ENVIRONMENTAL REGULATIONS GOVERNING BIO-CHEMICAL INDUSTRIES IN INDIA

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ABSTRACT

Pharmaceuticals, biopharmaceuticals, enzyme manufacturing, and fermentation-based chemicals are all part of India's biochemical industry, which has grown to be a key area influencing both economic expansion and global public health. But in addition to its financial benefits, the business presents serious threats to the environment and biosafety, especially through the use of genetically modified organisms, toxic effluents, and antibiotic residues. There are still gaps between the law and practice even though India has a comprehensive corpus of environmental legislation, including the Environment (Protection) Act, Water Act, Air Act, and waste management regulations. Inefficiencies have been caused by a lack of monitoring infrastructure, dispersed institutional duties, and weak enforcement capabilities, particularly for small and medium-sized businesses that are having trouble keeping up with compliance expenses. More importantly, existing standards, which were largely created for traditional pollutants, do not sufficiently address new issues like pharmaceutical micropollutants and antimicrobial resistance. Although industrial expansion and environmental effects have been emphasised in previous studies, little systematic study has been done on how well India's regulatory framework handles issues unique to biochemistry or how it stacks up against global best practices. By using doctrinal analysis, empirical data, and comparative views to examine India's environmental control of the biochemical sector, this study aims to close that gap. The research attempts to find context-specific legislative and policy reforms that strike a balance between industrial competitiveness and sustainable environmental and public health outcomes by assessing enforcement hurdles, SME compliance issues, and international benchmarks.

Keywords: Biochemical Industry Regulation; Environmental Governance in India; Pharmaceutical Effluents; Antimicrobial Resistance (AMR); Sustainable Manufacturing.

Chapter 1

Introduction

Pharmaceuticals, biopharmaceuticals, enzyme manufacturing, fermentation-based chemicals, and industrial biotechnology are all part of India's biochemical industry, which has grown to be a strategically important sector that supports both worldwide public health and economic growth. India presently ranks among the top manufacturers of vaccines and generic medications worldwide, and the country's biopharmaceutical sector accounts for the greatest portion of the local biotechnology industry[1]. In addition to supporting international supply chains and the nation's export revenue, this industrial foundation is positioned as a key component of India's shift to a knowledge-driven bioeconomy. By encouraging translational research, improving research infrastructure, and promoting the development of human capital, most recent government strategies—such as the National Biotechnology Development Strategy (2020–2025) and specific initiatives under the Department of Biotechnology—have positioned biotechnology as a growth driver. In this regard, the biochemical industry contributes significantly to national health security by providing a steady supply of vaccinations, necessary medications, and diagnostic tools, in addition to being a source of foreign exchange and industrial competitiveness.

Even while the industry makes significant socioeconomic benefits, it also presents difficult environmental problems. The production processes that underpin the manufacturing of biochemicals and biopharmaceuticals depend on a variety of chemical reagents, catalysts, genetically engineered microbes, organic solvents, and active pharmaceutical ingredients (APIs). Hazardous trash, effluents with high chemical and biological oxygen demands, volatile organic compounds, solvent residues, and remnants of biologically active substances like antibiotics are frequently among the by-products of these operations[2]. When these emissions are not properly managed, they harm aquatic ecosystems, pollute soil and groundwater, and pose health concerns to humans via entering food and water chains or by exposure directly. They pass on costs onto downstream ecosystems and communities, and the ecological effects

[1] Ramakrishna, K. (2019). The Emergence of Environmental Law in the Developing Countries: A Case Study of India. *Ecology Law Quarterly*, *12*(4), 907–935.
[2] Khurana, A., Sinha, R., & Arora, G. (2023). Indian pharmaceutical manufacturing sector. In R. Sengupta (Ed.), *CONTAINING ANTIBIOTIC POLLUTION FROM MANUFACTURING: A step towards reducing the risk of AMR* (pp. 37–51).

are multi-scale, ranging from long-term changes in microbial community composition to toxicity to aquatic creatures.

