COMMERCIALISATION OF BIOTECH INVENTIONS AND SUSTAINABLE DEVELOPMENT GOAL: TOWARD A COHERENT POLICY FRAMEWORK

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ABSTRACT

While the commercialization of biotechnological inventions opens up valuable opportunities, it also brings complex legal, ethical and socio-economic challenges. In this paper the researcher seeks to highlight concerns related to the harmonization of technical standards, environmental sustainability, public health implications, ethical issues associated with genetic manipulation, equitable benefit sharing of genetic resources, socio-economic impacts on smallholder farmers and the likelihood of concentration of corporate control within the global food system. The findings of this research paper show that genetically engineered biotechnological products are located at the intersection of scientific development, legal regulation, environmental protection and economic interests. It is necessary to create a strong environmental safeguard mechanism to align biotechnological inventions with sustainable development Goals, efficient equitable benefit-sharing mechanisms and participation of the interest of the all stakeholders including custodians of the natural resources.

Keywords: Equitable Access, Risk Assessment, Biosafety standards, Harmonised Technical Standard, Quality biotech foods**.**

1.0. Introduction

The commercialization of biotechnological inventions offers valuable opportunities, but it also creates complicated legal, ethical and socio-economic challenges. Concerns about the convergence of technical standards, environmental sustainability and public health implications and ethical concerns about genetic manipulation have been raised in academic and policy debates. The researchers also highlighted the issue of ensuring fair benefit-sharing with the custodians of genetic resources. There are very few researchers who in their papers raised concerns about its impacts on small farmers and alleged that the control of concentration of corporate houses may have a negative impact on the global food system.[1] In addition, global trade in biotechnology has raised concerns about safety of products and effectiveness of regulatory measures. The sector has also raised questions about ownership rights, market access and the decline of public trust.[2] This has led to demands for common technological standards, the creation of regulations to evaluate any effects on the ecosystem and human health, and the prioritization of ethical concerns related to genetic modification. Economic impact on small scale farmers. Growing hegemony of large corporations over the global food supply. Fair treatment of genetic resource custodians. Many people worry about the fact that giant multinational corporations own almost all these patents and that this could take away countries' control over their natural resources, undermine traditional knowledge and deny fair benefit sharing with the communities from which these resources are obtained. It is very important to have comprehensive policies to fix the responsibilities and avoid the mis-happenings.

In this paper, the researcher aims to highlight concerns about the harmonization of technical standards, environmental sustainability, public health issues linked to genetic manipulation, fair sharing of genetic resources, socio-economic effects on smallholder farmers, and the risk of corporate control in the global food system. This study seeks to create a set of principles that promote technology development that is inclusive and fair. It identifies key policy challenges at the crossroads of biotechnology and sustainable development, focusing on potential risks and the adequacy of current regulations. The researcher has tried to examine the challenges

[1] K.M.A. Gartland and J.S. Gartland, "Opportunities in Biotechnology" 282 *J Biotechnology* 38-45, (2018 September, 20). 10.1016/j.jbiotec.2018.06.303.

[2] Zarrilli, Simonetta, "International Trade in GMOs and GM Products: National and Multilateral Legal Frameworks, *UNCTAD Policy Issues in International Trade and Commodities Study Series* No. 29, at 1–12 (2005).

which may occur due to commercialisation of biotech inventions and how we can use it for promotion of SDGs. This paper tries to find out the limitations of existing legal frameworks, and offers recommendations to strengthen protections for the custodian of biological resources.

2.0. Regulatory Concerns in Development of Unified Policies for Commercializing Biotechnological Invention

This section examines the current laws that govern the commercialization of biotechnological inventions. It focuses on how effective, consistent, and appropriate these laws are. This research paper aims to help create balanced policies that support innovation, environmental sustainability, and fair regulation for everyone.[3] This debate has been further complicated by the use of AI in drug discovery. Patents are usually granted to encourage human creativity, especially regarding new inventions. Critics say that intellectual property rights create barriers for developing countries, preventing them from participating fairly in the global bioeconomy.[4] These disputes show us that there are problems between what is good for the public what is owned by private companies and how intellectual property is protected when it comes to new biotechnology inventions. People who fight for rights say that giving patents to biotechnology inventions can make life into something that can be bought and sold which can hurt human rights. When human genetics are turned into products that companies own it can threaten our rights as humans and who we are as people. To stop people from being taken advantage of the laws, about patents should have rules to protect human dignity and the rights of people especially when it comes to biotechnology inventions and human genetics.[5] These issues have led to ongoing debates about how to support innovation while also protecting public health and the environment.

We need to think about these problems. All countries must make rules about technology that everyone can understand. These rules have to consider how technology affects the people who own resources and the Sustainable Development Goals. The use of Genetically Modified Organisms is going up. This is causing worries. People are worried that traditional and local

[3] I. Khanna, P. Mehra & S. Verma, "Balancing economic growth and environmental sustainability in G-20 countries using green innovation" 6 *Discov Sustain* 669 (2025). https://doi.org/10.1007/s43621-025-01513-1.

