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Biotechnology Policy and Governance in India: Challenges and Opportunities

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Abstract

Biotechnology has become a crucial driver of economic growth and social transformation in India. Over the past three decades, India has developed a comprehensive policy and institutional framework to regulate and promote biotechnological innovations in healthcare, agriculture, and industry. This paper analyzes the evolution of biotechnology policy and governance in India, emphasizing the roles of major institutions such as the Department of Biotechnology (DBT) and the Biotechnology Industry Research Assistance Council (BIRAC). It explores existing challenges—such as fragmented regulation, ethical dilemmas, and limited coordination—while also identifying emerging opportunities in bioeconomy expansion, startup ecosystems, and global collaborations. The paper concludes that India's future success in biotechnology depends on strengthening governance mechanisms, promoting ethical oversight, and integrating innovation with sustainability goals.

Keywords: *biotechnology policy; governance; bioethics; regulation; India; innovation*

1. Introduction

Biotechnology has emerged as one of the most transformative disciplines of modern science, revolutionizing healthcare, agriculture, and environmental management. In India, biotechnology plays a pivotal role in achieving sustainable development, public health improvement, and industrial innovation. The government's consistent policy support and institutional framework have accelerated research and commercialization in the sector (Department of Biotechnology [DBT], 2022). However, as biotechnological applications expand rapidly, the governance of ethical, legal, and regulatory aspects poses growing challenges that require comprehensive policy reform (Kumar & Gupta, 2020).

2. Evolution of Biotechnology Policy in India

India's structured approach to biotechnology began with the establishment of the Department of Biotechnology (DBT) in 1986 under the Ministry of Science and Technology. This marked the beginning of an institutionalized framework for biotechnology research and development. Early initiatives focused on capacity building, infrastructure creation, and human resource development (Kumar & Gupta, 2020).

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In 2001, the National Biotechnology Development Strategy (NBDS) provided India with a systematic policy blueprint for promoting innovation, biosafety, and public–private partnerships. This strategy was further refined through the NBDS 2015–2020, which emphasized translational research, entrepreneurship, and global competitiveness (DBT, 2015). The government set a vision to achieve a USD 100 billion bioeconomy by 2025, reinforcing biotechnology's strategic importance in national development (NITI Aayog, 2021).

The most recent Draft National Biotechnology Development Strategy 2021–2025 (DBT, 2022) expands upon these goals by emphasizing bio-manufacturing, societal applications, and an inclusive innovation ecosystem.

3. Institutional and Regulatory Framework

India's biotechnology sector operates under a multi-layered governance system designed to ensure safety, ethical compliance, and innovation. The Review Committee on Genetic Manipulation (RCGM) under DBT oversees research involving genetic engineering, while the Genetic Engineering Appraisal Committee (GEAC) under the Ministry of Environment, Forest and Climate Change (MoEFCC) regulates environmental release of genetically modified organisms (MoEFCC, 2020).

The Biotechnology Industry Research Assistance Council (BIRAC), established in 2012, plays a crucial role in promoting innovation and entrepreneurship through funding, incubation, and technology transfer programs (BIRAC, 2021). Additionally, the proposed National Biotechnology Regulatory Authority (NBRA) aims to unify regulatory oversight and enhance transparency, though it is yet to be legislatively implemented (Kaur, 2019).

Despite these institutional mechanisms, coordination gaps and overlapping jurisdictions often delay decision-making and reduce regulatory efficiency (Sharma, 2022).

4. Challenges in Biotechnology Governance

One major governance challenge is the fragmented regulatory framework, where multiple agencies operate independently with overlapping mandates. This complexity often slows down approvals for new technologies and limits inter-departmental coordination (Kaur, 2019).

Ethical and social concerns also remain significant. Public skepticism toward genetically modified crops and biopharmaceuticals reflects a lack of trust and insufficient risk communication (Sharma, 2022). Additionally, issues of genetic privacy, consent in human genome research, and equitable access to biotechnology benefits necessitate robust ethical governance.

Intellectual property rights (IPR) continue to pose policy dilemmas, as patent protection must balance innovation incentives with affordable access to medicines and agricultural technologies (Rao, 2021). Furthermore, India faces limited R&D investment, weak university–industry linkages, and insufficient biosafety infrastructure, which collectively constrain innovation potential.

5. Opportunities for India's Biotechnology Sector

India's biotechnology landscape offers vast opportunities for growth and global leadership. The country has a strong scientific base, cost-effective manufacturing capacity, and a rapidly expanding bio-entrepreneurial ecosystem. Government initiatives such as Startup India, Make in India, and Atmanirbhar Bharat have created a supportive environment for biotechnology startups and research commercialization (NITI Aayog, 2021).

The COVID-19 pandemic showcased India's capabilities in vaccine innovation and biomanufacturing, strengthening its global standing in health biotechnology (DBT, 2022). Emerging areas such as synthetic biology, precision medicine, and bioinformatics hold significant promise for economic diversification and public welfare.

By improving regulatory efficiency, ensuring ethical accountability, and integrating sustainability into biotechnology policies, India can realize its vision of becoming a global bioeconomy leader.

6. Conclusion

India's biotechnology policy and governance framework has evolved considerably since the 1980s, reflecting both ambition and adaptability. However, persistent challenges—fragmented regulation, ethical concerns, and limited coordination—continue to impede policy effectiveness. Future governance must emphasize regulatory integration, bioethics, and public engagement to ensure responsible innovation. If guided by transparent, inclusive, and ethical principles, biotechnology can serve as a cornerstone for India's sustainable development, public health advancement, and global competitiveness.

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