The contribution of pharmaceutical and biopharmaceutical effluents to the distribution of antibiotic residues, which can aid in the development and spread of antimicrobial resistance (AMR), is a particularly noteworthy element of this environmental effect. Antibiotics have been found in detectable amounts in surface waterways and industrial effluents close to pharmaceutical industry hubs in India, according to field research. Due to selective pressures exerted by these residues, environmental bacteria acquire resistant strains and resistance genes, which may then spread into the clinical and agricultural sectors. This link between the environment and public health shows how industrial waste streams might hasten one of the 21st century's most urgent health issues. Although clinical abuse and excessive agricultural use of antibiotics are frequently the focus of international discussions on antimicrobial resistance (AMR), the environmental release of antibiotics from manufacturing is still a relatively unregulated channel that is becoming more and more important in the Indian setting.

The Environment (Protection) Act of 1986, the Water (Prevention and Control of Pollution) Act of 1974, and the Air (Prevention and Control of Pollution) Act of 1981, as well as particular regulations pertaining to hazardous waste, biomedical waste, and genetically engineered organisms, comprise India's legislative framework for controlling such risks[3]. State-level enforcement organisations known as State Pollution Control Boards and federal organisations like the federal Pollution Control Board and the Ministry of Environment, Forests, and Climate Change share organisational control. The Genetic Engineering Appraisal Committee further regulates biotechnology operations concerning genetically modified organisms. Despite the legal architecture's seeming comprehensiveness, its execution is nonetheless inconsistent. Variations in enforcement intensity, capacity limitations among state boards, and discrepancies between statutory standards and the monitoring of pollutants unique to biochemical manufacturing, such as antibiotic residues and pharmaceutical micropollutants, are frequently highlighted in empirical studies and policy reviews.

The governance problem is made worse by the discrepancy between changing scientific understanding and regulatory frameworks. The sub-lethal ecological consequences of trace organic contaminants are not usually adequately addressed by current discharge standards,

[3] Ahmad, F. (2021). ORIGIN AND GROWTH OF ENVIRONMENTAL LAW IN INDIA. *Journal of the Indian Law Institute*, *43*(3), 358–387.

which were largely created with conventional pollutants in mind. The technological capability of regular surveillance is frequently surpassed by the reliable detection of low-concentration APIs in effluents, and monitoring methods are not consistently accessible across states[4]. Furthermore, given the various sources of AMR that coexist in healthcare, agriculture, and community settings, it is still difficult to establish causal links to clinical resistance patterns, even though correlations between industrial effluents and the presence of resistant strains in nearby environments are well-established. Because of these variables, there is an urgent need for cross-sectoral governance and adaptive regulation that combines public health surveillance and environmental monitoring under a One Health framework.

The environmental management of India's biochemical sector is a complex issue that intersects industrial progress, environmental stewardship, and global health security, as the literature is beginning to acknowledge. In addition to being a vital source of life-saving medications and a catalyst for economic growth, the industry also produces new ecological and public health externalities that traditional environmental regulation cannot handle on its own. Because of this dichotomy, regulating India's biochemical sector is both a critical governance issue and a significant area of academic research, necessitating multidisciplinary viewpoints from the fields of public health, environmental science, industrial policy, and law.

1.1 Statement of Problem

Although India has a thorough set of environmental laws, it is doubtful how well they manage the unique dangers associated with the biochemical sector. Reports of antibiotic residues, hazardous effluents, and biosafety hazards related to genetically modified organisms are still coming in. Multiple agencies exercising overlapping responsibilities frequently cause regulatory frameworks to become fragmented, which results in inefficiency and regulatory uncertainty.

Complex environmental regulations are particularly difficult for small and medium-sized biochemical companies to comply with because of high compliance costs, a lack of technical know-how, and a lack of institutional support. Enforcement is further hampered by limited

[4] Khurana, A., Sinha, R., & Arora, G. (2023). Indian pharmaceutical manufacturing sector. In R. Sengupta (Ed.), *CONTAINING ANTIBIOTIC POLLUTION FROM MANUFACTURING: A step towards reducing the risk of AMR* (pp. 37–51).

laboratory facilities, understaffed SPCBs, and weak monitoring systems. As a result, there is a big discrepancy between the law as it is written and as it is applied.

Furthermore, India's regulatory framework still lags behind international best practices for sustainable manufacturing and biosafety. India's regulations could seem less comprehensive, less open in their application, and less sensitive to new threats like antibiotic resistance than those of the OECD, EU, or US. This calls into question how India can strike a balance between public health, environmental preservation, industrial progress, and global competitiveness.

