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REGULATORY SYSTEMS IN INDIA

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ABSTRACT

India incorporated environmental protection measures in the Constitution to implement decisions taken at International Conventions and Conferences. In addition, the Bhopal Gas Tragedy necessitated the Government of India to enact a comprehensive environmental legislation to mitigate externalities. On the basis of these, the Indian Parliament enacted the Environmental Protection Act, 1986. This is an umbrella legislation that consolidated the provisions of the Water Act of 1974 and the Air Act of 1981. Within the framework of the legislation(s), India established Pollution Control Boards (PCBs) in order to prevent, control, and abate environmental pollution. The focus of this article is to evaluate the functioning of PCBs (in particular, the State Pollution Control Board of Andhra Pradesh, and the Central Pollution Control Board, New Delhi) in relation to the prevention of externalities. The analysis of the paper is based on primary as well as secondary data. The data has been collected from published and un-published records. Based on the review of these documents, a questionnaire was prepared to obtain the opinion of the officials of PCBs on the functioning of the Boards. The primary emphasis was on the degree to which the objective of improving environmental quality in India has been fulfilled. The inferences drawn from the empirical analysis were then critically evaluated in the light of the theory of regulatory system. This provides insights into the effectiveness of providing incentives to

polluters to take precautionary measures. The study reveals that the regulatory system is unable to improve the environmental quality effectively and efficiently because of an increase in its responsibilities, and the absence of deterrence mechanisms within the PCBs for imposing fines against rogue industries.

INTRODUCTION

India's pharmaceutical regulatory system is overseen by the Central Drugs Standard Control Organization (CDSCO), which regulates drug approvals, clinical trials, and quality control under the Drugs and Cosmetics Act. Other key bodies include the Department of Chemicals and Petrochemicals (DCP) for policy, the National Pharmaceutical Pricing Authority (NPPA) for drug pricing, and state-level drug control organizations that work with CDSCO to issue manufacturing licenses and monitor quality.

Central Drugs Standard Control Organization (CDSCO)

The Central Drugs Standard Control Organization (CDSCO) is the Central Drug Authority for discharging functions assigned to the Central Government under the Drugs and Cosmetics Act. CDSCO has six zonal offices, four sub-zonal offices, 13 port offices and seven laboratories under its control. Regulatory control over the import of drugs, approval of new drugs and clinical trials, meetings of Drugs Consultative Committee (DCC) and Drugs Technical Advisory Board (DTAB), approval of certain licenses as Central License Approving Authority is exercised by the CDSCO headquarters. The primary regulatory body for drugs, cosmetics, and medical devices.

Responsible for approving new drugs, conducting clinical trials, and setting quality standards. Supervises the import of drugs and grants licenses for the manufacture of certain critical drugs like vaccines and blood products, working alongside state regulators The Drug Controller General of India (DCGI) heads the CDSCO The Indian government has announced its plan to bring all medical devices, including implants and contraceptives under a review of the Central Drugs and Standard Control Organisation (CDSCO). Within the CDSCO, the Drug Controller General of India (DCGI) regulates pharmaceutical and medical devices and is positioning within the Ministry of Health and Family Welfare. The DCGI is advised by the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC). Divided into zonal offices, each one carries out pre-licensing and post-licensing inspections, post-market surveillance, and drug recalls (where necessary). Manufacturers who deal with the authority required to name an Authorized Indian

Representative (AIR) to represent them in all dealings with the CDSCO in India. Drugs Controller General of India (DCGI) is the head of department of the Central Drugs Standard Control Organization of the Government of India responsible for approval of licences of specified categories of drugs such as blood and blood products, IV fluids, vaccines, and sera in India. Drugs Controller General of India, comes under the Ministry of Health & Family Welfare DCGI also sets standards for manufacturing, sales, import, and distribution of drugs in India.

DCGI lays down the standard and quality of manufacturing, selling, import and distribution of drugs in India.

