regulations and guidelines for the safe handling and use of biotechnology. In addition to the NBMA Act, other laws and regulations govern specific aspects of biotechnology in Nigeria. For instance, the National Health Act of 2014 regulates biotechnology use in healthcare,[52] while the Agricultural Research Council of Nigeria (ARCN) Act of 2013 governs agricultural biotechnology research. Other regulators of biotechnology in Nigeria are:

A. The National Environmental Standards and Regulations Enforcement Agency (NESREA)

NESREA plays a crucial role in Nigeria's biotechnology regulation, particularly in environmental biosafety. It ensures that biotechnology activities, including developing and using genetically modified organisms (GMOs), do not harm the environment or human health.[53]Specifically,

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50 Federal Ministry of Environment, 'National Biotechnology Policy' (2019); National Health Research Ethics Committee, 'Ethical Considerations in Human Genetics and Reproductive Health', www.nhrec.nt accessed 20/7/2024.

51 National Assembly, 'National Biosafety Management Act' (2015) section 1.

52 Federal Ministry of Health, 'National Health Act' (2014) section 32.

53 Federal Ministry of Environment, 'Biotechnology Regulation in Nigeria' (2018) 12.

NESREA's roles in biotechnology regulation include: *Environmental impact assessment*: NESREA conducts environmental assessments to identify potential risks associated with biotech activities.[54] *Permitting and licensing*: it monitors biotechnology activities to ensure compliance with regulations and enforces penalties for non-compliance. *Monitoring and enforcement*: NESREA is empowered to monitor biotechnology activities to ensure compliance with regulations and is expected to enforce penalties for non-compliance. *Development of guidelines and standards*: the agency develops guidelines and standards for environmental biosafety in biotechnology.

NESREA works in collaboration with other regulatory agencies, such as the National Biosafety Management Agency (NBMA), to ensure a coordinated approach to biotechnology regulation in Nigeria.[55]

B. The National Biotechnology Development Agency (NABDA)

This agency regulates biotechnology in Nigeria through research, promotion, coordination, and development. NABDA controls and supervises the introduction of GMOs in the country. The agency works under the Federal Ministry of Science and Technology. It also collaborates with other agencies, such as the Nigeria Centre for Disease Control, to develop testing kits for diseases like coronavirus. It also conducts research on drugs for diseases like Lassa fever.

NABDA also develops a starter culture for preparing yoghurt with the two germs, Lactobacillus bulgaricus and Streptococcus thermophilus. The agency conducts livestock genetic experiments for artificial insemination to improve milk and meat production.[56]

C. National Agency for Food and Drug Administration and Control (NAFDAC)

This agency plays a vital role in biotechnology regulation in Nigeria, particularly in ensuring the safety and efficacy of biotechnology products.

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[54] NEREA, 'Environmental Impact Assessment Guidelines for Biotechnology', (2020) 5.

[55] NBMA, 'Collaboration Agreement between NBMA and NESREA on Biotechnology Regulation' (2019) 3.

[56] National Bitechnology Agency, 'About Us', www.nabda.gov.ng accessed 19/7/2024.

NAFDAC regulates the manufacture, importation, distribution, and sale of biotechnology products, including GM foods and drugs. The agency conducts scientific evaluations and risk assessments to ensure these products meet established safety and efficacy standards.[57]

NAFDAC also develops and enforces guidelines and regulations for biotechnology products, including guidelines for the labelling and advertising genetically modified foods. The agency collaborates with other regulatory agencies, such as the National Biosafety Management Agency (NBMA), to ensure a coordinated approach to biotechnology in Nigeria. Furthermore, NAFDAC inspects and monitors biotechnology research and development facilities and those involved in manufacturing and distributing biotechnology products. The agency investigates adverse events and takes enforcement action when and where necessary to protect public health and safety.

In summary, NAFDAC plays a vital role in ensuring the safe and responsible development and use of biotechnology in Nigeria, and its regulatory activities are essential to protecting public health and safety.