[4] K. Kumar, & S. Jawed, "Emerging Issues of IPR in Developing and Under Developed Countries". 7(10) *International Journal of Social Science Research and Review* 202-210 (2024). https://doi.org/10.47814/ijssrr.v7i10.2379.

[5] Esra Demir and Evert Stamhuis, "Patenting human biological materials and data: balancing the reward of innovation with the ordre public and morality exception" 18 (7) *Journal of Intellectual Property Law & Practice* Pages 546–553 (July 2023). https://doi.org/10.1093/jiplp/jpad052.

crops will slowly disappear. We have to think about the impact of Genetically Modified Organisms, on our food. The owner of resource right and the Sustainable Development Goals are very important when we talk about Genetically Modified Organisms.[6] There have been several concerns raised about the potential toxicity of genetically modified organisms (GMOs). To detect and control any unforeseen environmental variations, regular monitoring and surveillance systems are very important.[7] It's important to find a balance between selling new products and protecting the environment, making sure that new ideas don't harm nature or reduce the variety of plants and animals.[8] We need to develop a good biosafety management policy focusing health, farming, environment, and trade.[9].

3. Biotech Inventions, Sustainable Development and Cross Border Commerce

3.1. Sustainable Development Goal and Governance of Biotech Inventions

In this section the researcher tried to evaluate how policies of biotechnological inventions could facilitate in achieving sustainable development goal. The commercialization of biotechnology inventions extends beyond technology transfer and market adoption; it encompasses intellectual property management, regulatory compliance, sustainable development objectives, and ethical responsibilities.[10] We need to connect biotechnology innovation with food security and sustainability goals while emphasizing ethical decision-making and stakeholder engagement.[11] Agricultural biotechnology can contribute to increased crop productivity, improved nutritional outcomes, and climate resilience, making it particularly relevant to Sustainable Development Goal 2 (Zero Hunger).[12] Nations need to evolve balance policies where bio prospecting takes the shape for circular economy and commercialisation of biotech

[6] Dominic Glover, "The Corporate Shaping of GM Crops as a Technology for the Poor" 10 *J. Peasant Stud.* 1, 12–15 (2010).
[7] S. Yuvaraj, E. Sumitha & C Mesta Sunitha, "Biological Invasions And Biodiversity Threats Linked To Genetically Modified Organisms" *25*(1) *Revista Electronica De Veterinaria* 2158-2169 (2024). https://doi.org/10.69980/redvet.v25i1.1006.
[8] A. Hilbeck, M. Meier, & M. Trtikova, "No scientific consensus on GMO safety" *27 Environmental Sciences Europe*, 4 (2015). 10.1186/s12302-014-0034-1..
[9] Y. Xue, H. Yu, & G. Qin, "Towards Good Governance on Dual-Use Biotechnology for Global Sustainable Development" *13*(24), *Sustainability* 14056 (2021). https://doi.org/10.3390/su132414056.
[10] Yvonne Lokko et. al, "Biotechnology and the bioeconomy-Towards inclusive and sustainable industrial development". 40 *New Biotechnology*, 5–10 (2018).
https://doi.org/10.1016/j.nbt.2017.06.01.
[11] Paul B. Thompson, "Promoting ethically responsible use of agricultural biotechnology" , 39(3) *Trends in Biotechnology*221–223 (2021).. https://doi.org/10.1016/j.tibtech.2020.10.013
[12] United Nation, *Transforming our world: The 2030 agenda for sustainable development* (New York, NY: United Nations . 2015).
https://sdgs.un.org/2030agenda.

inventions is linked to protection of the environment, human health, fair social and economic treatment. For efficient policy outcome, global leaders need to develop an interlinked policies for biotech inventions commercializing, environmental regulation, human rights frameworks, and sustainable development goals. Contemporary scholarship highlights that successful biotechnology commercialization should balance economic value creation with contributions to the Sustainable Development Goals (SDGs), while ensuring safety, accessibility, social responsibility, and environmental sustainability.[13]

World Trade Organization's (WTO) rules on health and safety (SPS) and technical standards (TBT) may be used as starting point for harmonisation. Which should be reviewed and be modified when we face any practical difficulty in execution or wherever conflict arise in between the objectives of SDG and commercialization of the biotech inventions. These rules are required to be based on scientific risk assessments and shouldn't create unfair trade barriers.[14] These agreements were designed to create a tricky balance between scientific rules and a country's right to decide its own biosafety policies.