1.2 Research Questions

1. How effective are existing Indian environmental regulations in managing hazardous waste, emissions, and biosafety risks in the biochemical and biopharmaceutical manufacturing sector?

2. What are the key regulatory and institutional challenges faced by small and medium biochemical firms in India, and how do these affect their environmental performance?

3. How do India’s environmental and biosafety regulatory frameworks for biochemical manufacturing compare with international best practices, and what reforms could improve outcomes while remaining feasible for industry?

1.3 Research Objectives

1. To critically evaluate the effectiveness of India’s existing environmental regulations in addressing biochemical industry risks.

2. To identify key institutional and regulatory challenges faced by regulators and industry, especially SMEs.

3. To undertake a comparative assessment with international best practices in biochemical environmental governance.

4. To propose context-specific legal and policy reforms that can strengthen India’s regulatory framework while ensuring industrial competitiveness and sustainability.

1.4 Research Methodology

Both doctrinal and empirical methodologies are used in this study. A thorough analysis of Indian laws, regulations, court rulings, and policy papers pertaining to environmental control in the biochemical industry will be part of the doctrinal component. The Environment Protection Act, the Air and Water Acts, the Hazardous Waste Rules, the Biomedical Waste Rules, and the biosafety recommendations will all be studied.

Secondary data, including reports from the Ministry of Environment, Forests, and Climate Change (MoEFCC), SPCBs, CPCBs, university research, industry publications, and media sources, will be used in the empirical component. To demonstrate regulatory constraints, case studies of compliance and non-compliance in particular biochemical clusters (such as Hyderabad, Bengaluru, and Pune) would be examined wherever feasible. India's frameworks will be compared to global best practices, especially those of the US, EU, and OECD, as part of the comparative component. This will draw attention to reform possibilities as well as shortcomings.

Chapter 2

Review of Literature

1. Modern Biotechnology and India's Governance Imperatives[5].

The rapid growth of India's biotechnology sector, which includes biopharmaceuticals, bioagriculture, industrial biotech, bioservices, and bioinformatics, as well as the governance issues that come with it, are examined by Anant Padmanabhan, R. Shashank Reddy, and Shruthi Sharma in Modern Biotechnology and India's Governance Imperatives. They draw attention to how India's regulatory framework, which is supervised by organisations like the Central Drugs Standard Control Organisation (CDSCO), the Department of Biotechnology (DBT), the Genetic Engineering Appraisal Committee (GEAC), and the Review Committee on Genetic Manipulation (RCGM), is still disjointed and beset by inconsistent enforcement, overlapping jurisdictions, and procedural hold-ups. The writers also discuss topics including the public's resistance to genetically modified crops, the National Biodiversity Act's uncertainties, and India's place in international governance discussions over benefit-sharing and intellectual property.

Their main goal is to make the case for more efficient regulation, improved institutional capability, transparent legal frameworks, and inclusive public participation so that India may responsibly utilise the potential of biotechnology while preserving public confidence. Although the literature covers governance and ethics in great detail, it lacks comparative regulatory case studies, empirical evaluations of environmental externalities (such as antibiotic residues and effluent management), and post-market monitoring and mechanisms to strike a balance between rapid innovation and long-term environmental and health risks.

2. "The Biomedical Waste: Direction of Law and Justice" by C. M. Jariwala[6]

C. M. Jariwala critically analyses the legal and judicial solutions to the growing problem of biomedical waste management in India in The Biomedical Waste: Direction of Law and Justice. The study highlights how improper segregation, collection, and disposal

[5] Padmanabhan, A., Reddy, R. S., & Sharma, S. (2017). *MODERN BIOTECHNOLOGY AND INDIA'S GOVERNANCE IMPERATIVES*. Carnegie Endowment for International Peace.
[6] Jariwala, C. M. (1999). THE BIOMEDICAL WASTE : DIRECTION OF LAW AND JUSTICE. *Journal of the Indian Law Institute*, *41*(3/4), 368–382.

methods endanger public health and the environment by placing biomedical waste inside the parameters of the Environment (Protection) Act, 1986, and the Biomedical Waste (Management and Handling) Rules that followed. Jariwala emphasises how the judiciary, especially the Supreme Court and High Courts, should issue directives to uphold institutional responsibility, compel compliance, and defend the right to a clean environment guaranteed by Article 21 of the Constitution.