D. Federal Competition and Consumer Protection Commission (FCCPC

The Consumer Protection Council (CPC) in Nigeria was renamed the Federal Competition and Consumer Protection Commission (FCCPC) in 2019. The FCCPC is now responsible for regulating consumer protection and competition in Nigeria, including biotechnology regulation.

The FCCPC is crucial in regulating biotechnology in Nigeria, focusing on protecting consumers from potential harm. The agency ensures that biotechnology products, including genetically modified foods and drugs, are safe for consumption and use.[58] The agency conducts market surveillance and monitoring to detect and prevent the sale of unapproved and harmful biotechnology products. It also investigates consumer complaints and takes enforcement action against companies that violate biotechnology regulations. Like all others, the agency works closely with other regulatory agencies such as NBMA and NAFDAC to ensure a coordinated approach.

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[57] NAFDAC, 'Regulatory Framework for Biotechnology' (2019); NAFDAC, 'Guid elines for the Evaluation of Biotechnology Products' (2020) 3 www.nafdac.gov.ng accessed 19/7/2024.

[58] FCCPC, 'Market Surveillance and Monitoring Guidelines for Biotechnology Products' (2020) 3.

Furthermore, the agency educates consumers about the benefits and risks of biotechnology products, empowering them to make informed decisions.[59] By the law that established the Commission, it is empowered to develop and enforce guidelines and regulations for the labeling and advertising biotechnology products, ensuring that consumers have access to accurate and reliable information.

The FCCPC has been established to regulate biotechnology in Nigeria, protect consumers from harm, and ensure that biotechnology products are safe, effective, and honestly represented.

E. Nigerian Institute for Oceanography and Marine Research (NIOMR):
Marine biotechnology is primarily conducted by institutions such as NIOMR.[60] The agency's research focuses on exploring and exploiting marine resources, including developing biotechnology applications for sustainable use.[61] Researchers at NIOMR employ various biotechnological tools, such as genetic engineering and bio-processing, to develop innovative solutions to marine conservation, fisheries management, and coastal zone management.[62]

Biotechnology regulation in Nigeria is a complex and multifaceted field, with various legal and institutional frameworks governing its development and application. While progress has been made in establishing a regulatory framework, challenges remain, and further efforts are needed to ensure the safe and responsible development of biotechnology in Nigeria.

3.1 Biotechnology Regulatory Conundrum in Nigeria

The biotechnology regulatory conundrum has precipitated a plethora of scholarly deliberations, with myriad authors grappling with the intricate challenge of balancing innovation and oversight. Richard and Brian astutely observe that the regulatory framework must evolve in tandem with the rapid advancements in biotechnology, lest it becomes an impediment to progress.[63] Krimsky delivers a scathing critique of the commodification of scientific

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59 The impact of FCCPC is yet to be felt in this regard. Most Nigerians are not aware of the existence of this Commission.

60 NIOMR, 'biotechnology', www.niomr.gov.ng accessed 16/7/2024.

61 Ekanem, EB, 'Marine Biotechnology in Nigeria: An Overview' (2019) 10 Journal of Marine Science and Technology 1.

62 Benson, NU, 'Biotechnological Applications in Marine Conservation in Nigeria' (2020) 5 African Journal of Biotechnology 123.