- Preparation and maintenance of national reference standard.
- To bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.
- Training of Drug Analysts deputed by State Drug Control Laboratories and other Institutions
- Analysis of Cosmetics received as survey samples from CDSCO (central drug standard control organisation).

With the notification of Medical Device Rules 2017 by the Government of India, DCGI will also act as Central Licensing Authority (CLA) for the medical devices which fall under the purview of these rules. Out of four Classes of medical devices from Class A to Class D, DCGI will be the direct licensing authority for Class C and Class D devices, whereas it will coordinate licensing for Class A and B devices through State drug controllers, who will act as State Licensing Authority or SLA The government on 1 February 2023 appointed Dr. Rajeev Singh Raghuvanshi as Drug Controller General of India. The government earlier on 14 August 2019 appointed Dr. VG Somani as Drug Controller General of India (DCGI). Dr. VG Somani succeeded S Eswara Reddy, the interim DCGI who was appointed in February 2018. DCGI heads the Indian drug regulatory body the Central Drugs Standard Control Organisation (CDSCO), whose functions include ensuring the quality of drugs and cosmetics sold in the country, approval of new drugs and regulating clinical trials.

Key objectives and functions that support this mission include

- Setting Standards: Laying down comprehensive standards for drugs, cosmetics, diagnostics, and medical devices.
- Regulating Imports: Exercising regulatory control over the quality of all imported medical products into the country.

- Approving New Products and Clinical Trials: Granting marketing authorization for new drugs and regulating the conduct of clinical trials and bioavailability/bioequivalence (BA/BE) studies in India.
- Centralized Licensing: Serving as the Central License Approving Authority (CLAA) for certain critical categories of products, such as blood banks, vaccines, sera, large volume parenterals (LVP), and r-DNA products.
- Ensuring Uniform Enforcement: Coordinating the activities of state drug control organizations to ensure uniform administration and enforcement of the Drugs and Cosmetics Act and Rules across the country.
- Providing Expert Advice: Offering expert advice to help bring about consistency in the enforcement of the Act and associated rules.
- Monitoring and Surveillance: Conducting post-market surveillance, monitoring adverse drug reactions (ADR) through the Pharmacovigilance Program of India, and taking action against non-compliant or substandard products.
- Enhancing Regulatory Practices: Upgrading the quality of regulatory practices, building a science-based regulatory framework to support research and development, and conducting training programs for regulatory officials.
- Promoting Transparency: Striving for transparency, accountability, and consistency in all regulatory functions and processes and state licensing authority
- Central Drugs Standard Control Organisation (CDSCO): Headed by the Drugs Controller General of India (DCGI), the CDSCO is the national regulatory authority.

- **FUNCTIONS**
- Approval of new drugs and the conduct of clinical trials.
- Laying down standards for drugs, cosmetics, and medical devices.
- Controlling the quality of imported drugs.
- Granting licenses for certain specialized, critical categories of drugs like blood products, vaccines, and large volume parenterals (LVPs).
- Coordinating the activities of State Licensing Authorities to ensure uniform enforcement of the Act.
- Maintaining the Pharmacovigilance Programme of India (PvPI) to monitor adverse drug reactions.
- State Licensing Authorities (SLAs): These authorities operate at the state level.

- **FUNCTIONS**

Granting licenses for the manufacture, sale, and distribution of approved drugs within their respective states. Monitoring the quality of drugs and cosmetics by drawing samples from the market. Conducting pre- and post-licensing inspections of manufacturing and sales premises. Investigating and prosecuting in cases of violations of the Drugs and Cosmetics Act. National Pharmaceutical Pricing Authority (NPPA): Established in 1997, this body is responsible for fixing and revising the prices of controlled bulk drugs and formulations to ensure affordability and availability of essential medicines.