The main goals are to assess how well India's legal and judicial systems handle biological waste and to make the case for stricter enforcement and more coherent policies.
The study under examines the importance of local governance and technology innovation in sustainable biomedical waste management, leaves out comparative international viewpoints, and fails to empirically evaluate ground-level compliance.

3. ” Journal of Pharmaceutical Policy and Practice, 2023[7]

Anita Kotwani, Ajita Kapur, Mihir Chauhan, and Sumanth Gandra examine how pharmaceutical manufacturers in Telangana and Haryana handle effluents that might contain antibiotic residues in their paper, Treatment and Disposal Practices of Pharmaceutical Effluent Containing Potential Antibiotic Residues in Two States in India, which was published in the Journal of Pharmaceutical Policy and Practice (2023). The report highlights the significant disparities in business practices between small and medium-sized businesses and multinational firms through interviews with industry groups, regulators, and civil society stakeholders. It draws attention to deficiencies in effluent treatment, the State Pollution Control Boards' limited ability to monitor, and differing opinions about how industrial effluents contribute to antibiotic resistance.

In addition to evaluating stakeholder and regulatory viewpoints on AMR, the article attempts to analyse wastewater treatment and disposal techniques in India's pharmaceutical centres. The study lacks quantitative measurements of effluent pollution, has a narrow geographic focus, and offers neither long-term policy assessments nor comparable international viewpoints.

[7] Kotwani A, Kapur A, Chauhan M, Gandra S. Treatment and disposal of pharmaceutical effluents with antibiotic residues in India and stakeholder perceptions on antimicrobial resistance: a qualitative study. Journal of Pharmaceutical Policy and Practice. 2023;16-59.

Chapter 3

India's Regulatory Framework for Biochemical Manufacturing

3.1 Indian Environmental Regulations: Hazardous Waste, Emissions & Biosafety in Biochemical/Biopharma Manufacturing

India has a thorough legal and technical framework for environmental regulations that cover hazardous waste, pollutants, and biosafety in the biochemical and biopharmaceutical production industry, but its actual efficacy varies. The Biomedical Waste Management Rules, 2016 and the Hazardous & Other Wastes (Management & Transboundary Movement) Rules, 2016 provide the legal foundation for approval and enforcement, prescribe manifesting, segregation, and treatment standards, and clearly define the legal obligations of generators, transporters, and treatment facilities. In addition to these, the Central Pollution Control Board has created sectoral effluent and emission schedules and industry-focused instructions, including draft pharmaceutical industry guidelines, that specifically identify pharmaceutical active ingredients (APIs), solvents, and process chemicals as pollutants that need specialised treatment and, in certain situations, technologically advanced or zero-liquid-discharge solutions. The Department of Biotechnology (DBT) and the Review Committee on Genetic Manipulation (RCGM) have established a tiered biosafety governance structure for labs and manufacturing facilities by requiring institution-wide Biosafety Committees, containment-level designations, and regulatory approvals for recombinant and high-risk work in order to address biological risk.

Even with this robust legal framework, monitoring research and evaluations that document the presence and movement of antibiotics and other pharmaceutical residues in Indian aquatic environments show that API discharges from production clusters and poorly treated effluent continue to pose a threat to the environment and public health, demonstrating that technical standards are not consistently translated into efficient pollution reduction[8]. A lack of adequate treatment facilities at the scale needed for pharma-specific pollutants (many CETPs and on-site ETPs are not built or operated to eliminate APIs or cytotoxic compounds), inconsistent capacity and inspection quality among State Pollution Control Boards, and under-resourced or poorly constituted biosafety oversight at the institutional and regional level are

[8] Padmanabhan, A., Reddy, R. S., & Sharma, S. (2017). *MODERN BIOTECHNOLOGY AND INDIA'S GOVERNANCE IMPERATIVES*. Carnegie Endowment for International Peace.

the main causes of this implementation gap, as well as the results of official audits and the literature. Due to market and customer demand, major, export-oriented firms and structured parks frequently achieve or surpass norms, whereas smaller businesses, informal clusters, and some healthcare generators frequently fall short[9]. These factors together produce geographically varied results. Thus, there are practical priorities that are shared by the combined research and policy literature improve CETP/ETP design standards for API elimination and performance-based KPIs; implement interoperable electronic manifests and public dashboards for traceability; bolster institutional biosafety and SPCB capacities through external audits and designated funding and align roles among MoEFCC/CPCB, SPCBs, and DBT/RCGM to close response and inspection gaps. The regulatory framework can significantly lower hazardous-chemical and biosafety hazards when these steps are taken; without them, legislative completeness alone cannot guarantee constant protection.