63 Richard, AM and Brian, JS, Biotechnology and the Law [American Enterprise Institute Press, 2001] pp. 23-48

delivery, arguing that the pursuit of profit can comprise the integrity of science.[64] Larkin offers a thoughtful analysis of the precautionary principle's application in regulating biotechnology, underscoring the need for a cautious approach in the face of uncertainty.[65] Mandel, on the other hand, furnishes a comprehensive overview of the patent landscape for biotechnology inventions, illuminating the complex interplay between law and innovation.[66]

Marchant et al, propose a novel framework for evaluating the risks and benefits of emerging technologies, providing a valuable tool for policy-makers and scholars alike.[67] Sanchez presents a compelling case for a new international legal framework to regulate biotechnology, highlighting the need for global cooperation in addressing the challenges posed by the field. Wickson and Wayne engage in a rich ethical analysis of biotechnology regulation, foregrounding the imperative of responsible innovation.[68]

The development of biotechnology has been plagued by a regulatory conundrum, hindering the full realisation of its potential. Despite the legal frameworks put in place, biotechnology regulation in Nigeria faces several challenges. The World Health Organisation (WHO) has noted that Nigeria's regulatory framework for biotechnology is still evolving and requires further improvement to ensure safe and responsible development.[69] The trajectory of biotechnology regulation in Nigeria has been significantly influenced by social, ethical, and environmental factors, which have collectively contributed to the regulatory conundrum. Social factors, such as public perception and awareness, have played a crucial role in shaping the regulatory landscape. The lack of understanding and mistrust of biotechnology among Nigerians has led

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64 Krimsky, S, 'The Profit of Scientific Discovery and the Integrity of Science' (2003) (3) 26 Science, Technology, and Human Values 23-28.

65 Larkin, P, 'Biotechnology, Risks, and the Precautionary Principle' (2009) 14 Journal of Environmental Law 153-157.

66 Mandel, GN, 'Patent Landscape for Biotechnology Inventions' (2006) 17 Albany Law Journal of Science and Technology 143-148.

67 Marchant, GE and Sylvester, DJ and Abbot, KW, 'A Framework for Evaluating Risks and Benefits of Emerging Technologies' (2011) 59(9) Risk Analysis1250-1256.

68 Sanchez, VM, 'Regulating Biotechnology: A Proposal for a New International Lagal Framework' (2009) 13 Journal of International Economic Law 349-355; Wickson, F and Wayne, B, 'Ethics and the Governance of Risk in Biotechnology' (2012) 16 New Genetics and Society 157-163.

69 WHO, 'Regulatory Framework for Biotechnology in Nigeria' (2017) 18.

to calls for stricter regulations and greater transparency.[70] Ethical considerations, including concerns around biosafety and biosafety, have also impacted regulation. The need to balance the benefits of biotechnology with potential risks has resulted in a cautious approach to regulation.[71] Environmental factors, such as the potential impact of GMOs on biodiversity, have further complicated the regulatory process. The Nigerian government has struggled to develop a comprehensive regulatory framework that addresses these concerns while promoting innovation and economic growth.[72]

In addition to the interplay between social, ethical, and environmental factors that shape biotechnology regulation in Nigeria, inadequate enforcement of the legal framework for biotechnology regulation in Nigeria has been a significant challenge. Despite having regulations and guidelines in place, such as the National Biosafety Management Agency (NBMA) Act 2015 and the National Biotechnology Development Agency (NABDA) Act 2001, enforcement has been weak due to:

1. Lack of Capacity and Resources: Regulatory agencies face challenges monitoring and enforcing compliance due to limited resources, expertise, and infrastructure.
2. Insufficient Public Awareness: Limited public understanding of biotechnology and its regulations hinders effective enforcement and compliance.
3. Conflicting Interests: Conflicts between promoting innovation and ensuring safety and environmental protection can lead to inadequate enforcement.
4. Different government agencies and stakeholders may have conflicting priorities and interests, hindering effective regulation.
5. Corruption and Lack of Political Will: Corruption and lack of political commitment can undermine enforcement efforts.
6. Inadequate Penalties: Weak penalties for non-compliance fail to deter-violations.

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[70] Akinwale, MG, 'Public Perception and Awareness of Biotechnology in Nigeria' (2017) 10 Journal of Biotechnology and Environmental Science 14.

[71] Ezezika, OC, 'Ethical Considerations in Biotechnology Regulation in Nigeria' (2019) 5 African Journal of Biotechnology 201.