Regulatory System in India

The PCBs are a two-tier system, i.e., the Central Pollution Control Board (CPCB) at the central level and the State Pollution Control Boards (SPCBs) at the state level. Water Boards were established under the provisions of the Water Act of 197421 in order to prevent water pollution. The Boards later received the additional responsibility to control air pollution under the provisions of the Air Act of 1981. The Water Boards were then renamed as Pollution Control Boards under the provisions of the Environmental Protection Act of 1986. The responsibilities of PCBs increased with the adoption of environmental protection rules in the context of prevention of water pollution, supervision of hazardous wastes, implementation of court directions, etc

AIM

To study and understand the structure, role, and functioning of regulatory systems in India with special reference to healthcare, pharmaceuticals, food, and allied sectors, and to evaluate their importance in ensuring safety, efficacy, quality, and compliance with legal standards. this study helps to understand India's regulatory systems is to ensure compliance, protect public interests, and promote economic stability by understanding the complex framework of rules and agencies that govern various sectors. Key goals include fostering market fairness and competition, safeguarding consumers and investors, and improving governance through transparency and accountability. To safeguard consumers from malpractice, protect investor interests, and ensure the environment, health, and safety standards are met. To ensure the nation's financial stability, promote fair trade, encourage innovation and fair competition, and maintain confidence in the market.

OBJECTIVES

1. To provide an overview of the key regulatory authorities in India (e.g., CDSCO, FSSAI, AYUSH, NPPA, DCGI).
2. To analyze the roles and responsibilities of these regulatory bodies in governing drugs, medical devices, cosmetics, food, and traditional medicines.
3. To understand the regulatory framework that ensures safety, quality, and efficacy of products in the Indian market.
4. To identify the procedures for approval, licensing, and post-marketing surveillance of pharmaceutical and healthcare products.
5. To highlight challenges in the Indian regulatory system such as harmonization with global standards, delays, and enforcement issues.
6. To explore the impact of regulations on public health, industry growth, and international trade.
7. India's regulatory landscape is dynamic, with frequent updates to align with evolving economic conditions and technological advancements. Studying these systems helps businesses remain adaptable and compliant.
8. Studying India's regulatory systems provides critical insights for a wide range of stakeholders, including investors, business managers, policymakers, and academics. The primary objectives are to foster economic stability, ensure consumer and public safety, promote fair competition, and guide ethical business practices.
9. To suggest improvements in the regulatory system for enhancing transparency, efficiency, and global competitiveness.
10. A key objective is to foster a transparent regulatory environment where policymakers can be held accountable. This involves studying how regulatory bodies function and report their activities to the public.
11. Their shared objective is to ensure orderly market functioning, consistently enforce regulatory standards and strengthen the broader financial system against potential risks and disruptions. Their oversight has been instrumental in preserving financial stability through major global disruption

RESULTS AND DISCUSSION

Why Understand India’s Environmental Regulations?

India has emerged as one of the fastest-growing economies in the world in the 2010s. Its growth model, led by extensive natural resource extraction and consumption, has been

registering strong gross domestic product (GDP) growth. The cost of this growth has been the precipitous deterioration of environmental quality, with serious impacts on the environment and human health. Air pollution alone accounted for 1.4 million premature deaths in 2013, and in economic terms the welfare loss was estimated to be 7.7% of GDP. With an economy that is expected to continue to grow rapidly in or- der to feed millions of its people still living in poverty, an energy mix that is dominated by fossil fuels (coal accounts for 60%), and as a country vulnerable to large-scale impacts from climate change, India has also been a key player in global climate change discourse.

This article examines India's environmental regulatory regime. India presents an interest- ing case for a few reasons. First, the country instituted environmental laws as early as 1970s, when its democracy and economy were in their infancy, and around the same time most of the industrialized countries started enacting environmental laws. It has enacted several laws and regulations to protect its air, water, land, coastal areas, forests, biodiver- sity, and wildlife and a fairly elaborate institutional structure to enforce the regulations.

Second, it is one of only a few countries that have made environmental protection a con- stitutional responsibility of both the state and the citizens. Third, a vibrant democratic governance system provides spaces for non-state actors to participate and shape environ- mental governance, generating potentially innovative institutional mechanisms.