3.2. Product Quality Regulation

The first and foremost factor in commercialization of biotechnological inventions need compliance of quality norms of the product. Product quality regulation constitutes a fundamental component of biotechnology governance, as it establishes regulatory mechanisms to ensure that biotechnological products consistently satisfy requirements for quality, safety, efficacy, and reliability before and after market authorization.[15] Regulatory systems will serve a dual purpose in the commercialization of biotechnological inventions, firstly it will safeguard human health and secondly will promote market efficiency and consumer trust along with environmental integrity. Well-designed regulations reduce uncertainty, support fair competition, encourage responsible innovation, and enhance public confidence in biotechnology-derived products, thereby facilitating their successful adoption and commercialization.[16] The WTO regulations relating to TBT Agreement has enumerated

[13] American Society for Microbiology, "Integrating safety, security, sustainability, and social responsibility principles into the U.S. bioeconomy". *9*(2) *mSphere* (2024). https://doi.org/10.1128/msphere.00084-24.

[14] Ghimire, et al. "Assessment of Benefits and Risk of Genetically Modified Plants and Products: Current Controversies and Perspective" 15(2), *Sustainability* 1722 (2023). https://doi.org/10.3390/su15021722.

[15] A. Kenneth Getz, "Regulatory and quality considerations in biotechnology product development" *29*(6) *Nature Biotechnology* 510–515 (2011).

[16] G, Brookes & S.J. Smyth, "Risk-appropriate regulations for gene-editing technologies" *GM Crops Food*. 2024

explicit rules about labelling, treating all products fairly and making sure labels don't create more trade problems than needed.[17] One of the most important rules of the Agreement is non-discrimination, which means that imported products must be treated just as fairly as similar local or other foreign products.[18] But applying this rule can be hard, especially with sensitive issues like GMOs, biosafety, and public health, because of legal and institutional challenges. Even, decisions-like US-Clove Cigarettes and US-Tuna II (Mexico-2012)-have been criticized for being too strict and limiting countries' rights to make their own rules. It is very difficult to distinguish between a "like" product, especially when are comparing GMOs to non-GMOs. This uncertainty makes it difficult to apply the non-discrimination rule properly. Since there are no objective parameter for similar GMO and non- GMO the TBT rules may cause confusion for governments and sellers. Moreover developing countries may claim strict safety standards may work as obstacles to their economic growth, due to high compliance costs and lack of technical infrastructure and scientific competency.[19] In this circumstances it is advisable to use liberal approach for supporting developing countries by facilitating dissemination of technology assessment competency and tools for a "better safe than sorry" approach.

3.3. Liability and Compensation

For efficient governance of biotech inventions and its commercialisation, liability and compensation systems play an important role. It is based on philosophy of attributing responsibility when harm results from the development, application, or commercial use of such technologies. These policies need to be focusing on injuries to human health, environmental degradation, and biodiversity loss, along with ensuring that individuals and communities affected by such harms have access to appropriate remedies and redress.[20] In this regard the

Dec 31;15(1):1-14. doi: 10.1080/21645698.2023.2293510. See also Stuart J. Smyth., "Risk-appropriate regulations for gene-editing technologies" *15*(1) *GM Crops & Food,* 233–245 2024). https://doi.org/10.1080/21645698.2024.2301234.

[17] Ana Cristina Molina & Vira Khoroshavina, "TBT provisions in Regional Trade Agreements: To what extent do they go beyond the WTO TBT Agreement*?" WTO Staff Working Paper, No. ERSD-2015-09*, World Trade Organization (WTO), Geneva (2015). https://doi.org/10.30875/bc4063c7-en.

[18] Mitsuo Matsushita, Thomas J. Schoenbaum, Petros C. Mavroidis, & Michael Hahn, *The World Trade Organization: Law, Practice, and Policy* (3rd ed.) (Oxford University Press 2015).

[19] T. Roullier & J. Larouzée, "How Do Countries with Identical Hazards End Up with Different Industrial Safety Regulations?" 116 *Chemical Engineering Transactions* 619-624 (2025).
https://doi.org/10.3303/CET25116104.

[20] See E. Tsioumani, & F. Rabitz, "The de-legalization of novel biotechnology governance under the Convention on Biological Diversity" *Transnational Environmental Law* (2025).
https://doi.org/10.1017/S2047102525100137.
See also M. Faure, & M. Jiang, "Financial security mechanisms to cover biodiversity damage resulting from the use of genetically modified organisms" *37*(4) *Emory International Law Review,* 561–590 (2023)..