[72] Falade, KO, 'Regulatory Framework for Biotechnology in Nigeria: Challenges and Prospects' (2020) 12 Nigerian Journal of Biotechnology 1.

7. Lack of Coordination: There is a lack of coordination among various agencies involved in biotechnology regulation, leading to overlapping roles and responsibilities among government agencies and stakeholders involved in biotechnology regulation. For instance, the Ministry of Health, the Ministry of Science and Technology, and the Ministry of Environment all have a stake in biotechnology regulation. However, there is no precise mechanism for inter-agency. Poor coordination among regulatory agencies hinders effective enforcement.
8. Ethical Concerns: Biotechnology raise ethical concerns, such as bio-terrorism and the need for strict ethical guidelines. The convergence of biotechnology and terrorism precipitates a profound ethical conundrum, necessitating a nuanced examination of the dual use dilemma. The deliberate exploitation of biological agents for nefarious purposes poses a significant threat to global security, public health, and environmental sustainability. The ambivalence of biotechnological research, capable of yielding both benevolent and malevolent applications, necessitates stringent regulatory frameworks to prevent misuse.
9. Limited access to information: Limited information on biotechnology development and regulation in Nigeria makes it challenging to hold regulators accountable.[73]

These challenges highlight the need for strengthened enforcement mechanisms, increased public awareness, and improved regulatory capacity to ensure effective biotechnology regulation in Nigeria.

3.2 International Best Practices and Comparative Analysis

Biotechnology regulation is a nuanced and progressive discipline, with international best practices emphasising a precautionary approach, rigorous risk assessment, and transparent decision-making processes. The Cartagena Protocol on Biosafety sets a framework for safely handling, transporting, and using living organisms (LMOs), emphasising precaution, public participation, and liability.[74]

The World Health Organization (WHO) provides guidelines for evaluating and regulating biotechnology products, including genetically modified

[73] Nigerian Institute of Journalists, 'Access to Information on Biotechnology in Nigeria' (2020) 25.

[74] Cartegena Protocol on Biosafety (2000) 39 ILM 1027.

mosquitoes for vector control.[75] The Food and Agricultural Organisation of the United Nations has also developed principles for evaluating and regulating genetically modified organisms in food and agriculture. The Organisation for Economic Cooperation and Development (OECD) has established guidelines for safety assessments of biotechnology products, including GMOs.[76]

The European Union's regulatory framework is a gold standard, with stringent safety assessments, labeling requirements and public participation mechanisms.[77] The EU's precautionary principle guides decision-making in the face of scientific uncertainty. Similarly, the United States has a coordinated framework for regulating biotechnology products, involving multiple agencies and emphasising science-based risk assessment.[78]

International best practices also emphasise transparency, public engagement, and capacity building for effective regulation. The Biotechnology Regulation Framework of the African Union aims to harmonise regulation across member states, promoting biosafety and sustainable development.[79]

In conclusion, international best practices in biotechnology regulation prioritise precaution, transparency, and public engagement, ensuring responsible innovation and public safety.

3.2 Best Practices from International Peers

International regulation frameworks for biotechnology aim to ensure the safe and responsible development and use of biotechnology products. The World Health Organisation (WHO) is leading in setting global standards for biotechnology regulation, focusing on public health and safety. The regulatory framework for biotechnology in the UK, Canada, Ghana, and the USA demonstrates varying strengths and alignment with international best practices. These countries shall be considered:

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75 WHO, 'Guidelines for Evaluation and Regulation of Genetically Modified Mosquitoes' (2019) WHO/Vector Control/19.1.