In analyzing India's environmental regulations, we draw on the academic and practitioner environmental literature from public policy, economics, law, and to some extent political science. The rich and complex story of India's regulatory regime requires that we draw boundaries for our article. Thus we predominantly focus on regulations related to pollu- tion control, recognizing that we exclude important and rich debates related especially to climate change, forests, and coastal zones. The goal of the article is to use pollution con- trol regulations as the context within which we discuss a wide range of issues central to debates surrounding environmental regulations and governance in India. Thus we focus less on specific pollution problems, such as air and water pollution, and more on regulato- ry structure, governance, institutions, and related debates.

The article is organized as follows. In the next section, we present the existing environ- mental regulatory system in India. We do this by identifying and discussing a few major themes related to the historical evolution of environmental regulations, starting from India's

independence in 1947. In the section that follows, we analyze the ongoing debates and regulatory initiatives that are likely to shape the future of environmental regulations in the country. We conclude with an overall assessment of the future of the environmental regulatory regime in India.

Over view of Environmental Regulatory Governance in India

In this section, we broadly present the origins of environmental regulations and their evolution to 2020. We organize the discussion in two phases: pre-economic liberalization and post-liberalization. Environmental regulations prior to liberalization were largely driven by the country's commitment to international environmental negotiations. Economic liberalization led to the expansion of private industry, including in the small-scale sector, of the number of vehicles, and of consumption in general. The rapid expansion and the changing nature of pollution, along with India's unique socioeconomic and political con- text, presented a new set of challenges for environmental regulation post-liberalization.

Thus it is logical to divide the discussion into these two phases.

Environmental Regulation in the Pre-Liberalization Era (1947–early 1990s)

Environmental regulation in pre-liberalization India (1947–early 1990s) was characterized by a fragmented system with limited scope, based on pre-independence laws and early post-independence measures like the Factories Act of 1948 and the Forest Act of 1927. This period sawa shift in focus after the 1972 Stockholm Conference, which spurred the creation of key laws such as the Water Act of 1974 and the Air Act of 1981, along with pollution control boards. However, the Bhopal gas tragedy of 1984 exposed the severe weaknesses in the system, leading to thecomprehensive Environment Protection Act of 1986 and the Public Liability Insurance Act of 1991.

A Brief History of Environmentalism in India

Environmental consciousness has been an integral part of the fabric of Indian society, interwoven into its history, culture, traditions, and politics. Historically both material and non-material considerations have shaped Indian environmentalism. Protection of communal access to natural resources, defense of livelihood, and concerns for health and well-being as a result of toxicity and degradation of the bios- phere were the primary material considerations while non-materi- al factors were mainly rooted in the biocentric beliefs of natives attributing divine status to nature and its elements. Sacred personifications of rivers and lakes, plains and

moun- tains, flora and fauna are widely found in native mythology, folklore, and the vernacular customs and practices of communities all across the country.

This blend of the material and the non-material has inspired many grassroots environ- mental movements, and the current state of environmental regulations is better under- stood against the backdrop of these environmental movements, the thought leadership that produced them, and the conflicts that defined the relationship of the people, the state, and the markets with the natural environment. One of the earliest and most influential people's environmental movements dates back to 1730 CE, when the vil lagers of Khejadli in the modern-day Jodhpur district of Rajasthan hugged the Khejri (Prosopis cineraria) trees to protect them from felling for timber by a royal party sent by Maharaja Abhai Singh of Marwar.1 In the ensuing conflict, 363 villagers of the Bishnoi community sacrificed their lives to protect the trees they considered sacred.