Nagoya-Kuala Lumpur Supplementary Protocol provides important guideline with regard to issue of liability and compensation when damage occurs. This protocol mandates parties to ensure that operators undertake appropriate response actions regarding containment, mitigation, or environmental restoration, when damage occurs or there is an imminent risk of harm. These rules are beyond traditional principle of fault-based liability. It tried to focus on administrative and regulatory response mechanisms, while allowing flexibility to countries in implementation and enforcement of these obligations.[21] This framework shows consistency with strict liability priciple, while still allowing individual countries to define the precise liability standards through their own domestic legislation. This Protocol promotes fair treatment of individuals and communities, who may be affected by environmental harm through access to information, legal assistance, and participation in decision-making processes, in line with Principle 10 of the Rio Declaration. These rules may also assist developing countries through capacity-building measures, including training and resource support, to enable effective implementation of these obligations. In principles of these rules are sound but translating these provisions into practice is challenging due to legal, technical, and political constraints.[22] In many developing and least-developed countries, assessing environmental harm, carrying out ecological restoration, and enforcing accountability under biosafety regulations demand substantial scientific expertise and financial resources, are often limited or unavailable.[23] Even, cross-border movement of living modified organisms makes it difficult to determine liability, especially where national laws are incomplete and key legal terms such as "damage," "operator," and "response measures" remain inconsistently defined.[24]

3.4. Harmonised Technical Standard

Harmonisation of scientific technical standards will promote objectivity and will guarantee predictability. That is why every scholar recognize this as key instruments in biotechnology

[21] *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*- 2000. United Nations. https://bch.cbd.int/protocol/text/.
See also M. M. Roggenkamp, "Environmental liability and administrative response mechanisms in international environmental*"* 32(3) *Law* Journal of Environmental Law 455–478 (2020).
[22] Riccardo Pavoni, "Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress: The Legal Significance and Implementation Challenges" 20 *J. Envtl. L*. 417 (2013).
[23] John Komen, & Muffy Koch, "Building human capacity and skills in biosafety: Lessons learned and emerging best practices*"*. In Ademola A. Adenle , E. Jane Morris & Denis J. Murphy (eds.) *Genetically Modified Organisms in Developing Countries: Risk Analysis and Governance* 75–88 (Cambridge University Press 2017). https://doi.org/10.1017/9781316585269.008.
[24]A. Gupta, & A. Orsini, Liability, "Redress and the Cartagena Protocol". in E. Morgera & J. Razzaque (Eds.), *Biodiversity and Nature Protection Law* 445-454. (Edward Elgar Publishing 2017).

governance.[25] Having common technical standards is crucial for the international trade of biotechnology products. **Fernández** highlights that the regulation and global trade of genome-edited agricultural products face significant challenges due to differences in national regulatory approaches, scientific uncertainty, and fragmented international governance. The use of harmonised rules for assessing product safety, environmental impacts, and labelling requirements helps reduce technical barriers in global trade. When countries adopt shared standards, they are also better able to recognise and rely on each other's regulatory assessments, which facilitates smoother trade flows and strengthens mutual trust between regulatory systems.[26] Recent literature and WTO analyses confirm that harmonised technical standards play a crucial role in facilitating biotechnology and global trade by reducing regulatory fragmentation, improving conformity assessment reliability, and strengthening mutual recognition between trading partners. Many scholars have shown their apprehension that Different model of national regulatory frameworks could result in regional trading blocs. Variations in genetically modified (GM) import regulations and labelling requirements can create market access barriers, which will make it difficult for developing countries to participate in international trade.[27]

4.0 Equitable Justice to Custodian of Genetic Resources

Equitable justice for custodians of biological resources means ensuring that Indigenous peoples and local communities who have traditionally conserved and managed plants, animals, and ecosystems are treated fairly and benefit justly from the use of these resources. It emphasizes recognizing their long-term stewardship, protecting their rights, and sharing benefits in a fair and inclusive way.[28] The exploration of biological resources to discover and extract genetic, biochemical, and pharmacologically active compounds highlights the importance of ensuring fair and equitable sharing of benefits with Indigenous peoples and local communities who act as custodians of these resources. Their traditional knowledge and long-term stewardship must

[25] M. Ghodsi, "Regulatory convergence within technical barriers to trade" *47*(6) *The World Economy,* 1870–1915 (2024).
https://doi.org/10.1111/twec.13515.
[26] *Fernández Ríos, D., et al., "*Regulatory challenges and global trade implications of genome editing in agriculture" 13 *Frontiers in Bioengineering and Biotechnology* 1609110 *(2025)*.
https://doi.org/10.3389/fbioe.2025.1609110.
[27] M. Kallummal, S. Khosla, & A. Kundu, *"*Quantifying the impact of market access barriers in the agricultural sector amidst rising food insecurity*"* 37(2) *Agricultural Economics Research Review* 147–164 (2024).
https://doi.org/10.5958/0974-0279.2024.00011.3.
[28] L. Kareyapath, D. Vijayan, M. Bavorova, & A. S. Sam*, "*Indigenous peoples' participation in Joint Forest Management: insights from the Western Ghats" 26 *India*. *Regional Environmental Change* 108 (2026). https://doi.org/10.1007/s10113-026-02604-z.

be recognized through just participation and benefit-sharing mechanisms.[29]

Oguamanam in his scholarly paper explains that genetic resources are often developed into commercial products without adequate compensation to Indigenous custodians, reinforcing the need for justice-based benefit-sharing systems.[30] Tone-Pah-Hote & Redvers, emphasizes that commercialization of genetic and biospecimen-derived products from Indigenous Peoples requires clear ethical benefit-sharing frameworks and respect for sovereignty.[31] Bioprospecting of biological resources for genetic and biochemical compounds underscores the need for fair and equitable benefit-sharing with Indigenous and local communities, who are the custodians of biodiversity and traditional knowledge.