3.2 Regulatory and Institutional Challenges of Small and Medium Biochemical Firms in India and Their Implications for Environmental Performance

The environmental performance of small and medium-sized biochemical companies in India is significantly hampered by a complex web of institutional and regulatory obstacles. First, businesses must traverse hazardous waste regulations, biomedical waste standards, CPCB effluent standards, and biosafety/DBT requirements. They sometimes lack the internal legal or technical teams that bigger organisations have[10]. This makes the regulatory framework complicated and requires a lot of compliance. Due to the combination of this compliance load, restricted access to finance, and economies of scale, many SMEs put off or underinvest in safe hazardous waste management, solvent recovery, and appropriate effluent treatment. Although SMEs are aware of environmental best practices, they lack formal environmental management systems and the resources necessary to regularly execute them, according to empirical surveys and sector studies[11].

Second, a recurring challenge is the lack of infrastructure and technology. Many SMEs rely on common biomedical waste facilities or common effluent treatment plants (CETPs),

[9] Ibid
[10] Lanoszka, A. (2023). The Global Politics of Intellectual Property Rights and Pharmaceutical Drug Policies in Developing Countries. *International Political Science Review / Revue Internationale de Science Politique*, *24*(2), 181–197.
[11] Ramakrishna, K. (2012). The Emergence of Environmental Law in the Developing Countries: A Case Study of India. *Ecology Law Quarterly*, *12*(4), 907–935.

which are inadequately planned for pharmaceutical-specific pollutants (APIs, cytotoxics, and solvents) and have variable intake quality, inefficient operation, and inadequate maintenance budgets. Pharmaceutical residues are found downstream of production clusters, according to scientific studies and field investigations. This suggests that traditional municipal or badly maintained CETPs are unable to effectively remove APIs, which has negative effects on the environment and public health (including contributing to antimicrobial resistance) [12]. Because technically suitable, cost-effective treatment methods are not accessible at their size, SMEs that operate inside or supply such clusters are more likely to release improperly treated wastewater, even in the presence of legislative regulations.

Third, non-compliance is made worse by institutional flaws in both companies and authorities. While centralised biosafety oversight (IBSCs, RCGM interfaces) tends to be inconsistent in capability and transparency, leaving many small biotech firms uncertain about approval pathways for higher-risk processes and waste-inactivation protocols, state pollution control bodies frequently struggle with staffing shortages, inadequate laboratory capacity, and weak inspection regimes, making enforcement uneven and predictable only in high-visibility cases[13]. Together, these factors lead to lower biosafety standards in smaller facilities without specialised biosafety officers, regulatory ambiguity, and delayed permits for process modifications.

These institutional, technical, and regulatory limitations result in observable environmental consequences, such as periodic CETP failures, inappropriate storage or informal disposal of hazardous waste, detectable API loads in wastewater, and repeated enforcement actions that occasionally result in closure orders or fines—outcomes that harm the firms' access to markets and the health of the community. Therefore, in order to translate India's comprehensive regulations on paper into consistent environmental outcomes on the ground, the literature suggests specific solutions for SMEs, such as subsidised access to pharma-grade CETP upgrades or mobile advanced-treatment units, incentives for the implementation of simple environmental management systems, common funding mechanisms for shared facilities, more detailed biosafety guidance and capacity-building for IBSCs, and more robust but predictable enforcement by adequately resourced SPCBs.

[12] Supra note 7
[13] MANNING, R. A. (2020). *Emerging Technologies: New Challenges to Global Stability*. Atlantic Council.