More than two hundred years later, the sacrifice of the Bishnois inspired the Chipko movement in a remote Himalayan village in 1973 when a group of peasants hugged the trees to stop commercial loggers. The Chipko movement, rooted in the prin- ciples of nonviolent resistance, turned out to be a harbinger of community-driven environ- mental movements in modern India. The earliest among the widely written about environ- mental movements in post-independence India, the Chipko movement also had distin- guishable traits of the Gandhian philosophy of nonviolent Satyagrah.3 The Chipko movement was a non-violent social and ecological movement in India, beginning in the 1970s, where villagers, particularly women, hugged trees to protect them from logging and deforestation. The Hindi word "chipko" means "to hug" or "to cling to," referring to this direct, peaceful action against commercial logging and the exploitation of natural resources. The movement advocated for forest conservation and highlighted the deep ecological connection between forests and the livelihoods of communities. The Chipko movement was a non-violent social and ecological protest that began in the 1970s in India's Himalayan region of Uttarakhand. The movement's name comes from the Hindi word "chipko," meaning "to hug" or "to cling," and it refers to the tactic of villagers physically embracing trees to prevent loggers from cutting them down. The movement's core goal was to protect forests from government-backed commercial logging, and it achieved a major victory in 1980 when a 15-year ban on green felling in the Himalayan forests was enacted.

The main slogan of the Chipko movement was "Ecology is Permanent Economy," which emphasized that protecting the environment was crucial for long-term economic health. This phrase was coined by environmentalist Sunderlal Bahuguna to counter the idea that economic development should come at the expense of nature The Chipko movement in due course became a prototypical inspiration for many others to follow—both the techniques of nonviolent civil resistance and the blueprints of Gandhian environmental ethics. Most of the conflicts that followed were due to industrial expansion and large resource extraction taking away livelihoods of local communities. Notable among them is the Narmada Bachao Andolan (Save Narmada movement) in the state of Gujarat and Madhya Pradesh, spearheaded by environmental activist Medha Patkar, against the construction of the Sardar Sarovar dam on the Narmada River.4.

Increased Environmental Pressure (Scale Effect): Economic liberalization often results in an expansion of private industry, consumption, and trade, which increases resource use, waste generation, and pollution levels. Studies in countries like India have shown an increase in air, water, and toxic metal pollution loads in the post-liberalization period

- Regulatory Response: The rise in environmental degradation and a growing awareness of environmental rights have spurred the creation of new, more stringent environmental regulations and institutions. For example, the Environmental Impact Assessment (EIA) notification in India.
- in 1994, and subsequent solid waste management rules, were direct responses to the challenges posed by rapid industrialization and urbanization.
- The "Pollution Haven" Hypothesis Debate: There is a concern that developing countries with weaker environmental standards may become "pollution havens," attracting polluting industries from developed nations looking to escape stricter regulations. While some evidence supports increased foreign direct investment (FDI) in pollution-intensive sectors in some developing nations, the overall evidence is mixed and often depends on the specific country and industry.

Environmental Impact Assessment Regulation

EIA regulations in India are governed by the Environment (Protection) Act, 1986 and the EIA Notification 2006, which mandates a comprehensive assessment of a project's potential environmental, social, and economic impacts before it is approved. The process involves project categorization (A and B), screening, scoping, public consultation, and expert appraisal

to ensure sustainable development. The regulations have been revised, with a significant 2020 draft amendment, though it faced criticism for its potential to weaken the process.

- Environmental Impact Assessment (EIA) is a process of evaluating the likely environmental impacts of a proposed project or development, taking into account inter-related socio-economic, cultural and human-health impacts, both beneficial and adverse.
- UNEP defines Environmental Impact Assessment (EIA) as a tool used to identify the environmental, social and economic impacts of a project prior to decision-making. It aims to predict environmental impacts at an early stage in project planning and design, find ways and means to reduce adverse impacts, shape projects to suit the local environment and present the predictions and options to decision-makers.
- Environment Impact Assessment in India is statutorily backed by **the Environment Protection Act, 1986** which contains various provisions on EIA methodology and process.