This potential can't be used straight from nature; it needs careful searching and research to find, develop, and turn valuable products and services into something useful.[32] Indigenous and local communities have played an active role in conserving and enhancing biodiversity.[33] It is claimed that compliance and respect of these rights is in consistency with international legal frameworks and shall promote fairness, cultural respect, and prior informed consent. In the absence of strong legal protections, traditional knowledge may be appropriated, commercialized, or misused without the consent of Indigenous and local communities.[34] There is often a significant power imbalance between Indigenous and local communities who possess traditional knowledge and external actors such as corporations or governments. In addition, determining ownership of genetic resources and traditional knowledge is complex because

[29] Laird , et al., "Biodiversity Prospecting: The Commercial Use of Genetic Resources and Best Practice", in Sarah A. Laird (ed.) *Benefit-Sharing, in Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice* 244 (Earthscan 2002).

[30] See C. Oguamanam, *Genetic resources, justice and reconciliation: Canada and global access and benefit sharing*. (Cambridge University Press 2019).
https://doi.org/10.1017/9781108557122.

[31] T. Tone-Pah-Hote, & N. Redvers, "The commercialization of biospecimens from Indigenous Peoples: A scoping review of benefit-sharing" 9 *Frontiers in Medicine* 978826 (2022).
https://doi.org/10.3389/fmed.2022.978826.

[32] M.S., Suneetha, Balakrishna Pisupati & Sanjay Kumar, "Framework for Benefit Sharing Guidelines for India" 11 *Asian Biotechnology & Dev. Rev*. 55 (2009).

[33] M. A. Altieri, *Agroecology: The Science of Sustainable Agriculture* (CRC Press 2004).
See also Lori B. Andrews, *Body Bazaar: The Market for Human Tissue in the Biotechnology Age* (Crown Publ'rs 7–12, 53–56 1999).

[34] A. Raj, & S. Shree, "The silent larceny: Exploitation of traditional knowledge by way of biopiracy" *SSRN Electronic Journal* (2024). https://ssrn.com/abstract=4819573.
See also, Brendan Tobin, "Setting protection of traditional knowledge to rights: Placing human rights and customary law at the heart of traditional knowledge governance' in E. C. Kamau & G. Winter (Eds.), *Genetic resources, traditional knowledge and the law: Solutions for access and benefit sharing*101–118 (Edward Elgar Publishing (2019). https://doi.org/10.4337/9781786437426.

these resources are usually collectively held rather than owned by individuals.[35]

To stop people from taking things that do not belong to them like plants and animals and to make countries trust each other the world came together to create the Convention on Biological Diversity, which's like a rule book that everyone has to follow. The Convention on Biological Diversity has made a difference in the laws of countries and the laws that the whole world follows when it comes to sharing the good things that come from plants and animals. It says that each country has control over the plants and animals that are found in their country so they can decide who can use them and how they can be used. The Convention, on Biological Diversity is very important because it helps countries work together and make sure that everyone is treated fairly when it comes to using resources.[36] The implementation of the Convention on Biological Diversity (CBD), particularly its rules on access to and use of biological resources, is the responsibility of individual countries, both those providing the resources and those utilizing them. At the same time, all member states share a collective obligation to cooperate in enforcing the agreement. Compliance with the CBD is therefore a legal duty for its parties, not merely a voluntary or ethical commitment.[37] However, in recent years, there have been many cases where countries' rights over their genetic resources have been ignored, especially when those resources were accessed or used without getting permission first from the source country or the Indigenous communities involved.[38]

If a business entity collects a genetic resource from one country but files a patent claiming to be the inventor of an isolated form of that resource, they do not automatically own the original genetic resource itself. This business entity has legal and ethical responsibilities toward the custodians of the genetic resources; this includes obtaining prior informed consent (PIC) and following access and benefit-sharing (ABS) rules, which ensure fair sharing of benefits with the provider country and Indigenous or local communities.[39] Therefore, knowing the exact