3.3 India's Environmental and Biosafety Frameworks for Biochemical Manufacturing: Comparison and Reform Options

Although India's environmental and biosafety regulations for the production of biochemicals and biopharmaceuticals are in line with many international standards, they are not entirely up to date with regard to technological specificity and best practices. The Central Pollution Control Board (CPCB) and the MoEFCC have established sectoral effluent and emission standards, pharmaceutical-focused guidance is currently being formalised, and India has a layered biosafety regime that is centred on Institutional Biosafety Committees (IBSCs), DBT/RCGM oversight, and ICMR/WHO-aligned laboratory guidance. These components, on paper, reflect international expectations for containment, permitting, and institutional oversight. International standard procedures, however, go one step further in two related ways: (1) they integrate mandatory advanced treatment techniques (e.g., performance standards that specifically require the elimination of active pharmaceutical ingredients (APIs) and monitoring for ARGs with stringent, chemistry-specific emission limits; and (2) they establish strong, transparent biosafety governance with regular third-party audits, accreditation pathways, and quick incident-reporting mechanisms[14]. Though India has led the way in ambitious regulatory measures, such as recent CPCB draft guidance classifying pharmaceutical sub-sectors and proposals to limit antibiotic residues in effluents, operationalising API-specific limits and integrating advanced oxidation or other tertiary treatments at scale are still uneven.

Empirical and review literature show that detectable levels of antibiotics and other pharmaceutical residues remain in downstream of Indian production clusters, demonstrating gaps between statutory limits and treatment performance; in contrary, jurisdictions viewed as models combine enforceable pollutant level restrictions with mandatory technology/effluent performance verification and open public data. In biosafety, India's DBT/RCGM framework and IBSC system are conceptually consistent with WHO and NIH models and serve as a necessary institutional scaffold; however, reviewers observe variability in IBSC capacity, inspection reach, and openness; international best practices increasingly favour formal accreditation of high-containment facilities, standardised national inspection teams, and public reporting of high-risk approvals— mechanisms that could minimise regulatory uncertainty. Possible reforms that bridge India's current position and global standards involve transforming

[14] URPELAINEN, J. (2022). INTERNATIONAL POLITICAL ECONOMY AND GLOBAL ENVIRONMENTAL POLITICS. In *Global Environmental Politics: The Transformative Role of Emerging Economies* (pp. 24–57).

CPCB's pharmaceutical guidance into binding, phased pollutant limitations for priority APIs coupled with enforceable performance metrics for CETPs/ETPs and providing funding or pooled financing for SME access to tertiary treatments (e.g., ozonation/AOPs) shown to eliminate APIs; and setting up a national biosafety accreditation and regular third-party auditing system for BSL-3/BS

To summarise, India's enforcement framework is largely in line with global norms, but advancing results calls for (a) shifting from descriptive standards to binding, chemistry-specific operational rules backed by scalable treatment financing, and (b) bolstering biosafety surveillance through certification, audits, and more transparency—reforms that are feasible and would significantly enhance environmental and safety performance instead of imposing unrealistic burdens.

Chapter 4

Findings

4.1 Compliance Patterns

An examination of compliance patterns in India's biochemical and biopharmaceutical sector reveals significant variability across firms and regions. Larger multinational corporations (MNCs) and export-oriented units generally demonstrate higher compliance levels, driven by reputational concerns, international client requirements, and access to technical expertise. Many of these firms maintain in-house environmental management systems (EMS), conduct regular audits, and invest in effluent treatment plants (ETPs) to meet both domestic and global standards. ISO 14001 certification and sustainability reporting are increasingly common among such entities.

By contrast, compliance among small and medium enterprises (SMEs) remains inconsistent. CPCB and SPCB reports highlight frequent violations of effluent discharge standards in pharmaceutical hubs such as Hyderabad (Telangana), Baddi (Himachal Pradesh), and Ankleshwar (Gujarat). Many SMEs rely on common effluent treatment plants (CETPs), which often operate beyond capacity or suffer from poor maintenance. Instances of untreated effluents being discharged into local water bodies are widely documented, contributing to river and groundwater contamination. Monitoring data also suggest a gap between "paper compliance" and "actual compliance." Firms may obtain consents-to-operate from SPCBs, but inspections are irregular, and self-reporting mechanisms lack independent verification[15]. A 2019 CSE study found that in Baddi, several pharmaceutical firms declared compliance despite downstream water samples showing excessive levels of antibiotics and heavy metals.

Enforcement actions, where they occur, are uneven. SPCBs occasionally issue closure notices or impose penalties, but such measures are often short-lived due to political pressures, industry lobbying, or the risk of disrupting local employment. Consequently, deterrence is weak, and violations recur. Judicial interventions, especially by the National Green Tribunal (NGT), have forced stricter enforcement in some cases, but reliance on litigation underscores the systemic weakness of administrative enforcement.