History of EIA in India

- The Indian experience with Environmental Impact Assessment began over 20 years back. It started in 1976-77 when the Planning Commission asked the Department of Science and Technology to examine the river-valley projects from an environmental angle.
- Till 1994, environmental clearance from the Central Government was an administrative decision and lacked legislative support.
- On 27 January 1994, the then Union Ministry of Environment and Forests, under the Environmental (Protection) Act 1986, promulgated an EIA notification making Environmental Clearance (EC) mandatory for expansion or modernisation of any activity or for setting up new projects listed in Schedule 1 of the notification.
- The Ministry of Environment, Forests and Climate Change (MoEFCC) notified **new EIA legislation in September 2006.**
  - The notification makes it **mandatory for various projects** such as mining, thermal power plants, river valley, infrastructure (road, highway, ports, harbours and airports) and industries including very small electroplating or foundry units **to get environment clearance.**
  - However, unlike the EIA Notification of 1994, the new legislation has **put the onus of clearing projects on the state government** depending on the size/capacity of the project.

Salient Features of 2006 Amendments to EIA Notification

- Environment Impact Assessment Notification of 2006 has decentralized the environmental clearance projects by categorizing the developmental projects in two categories, i.e., **Category A (national level appraisal)** and **Category B (state level appraisal).**
  - Category A projects are appraised at national level by Impact Assessment Agency (IAA) and the Expert Appraisal Committee (EAC) and Category B projects are apprised at state level.
  - State Level Environment Impact Assessment Authority (SEIAA) and State Level Expert Appraisal Committee (SEAC) are constituted to provide clearance to Category B process.

- **After 2006 Amendment the EIA cycle comprises of four stages**
  - Screening
  - Scoping
  - Public hearing
  - Appraisal
- **Category A projects** require mandatory environmental clearance and thus they do not undergo the screening process.
- **Category B projects** undergoes screening process and they are classified into two types.

  - **Category B1 projects (Mandatorily requires EIA).**

Category B2 projects (Do not require EIA).

- Thus, Category A projects and Category B, projects undergo the complete EIA process whereas Category B2 projects are excluded from complete EIA process.

The Future of Environmental Regulation In india

The future of environmental regulation in India is trending towards stricter enforcement, climate change focus, and integrating sustainability across sectors. Key developments include new laws for contaminated sites and climate change adaptation, updated eco-labelling rules, and efforts to strengthen implementation through technology and public participation. Balancing economic growth with environmental protection will continue to be a central challenge, with potential improvements in enforcement through greater public participation and technological integration. India has registered robust economic growth (as measured by GDP) since the introduc- tion of economic reforms in 1991; this growth, however, has been accompanied by deteri- orating environmental quality (e.g., EPI, 2019). A wide range of environmental legisla- tion, many regulations, and an elaborate institutional

structure to enforce the regulations have been put in place since the early 1980s. The empirical evidence on the effectiveness of these predominantly CAC regulations has been sparse, but the limited evidence shows only small pockets of success (e.g., Greenstone & Hanna, 2014). First, the tension between developmental concerns and deteriorating environmental qual- ity will continue to be one of the central features of the debates surrounding environmen- tal regulations. A case in point is the ongoing story of the implementation of environmen- tal standards for coal-fired power plants. In India, thermal power plants account for ap- proximately two-thirds of the electricity produced (Guttikunda, Jawahar, & Goenka, 2015), and an estimated 85,000–115,000 premature deaths are attributable annually to fine particulate matter (PM2.5) pollution from coal plants (Guttikunda & Jawahar, 2014). In December 2015, the MoEF and CC had established standards for sulfur dioxide, nitro- gen oxides, and mercury from coal-fired power plants and set a deadline of December 2017 to comply with the new standards (Shrivastava, 2017). No coal plant complied with the norms by the deadline and it was eventually extended by a further five years to 2022 (Garg, Narayanaswamy, Ganesan, & Viswanathan, 2019), although studies show that the human health benefits of complying with the norms outweigh the costs to industry (e.g., Srinivasan et al., 2018). This shows how economic concerns (with coal being perceived as central to India's energy mix in the foreseeable future) override environmental regula- tions, and regulations will continue to be influenced by this economy vs. the environment tension. Second, India's experiments with alternative instruments such as market-based instru- ments and public disclosure programs are likely to continue. The learnings from the rela- tively successful implementation of the PAT trading program for energy efficiency could pave the way for similar economic incentive-based policies to control local pollution. In fact, a cap and trade program for particulate matter pollution was launched in August 2019 in Surat, a densely populated industrial city in Gujarat (Down to Earth, 2019). An- other example of the use of economic instruments is a variant of the deposit refund system, mandated under the Batteries (Management and Handling) Rules, 2001 in which consumers receive discounts from retailers on new automotive batteries when they re- turn their old batteries (Gupt, 2015).