[35] P. Mishra, *"*From biopiracy to bio-justice: Legal reforms for traditional knowledge and agrobiodiversity in India*"* 30(4), *Journal of Intellectual Property Rights*, 440–450 (2025). https://doi.org/10.56042/jipr.v30i4.11674.
[36] Elisa Morgera,et al., *The 2010 Nagoya Protocol on Access and Benefit-sharing in Perspective: Implications for International Law and Implementation Challenges* (Brill/Martinus 2012).
[37] E. C. Kamau, B., Fedder & G. Winter, "The Nagoya Protocol on access to genetic resources and benefit sharing: What is new and what are the implications for provider and user countries and the scientific community?" 6(3) *Law, Environment and Development Journal* 246–263 (2010). https://ssrn.com/abstract=2178975.
See also Philippe Cullet, "Differential Treatment in International Environmental Law: A New Framework for the Realization of Environmental Rights" 30 Neth. Y.B. Int'l L. 111, 111–38 (1999).
[38] See Daniel F. Robinson, *Confronting Biopiracy: Challenges, Cases and International Debates*, Earthscan 41–75, 150–75 (2010)..
[39] See K. Bavikatte & D. F. Robinson, "Towards a people-led approach to conservation: The role of customary law and community governance in biodiversity protection" 18(1) *International Journal of Cultural Property*, 3–

source and origin of the genetic material is essential to decide who rightfully owns inventorship and how benefits should be fairly shared.[40] Accurate identification of the origin of genetic material is therefore essential for determining inventorship and ensuring equitable benefit-sharing under international biodiversity governance frameworks.[41]

Biological resources and traditional knowledge are generally collectively held by Indigenous and local communities, making individual ownership difficult to define.[42] In many developing countries, weak or incomplete legal frameworks further limit the protection of rights over these resources[43]. It has been observed that local communities often suffer challenge of structural power imbalances, which result in reducing their ability to negotiate fair agreements or safeguarding their interests.[44] Even want of formal documentation and legal recognition of customary rights also creates challenge of identification of real custodians and the equitable sharing of benefits from genetic resources and traditional knowledge.[45] These challenges led to uncertainty, administrative delays, and has been perceived as barriers to effective participation in access and benefit-sharing processes. It has been noticed that multiple communities assert their claim on the same traditional knowledge and each asserting custodianship or collective ownership rights, which result in conflict of interest and difficulty in benefit sharing. Such overlapping or competing claims often prolonged negotiations, verification procedures and legitimate custodianship; which affect equitable benefit-sharing outcomes.[46]

22 (2011). https://doi.org/10.1017/S0940739111000020.

[40] See A. E. M. Penteado, *"*The case of patent disclosure requirements for genetic resources and associated traditional knowledge, and the custodianship of traditional knowledge*:* A critique*" SSRN Electronic Journal* (2024). https://doi.org/10.2139/ssrn.5270659.

[41] E. Tsioumani, "Beyond access and benefit-sharing: Lessons from the law and governance of agricultural biodiversity" 21(1–2) *Journal of World Intellectual Property* 106–122 (2018). https://doi.org/10.1111/jwip.12094.

[42] See J. K. Weir, R. Morgain, K. Moon, & B. J. Moggridge, "Centring Indigenous peoples in knowledge exchange research-practice by resetting assumptions, relationships and institutions" 19(2) *Sustainability Science* 629–645 (2024). https://doi.org/10.1007/s11625-023-01457-3.

[43] See H. Macdonald, "Conceptual uncertainties and practical challenges in voluntary Nagoya Protocol compliance: The Australian situation" 23(1) *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 1–12 (2025). https://doi.org/10.1089/bio.2024.0090.

[44] See R. Wynberg, S. F. Ives, & J. Bam, *"*How access and benefit sharing entrenches inequity: The case of rooibos*"* 49(4) *Journal of Southern African Studies*, 589–610 (2024). https://doi.org/10.1080/03057070.2023.2301640.

[45] T. Jahan, & S. Saurav, "Homogenizing traditional knowledge and biodiversity conservation: A study intersecting IP rights and sustainable development", in Tlou Maggie Masenya*, and* Monicca Thulisile Bhuda (eds.) *Revaluation and Preservation of Indigenous Knowledge Systems in Modern Society* 447–464 (IGI Global 2025). https://doi.org/10.4018/979-8-3693-7964-6.ch022.

[46] T. J. Park, & S. P. Park, *"*Legal and economic perspectives on fair and equitable benefit sharing in the Nagoya Protocol" 39(2) *Conservation Biology* e14410 (2025). https://doi.org/10.1111/cobi.14410.

It has been observed that different approach of the signatories counties of the Convention on Biological Diversity (CBD) and the Nagoya Protocol resulting in fragmented legal frameworks with variations in definitions of prior informed consent (PIC), mutually agreed terms (MAT), and implementation procedures.[47] This lack of standardized regulatory framework consequently leads to uncertainty. Recent studies establishes that fragmentation increases challenge of compliance, delays, and uncertainty in biodiversity-related research and innovation. Even CBD's compliance review highlights persistent implementation gaps and uneven national capacities across Parties (CBD Secretariat, 2025). In addition, regulatory complexity and procedural requirements under ABS frameworks can discourage efficient access to genetic resources, particularly in time-sensitive commercial sectors.