[15] Supra note 5

Overall, compliance patterns indicate a dual reality: while larger firms align with environmental standards and international best practices, SMEs often lag behind, undermining the overall effectiveness of India's regulatory framework.

4.2 Case Studies

A series of case studies illustrate the environmental challenges posed by the biochemical industry. In Hyderabad's pharmaceutical cluster, decades of untreated discharges into the Musi River have created one of the world's highest concentrations of antibiotic residues in surface water. A 2017 study published in *Environmental International* found antibiotic levels near manufacturing sites that exceeded safe thresholds by several orders of magnitude. This contamination has been linked to the spread of antimicrobial resistance (AMR), a major public health concern. Despite repeated CPCB interventions, enforcement remains sporadic, with SMEs citing financial inability to upgrade treatment facilities.

In Baddi, Himachal Pradesh, one of India's largest pharmaceutical hubs, CETPs designed to treat effluents from multiple firms often fail to meet prescribed standards. Inspections by the Himachal Pradesh SPCB in 2018 revealed that untreated industrial waste was directly entering the Sirsa River, affecting both aquatic life and downstream drinking water sources[16]. Local NGOs have reported increased respiratory and dermatological ailments in nearby communities.

Smaller firms face unique challenges. For example, in Gujarat's Ankleshwar cluster, SMEs complained that the cost of effluent treatment—estimated at nearly 15–20% of production costs—erodes competitiveness. Many operate on thin margins and thus either bypass treatment or depend on underperforming CETPs. Financial constraints, combined with weak enforcement, perpetuate a cycle of non-compliance. These case studies demonstrate how pollution incidents are not isolated but systemic, particularly in clusters dominated by SMEs. They highlight the urgent need for stronger institutional capacity, financial support mechanisms, and credible enforcement.

[16] Institute for Global Environmental Strategies. (1998). Environmental Governance and Chemical Industry: - Chemicals -. In *Business and Environmental Governance* (pp. 47–57

4.3 Biosafety Regulation Effectiveness

Biosafety regulation in India operates under the 1989 Rules framed under the EPA, with oversight from the Genetic Engineering Appraisal Committee (GEAC) and supporting committees. On paper, the framework covers laboratory practices, field trials, and industrial use of genetically modified organisms (GMOs). Institutional Biosafety Committees (IBSCs) within firms and research institutions are tasked with ensuring compliance at the operational level. In practice, however, biosafety regulation remains underdeveloped. Scholars note that the GEAC is often overburdened, handling both agricultural biotechnology approvals and industrial biosafety cases[17]. This dual responsibility dilutes its focus on the biochemical sector. Reports suggest that inspections of industrial facilities handling GMOs are infrequent, and much of the monitoring depends on self-reporting by firms.

Awareness and technical expertise at the SME level are limited. Many smaller firms engaging in recombinant DNA research lack robust biosafety protocols, partly due to cost constraints and partly due to inadequate training. This creates risks of accidental releases and occupational exposure. Compared to international best practices, such as the EU's stringent risk assessment protocols or the U.S. NIH guidelines, India's biosafety oversight appears less rigorous. While there have been no reported large-scale biosafety accidents, the effectiveness of the system is questionable given its reliance on weak institutional capacity and limited transparency.

4.4 Implementation Bottlenecks

More than a lack of legislation, institutional and operational barriers compromise the efficacy of India's biochemical manufacturing regulatory framework. Overlapping mandates and unclear accountability result from the division of many bodies, including the DBT for technical advise, the GEAC for biosafety clearances, and the CPCB and SPCBs for effluents and emissions. The issue is made worse by a lack of institutional capability, particularly at the state level. SPCBs frequently lack the resources, qualified personnel, and suitable labs needed to keep an eye on intricate biochemical processes. Enforcement is mostly reactive, fuelled by judicial interventions rather than proactive control, and inspections are erratic.

[17] Sachin Chaturvedi. (2004). Biosafety Regulation: Need for Fine Balancing. *Economic and Political Weekly*, *39*(33), 3693–3697.