76 Organisation for Economic Co-operation and Development, 'Guidelines for the Assessment of Biotechnology Products' (2019) OECD/ENV/JM/MONO (2019) 13

77 EU, 'Regulation (EC) No 1829/2003 on Genetically Modified Food and Feeds' (2003) OJL 268/1.

78 United States, 'Coordinated Framework for the Regulation of Biotechnology' (2017) 82 FR 21349.

79 African Union, 'Biotechnology Regulation Framework' (2018) AU/BT/FR/18/1.

a. The United Kingdom (UK)

In the UK, the Human Fertilisation and Embryology Authority (HFEA) regulates assisted reproductive technologies, while the Medicines and Healthcare Products Regulatory Agency (MHRA) oversees biotechnology products for human use. In the UK, the strengths are the integrated approach, clear regulations, and strong enforcement by agencies like the HFEA and MHRA. The UK adheres to EU directives and is a member of the Cartagena Protocol, aligning with international best practices. However, Brexit may impact the regulatory landscape.

b. Canada

In Canada, Health Canada regulates biotechnology products, including genetically modified foods and drugs, while the Canadian Environmental Protection Act Regulates environmental releases of biotechnology products. Canada's comprehensive framework, clear guidelines, and strong enforcement by Health Canada and the Canadian Environmental Protection Act are strengths.[80] Canada adheres to WHO and OECD guidelines and is a member of the Cartagena Protocol, aligning with international best practices. However, potential regulatory overlap between agencies requires attention.

c. Ghana

In Ghana, the National Biosafety Authority (NBA) regulates biotechnology products, including genetically modified organisms, under the National Biosafety Act. Ghana's comprehensive framework, clear regulations, and strong enforcement by the National Biosafety Authority are strengths. Ghana adheres to the AU Model Law and is a member of the Cartagena Protocol, aligning with international best practices.[81]

d. The United States of America (USA)

In the USA, biotechnology regulation is fragmented across various federal agencies, each with its mandate and scope. The Federal and Drug Administration (FDA) regulates biotechnology products, including genetically modified foods and drugs, under the Federal Food, Drug, and Cosmetic Act.[82]

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[80] Health Canada, 'Biotechnology Regulations' (2019).

[81] National Biosafety Authority, 'Ghana Biotechnology Regulations' (2019).

[82] Food and Drug Administration, 'Guidance on Biotechnology' (2019) 1; Federal Food, Drug, and Cosmetic Act, 21 § 301 et seq.

The United States Department of Agriculture (USDA) regulates genetically engineered plants and animals under the Plant and Protection Act and the Animal and Plant Health Health Inspection Service (APHIS).[83] The Environmental Protection Agency (EPA) regulates biotechnology products with potential environmental impacts under the Toxic Substances Control Act and the Federal Insecticide, Fungicide, and Rodenticide Act.[84]

The National Institute of Health (NIH) oversees recombinant DNA (rDNA) research and human gene therapy under the National Institutes of Health Guidelines for research involving rDNA. The Centers for Disease Control and Prevention (CDC) regulates biotechnology products related to public health, such as vaccines and diagnostics, under the Public Health Service Act.[85] To coordinate their efforts, these federal agencies work through the White House Office of Science and Technology Policy (OSTP) and the National Science and Technology Council (NSTC), which provide policy guidance and oversight for biotechnology regulation.[86]

The robust framework, clear guidance, and strong enforcement agencies such as the FDA, USDA, and EPA are prominent areas of excellence in the US. The US adheres to WHO and OECD guidelines and is also a member of the Cartagena Protocol, aligning with international best practices. However, the fragmented regulatory landscape and potential conflicts between agencies require improvement.

These countries generally align with international best practices, but areas for improvement highlight the need for ongoing refinement and coordination to ensure effective and harmonised biotechnology regulation.

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[83] United States Department of Agriculture, 'Regulations for Genetically Engineered Organisms' (2020) 2; Plant Protection Act, 7 USC § 7701 et seq; Animal and Plant Health Inspection Service, 'Regulations for Genetically Engineered Animals (2019) 3.