5.0. How to Address Environmental Challenges of bioprospecting and Promote SDG

Addressing the environmental challenges of bioprospecting while promoting the Sustainable Development Goals (SDGs) requires balancing scientific discovery with biodiversity conservation, ethical practices, and equitable benefit-sharing. Regulating biotechnological inventions requires carefully balancing scientific progress with important ethical and environmental concerns. As biotechnology plays a bigger role in agriculture, medicine, and industry, it raises serious questions about how far humans should intervene in nature, the long-term environmental effects of genetically modified organisms, and how benefits and risks should be fairly shared.

Overexploitation of biodiversity is one of the most significant environmental challenges associated with bioprospecting.[48] The increasing demand for biologically valuable plants, animals, and microorganisms can lead to excessive harvesting of natural populations, threatening species survival and disrupting ecosystem balance.[49] Even concerns has been raised that unsustainable extraction may reduce genetic diversity, weakens ecosystem resilience, and may endanger rare or endemic species.[50] Remedy of this challenge lies in sustainable harvesting practices, cultivation of commercially valuable species, establishment of protected areas, strict regulatory frameworks, and active participation of local communities.[51]

[47] *Ibid.*
[48] See A. Sirakaya, *"*Is the Nagoya Protocol designed to conserve biodiversity?" 4(4) *Plants, People, Planet* 68-75 (2021). https://doi.org/10.1002/ppp3.10221.
[49] *Ibid.*
[50] See S. Sahasrabudhe, & A. E. Motter, "Rescuing ecosystems from extinction cascades through compensatory perturbation". *2*(1) *Nature Communications,* 170 (2011). https://doi.org/10.1038/ncomms1163.
[51] See I. N. Panayotova, J. Herrmann & N. Kolling, "Bioeconomic analysis of harvesting within a predator–prey

Additionally, advances in biotechnology and other alternative production methods can reduce pressure on wild populations while maintaining the benefits derived from biological resources.[52] These measures promote biodiversity conservation and support sustainable development by encouraging the sustainable use and management of biological resources. [53] The best options for reducing overexploitation are sustainable harvesting, cultivation of valuable species, strong conservation measures, effective regulations, community participation, and biotechnology-based alternatives. These approaches help conserve biodiversity while allowing continued scientific and economic benefits from bioprospecting. Addressing overexploitation supports SDG 3, 12, 14 and 15.

Moreover, unsustainable harvesting can significantly reduce species populations and genetic diversity within ecosystems.[54] When biological resources are collected faster than they can naturally regenerate, population sizes decline and become more vulnerable to extinction. Smaller populations often experience a loss of genetic variation, which reduces their ability to adapt to environmental changes, diseases, and climate-related stresses.[55] In bioprospecting, excessive collection of valuable medicinal or industrial species can further accelerate biodiversity loss and disrupt ecosystem functions.[56] Therefore, sustainable harvesting and conservation measures are essential to maintain biodiversity and ensure the long-term availability of biological resources.

Even, Vulnerable ecosystems may face additional pressure from resource extraction associated with bioprospecting and other human activities.[57] Few reports warn that excessive collection of biological resources could disturb ecological processes, alter species interactions, and may

system: A case study in the Chesapeake Bay fisheries" *480 Ecological Modelling,* 110330 (2023). https://doi.org/10.1016/j.ecolmodel.2023.110330
See also D. M. Prasad & S. C. Menon, "India: Implementing the Nagoya Protocol on Access and Benefit-Sharing: Emerging Legal Challenges" 50(4–5) *Environmental Policy and Law* 399–404 (2021).

[52] J. P. Colella, L. C. Silvestri, G. Suzan et al., "Engaging with the Nagoya Protocol on Access and Benefit-Sharing: Recommendations for Non-Commercial biodiversity Researchers" 104(3) *Journal of Mammalogy* 430–443 (2023). https://doi.org/10.1093/jmammal/gyac122.

[53] *Ibid.*

[54] See F. W. Allendorf, P. R. England, G. Luikart, P. A. Ritchie & N. Ryman, "Genetic effects of harvest on wild animal populations" 23(6) *Trends in Ecology & Evolution* 327-337 (2008). https://doi.org/10.1016/j.tree.2008.02.008.

[55]See R. Frankham, "Genetics and extinctio*n*" 126(2), *Biological Conservation* 131–140 (2005). https://doi.org/10.1016/j.biocon.2005.05.002.

[56] See A. C. Hamilton, *"*Medicinal plants, conservation and livelihoods*"* 13(8) *Biodiversity and Conservation*, 1477-1517 (2004). https://doi.org/10.1023/B:BIOC.0000021333.23413.42.