Costs associated with compliance further reduce the effectiveness of regulations for small and medium-sized businesses (SMEs). Due to tight profit margins and restricted access to financing, investing in biosafety measures and effluent treatment plants is frequently prohibitively expensive. Although there are group solutions like CETPs, their effectiveness is diminished by inadequate upkeep and a lack of accountability. Another layer of weakness is caused by political economy dynamics, since state governments, particularly in pharmaceutical hubs, usually place a higher priority on employment and industrial expansion than on stringent enforcement. As a result, penalties and closure orders are frequently rescinded or modified. India's regulatory framework will continue to fail to produce satisfactory environmental and biosafety results in the absence of improved institutional capacity and procedures to facilitate compliance for SMEs.

4.5 Comparative Insights

Comparing India's regulatory framework with OECD/EU systems reveals both strengths and weaknesses. India has a broad legal foundation covering hazardous waste, EIA, chemical safety, and biosafety comparable in scope to international regimes. However, enforcement capacity and institutional coherence lag behind.

In the EU, the precautionary principle underpins stringent risk assessments, while REACH regulations place the burden of proof on industry to demonstrate safety. The U.S. EPA similarly enforces strict monitoring, backed by strong laboratory infrastructure and penalties. By contrast, Indian regulators struggle with manpower shortages, limited transparency, and political pressures.

Furthermore, while OECD countries actively support SMEs through subsidies, technical assistance, and green technology funds, Indian SMEs face compliance costs with minimal state support. This divergence explains why international systems achieve higher compliance levels despite similar industrial pressures. India's challenge is not legal design but ensuring credible implementation and industry support mechanisms.

Chapter 5

Suggestions & Conclusion

The research of India's environmental management of the biochemical and biopharmaceutical sectors reveals a continuous gap between comprehensive rules on paper and inconsistent implementation in practice. To close this gap, changes must be multifaceted, concentrating on institutional strengthening, technical advancement, and industry-specific support systems. First, regulatory bodies such as the CPCB, SPCBs, and GEAC require more capacity in terms of technical personnel, laboratory facilities, and electronic monitoring systems. Establishing independent inspection wings and providing SPCBs with real-time effluent monitoring technology can boost transparency and lessen reliance on litigation-driven enforcement. Inter-agency collaboration also requires formalisation through integrated platforms that align the missions of the MoEFCC, DBT, and SPCBs, minimising redundancy and regulatory ambiguity for industry.

Second, SMEs require tailored assistance since their compliance deficiencies are frequently due to resource restrictions rather than intentional inaction. The state might create a pooled financing mechanism or a green technology fund to support access to sophisticated wastewater treatment technologies like ozonation and advanced oxidation processes (AOPs), which are otherwise prohibitively expensive on a small scale. Upgrading CETPs with pharma-specific treatment modules and establishing independent third-party audits of their operations might help communal facilities become more efficient. Simplified compliance processes, along with technical training programs for SME managers and biosafety officers, would improve environmental performance while minimising administrative responsibilities.

Third, biosafety regulations must be modernised to keep up with advancements in industrial biotechnology. A nationwide certification system for BSL-2/3 facilities, regular third-party audits of IBSCs, and a transparent incident-reporting procedure will help India meet OECD and EU criteria. Establishing a separate biosafety authority from GEAC's agricultural responsibilities might improve supervision and establish specialist capability for industrial biotechnology concerns. Integrating biosafety monitoring into a wider One Health framework, which connects environmental surveillance of antibiotic residues with public health data on antimicrobial resistance, will allow India to more effectively manage cross-sector concerns.

Finally, policy tools should move to a combination of regulatory stringency and incentive-based approaches. Mandatory pollution limitations for priority APIs, combined with reward systems for enterprises that surpass compliance, and access to international green money for sustainable production, might serve as both a deterrent and a motivator. Increased stakeholder engagement—via public compliance data dashboards, local community involvement in monitoring, and collaboration with civil society—would increase accountability and legitimacy even further.

In conclusion, India's biochemical industry is both an economic driver and a governance concern. While current legislation offer a solid framework, their efficacy is dependent on closing the enforcement gap, particularly in SME-dominated clusters, and harmonising domestic practices with international standards. India may establish a regulatory paradigm that combines economic competitiveness, environmental stewardship, and public health protection through institutional changes, technical improvements, financial assistance for SMEs, and transparent biosafety governance. Such a trajectory not only protects ecosystems and communities, but also positions India as a responsible worldwide leader in sustainable biopharmaceutical production.

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