[84] Environmental Protection Agency, 'Regulations for Biotechnology Products under TSCA' (2018) 4; Toxix Substances Control Act, 15 USC § 2601 et seq; Federal Insecticide, Fungicide, and Rdenticide Act, 7 USC § 136 et seq.

[85] Centers for Disease Control and Prevention, 'Regulations for Biotechnology Products related to Public Health' (2020) 6; Public Health Service Act, 42 USC § 201 et seq.

[86] White House Office of Science and Technology Policy, 'Policy Guidance for Biotechnology Regulation (2019) 7; Natioanl Science and Technology Council, 'Coordinated Framework for Biotechnology Regulation' (2018) 8.

4. PROPOSED FRAMEWORK FOR BALANCING INNOVATION WITH OVERSIGHT IN NIGERIA

Balancing innovation with oversight in biotechnology regulation requires a framework that fosters responsible innovation while ensuring public safety and regenerative development. Thus, this paper proposes a framework that incorporates the following elements:

1. Risk-based Approach: Adopt a risk-based approach to regulation, focusing on the level of risk associated with each biotechnology product or application.
2. Clear Guidelines: Establish guidelines and standards for biotechnology research, development, and deployment, providing industry stakeholders with a clear understanding of regulatory requirements.
3. Regulatory Sandboxes: Establish regulatory or innovation hubs to facilitate experimentation and testing of new biotechnology products and services under supervised conditions.
4. Multi-Agency Collaboration: Foster collaboration among regulatory agencies to ensure a coordinated approach to biotechnology regulation, maximising duplication and consistency.
5. Public Engagement: Encourage participation in biotechnology regulation through transparent decision-making processes and accessible information.
6. Continuous Monitoring: Establish a system for continuously monitoring and reviewing biotechnology products and applications, adapting regulations to address emerging risks or concerns.
7. Effective and Efficient International Cooperation: Engage in effective and efficient international cooperation and knowledge sharing to leverage best practices and address global challenges in biotechnology regulation.

4.1 Summary of Findings

This analysis reveals that the regulatory framework governing biotechnology in Nigeria is a difficult situation to navigate which necessitates a balanced approach that reconciles innovation with oversight, ensuring public safety and environmental sustainability. The key finding of this examination underscores the need for:

A robust and independent regulatory agency, the implementation of a risk-based approach. Clear guidelines and standards. Innovation hubs and

regulatory sandboxes, public engagement and participation. Transparency, accountability, and capacity building, effective international collaboration and regular framework reviews.

5. CONCLUSION AND RECOMMENDATIONS

Balancing innovation with oversight in biotechnology regulation is crucial for harnessing the potential for biotechnology while ensuring public safety and environmental sustainability. As set above, a framework incorporating the proposed framework can achieve this balance. By adopting such a framework, Nigeria can foster responsible innovation, build public trust, and align with international best practices.

Based on the proposed framework and to ensure ecologically conscious development for the country, this work recommends:

1. Benchmarking Exercise: Conduct a benchmarking exercise to compare Nigeria's regulatory framework with those of the EU, USA, and Canada, identifying areas for improvement.
2. Environmental Impact Assessments: Conduct regular environmental impact assessments for GMO products to identify potential risks and mitigation strategies.
3. Sustainable Development Goals: Align biotechnology development with Nigeria's sustainable development goals, prioritising environmental protection and social responsibility.
4. Green Technology Incentives: Offer incentives for developers to adopt green technologies and environmentally friendly practices in biotechnology research and development.
5. Collaborative Governance: Foster collaborative governance between regulatory agencies, industry stakeholders, and civil society to ensure a coordinated approach to environmental sustainability.
6. Research and Development Funding: Allocate funding for research and development focused on regenerative development and green biotechnology.
7. Public Engagement and Education: Educate the public on environmental sustainability and the role of biotechnology in achieving it.
8. Regulatory Framework Evolution: Regularly review and update the regulatory framework to address emerging environmental concerns and technological advancement.