[57] See Millennium Ecosystem Assessment*, Ecosystems and human well-being: Biodiversity synthesis* World Resources Institute (2005).

reduce ecosystem resilience. It has also been asserted that fragile habitats such as tropical forests, wetlands, and coral reefs are susceptible to degradation because many species within these ecosystems have limited capacity to recover from disturbance.[58] Even the result of climate change may intensify pressures by modifying environmental conditions and increasing the vulnerability of already stressed ecosystems.[59] Hence to address these challenges sustainable resource management and conservation strategies are essential to minimize environmental impacts and maintain ecosystem integrity for future generations.

It has been suggested that mandatory Environmental Impact Assessments (EIAs**)** mechanism before commercialisation of biotech inventions may prevent potential ecological damage. To monitor proper and controlled access to biological resources through licensing systems. Execution of Convention on Biological Diversity and the Nagoya Protocol for fair benefit-sharing may be guaranteed though introducing concept of local registration of traditional knowledge practice. In addition, it is suggested that strict enforcement of policies against illegal collection, combined with penalties and surveillance, shall help in reduce biodiversity loss and biopiracy. It was suggested that collectively these regulatory measures shall promote conservation, sustainable development, and responsible use of natural resources.

6.0. Conclusion and Suggestions

It is evident that commercialisation of biotechnological invention in collaborative approach together with trans disciplinary approach will be asset for future generation and may work as good assistant in achieving SDGs. A scientific approach with respect of ecology, environment and custodian of biological resources may support sustainable industries in achieving global goals. However, the worries about safety of biotech products, its harm to nature, loss of genetic diversity, and threat of unfair access-especially for poorer and unaware communities in developing countries needs to be part of check list before approval of commercialisation of any biotech products. Even bioprospecting of GMOs from lab to the market in several cases demonstrated that approving agency have to retract its decision on the apprehension of toxicity. In this backdrop it is imperative that there is a need of guarantying careful use without compromising environmental concerns. It is important to have strong environmental checks,

[58] See R. Dirzo, H. S. Young, & M. Galetti, et al., "Defaunation in the Anthropocene" *345*(6195) *Science,* 401–406 (2014). https://doi.org/10.1126/science.1251817.
[59] See Intergovernmental Panel on Climate Change, *Climate Change-2023-Synthesis Report* (Geneva Switzerland: IPCC (2023).

protect biodiversity, fair benefit sharing system to support equitable global development of biotech inventions and SDGs

For Ensuring equitable justice to custodians of biological resources, adoption of holistic and rights-based approach is mandatory. This could be targeted through local institutions such as Biodiversity Management Committees and active community participation. In addition to establishment of robust mechanisms for capacity building, grievance redressal, and international cooperation are essential for improving the trust among the producer and user countries. For transparent monitoring and protection of traditional knowledge; integration of technology is com pulsory along with the legal and institutional compliance. It will further empower the communities conceived initially. We should also try adopt a functional just and inclusive system for sustainable development of those who have historically preserved and nurtured the planet's biodiversity.

In reference to challenges of international instrument gaps frequent review and modification of policy as per need and demand is imperative. These systems shall work as a supplementary mechanism and strengthen the alarm system; which may speed up the processes. A unified and inclusive set of rules is important for developing reliable, transparent, and effective legal system for everyone. Moreover, it is necessary for farmers to know about the pros and cons of the biotech inventions commercialization. Because if they would not have sufficient knowledge they may losing everything and we will compromise with sustainable development.

At the end careful review mechanism of current international framework could help in creating fair and practical solutions. These solutions would support in development of fair access and sharing of benefits, as well as responsible management and exchange of digital sequence information (DSI). This approach will strengthen wider goals like environmental justice, safety for living things, and guarantee of sustainable development Goals.

7.0 Authors' Contribution

In this paper, entitled *Biotech Inventions and Sustainable Development: Analysis of Coherent Policy Framework*, the contribution of author is detailed to ensure transparency in the research process. The work was conducted at the Department of School of Law and Governance, Central University of South Bihar, Gaya, India by Professor (Dr.) Sanjay Prakash Srivastava.

Professor (Dr.) Sanjay Prakash Srivastava, as the lead researcher, spearheaded the conceptualization of the study. This study aims to critically examines the legal, ethical, and socio-economic dimensions of biotechnological inventions and intended to develop a coherent conceptual and normative basis for a policy framework that will advance inclusive and socially just innovation. Professor (Dr.) Sanjay Prakash Srivastava conducted refinement of the research methodology and theoretical framework. Professor (Dr.) Sanjay Prakash Srivastava edited the manuscript for academic precision, and ensured that the paper's coherence with broader Indian data governance contexts. Professor (Dr.) Sanjay Prakash Srivastava approving the ethical and structural integrity.