Third, public activism, especially by approaching higher courts, has been instrumental in the small gains that India has made in controlling pollution through environmental regu- lations (e.g., Greenstone & Hanna, 2014). While the limits to implementation of regula- tions through courts is well acknowledged, public activism in the form of research, advo- cacy, and

even protests will continue to play a significant role in improving the effective- ness of regulations. The increasing salience of air pollution as a problem in the country and the public demand for improving air quality is a good example. While the focus has been on Delhi for several years, efforts in the form of new data on air quality and advoca- cy of environmental groups such as the Center for Science and Environment and Green- peace (e.g., Greenpeace, 2017) has made air pollution a salient issue nationally. In re- sponse, the MoEF and CC in January 2019 released a National Clean Air Programme (NCAP) and acknowledged that more than 100 cities in the country do not meet National Ambient Air Quality Standards (NAAQS) and require serious attention, including targets and a plan for air pollution mitigation (MoEF & CC, 2019). Emerging low-cost technolo- gies to measure personal exposure to ambient air pollution, it is hoped, will further aid public activism to demand better air quality (e.g., Arasu, 2018).

National Ambient Air Quality Standards (NAAQS) are the limits for air pollutants set by a country to protect public health and the environment. In India, the Central Pollution Control Board (CPCB) sets these standards, which are based on a health-based approach and currently cover 12 pollutants, including PM2.5, NO2, SO2, and others. These standards ensure uniform air quality for the entire country, regardless of land use, and are monitored under the National Air Quality Monitoring Programme (NAMP).

Regardless of the instruments employed, the sustained success of environmental regula- tions will eventually depend on the ability of countries to build strong formal regulatory institutions (e.g., Blackman, 2010). Successful implementation of economic instruments in developing countries, for example, requires strong institutions that can strictly monitor and enforce pollution permits or fees, reduce transaction costs, and operate transparent- ly in order to build trust with industries and the public (e.g., Blackman, 2009; Coria & Sterner, 2010; Greenspan Bell & Russell, 2002). Similarly, informal regulation (e.g., com- munity pressure) in developing countries is more likely to influence polluter behavior in the presence of strong formal institutions (e.g., Féres & Reynaud, 2012; Zhao, 2019). It is clear from our review that India's regulatory institutions historically have been weak.

Thus, in the Indian context the key would be the political will to reform and strengthen existing regulatory institutions. This could involve allocation of greater resources for monitoring and enforcement, bringing more transparency in regulatory actions, and re- forming institutional structures to better represent the larger public interest (e.g., Lele &

Sahu, 2017). The proposal to create a new environmental regulatory authority in 2010 provided a context in which to debate ideas on reforming and redesigning regulatory institutions (e.g., Lele, Dubash, & Dixit, 2010; Sahu, 2018), and it would be helpful if such debates became central to the efforts to improve regulatory effectiveness. An emerging alternative view presents a critique of the prevailing industrialization-led economic development model itself and argues for an alternative model more in align- ment with the Gandhian principles of economic organization (e.g., Shrivastava & Kothari, 2012). The advocates of this model argue that after almost three decades of economic lib- eralization and strong GDP growth, the country still has millions of people with unfulfilled basic needs.16 The same period has witnessed widening economic inequities (e.g., Ghosh, 2015) and worsening environmental degradation (e.g., Guha, 2016), which disproportion- ately affects the poor and the vulnerable. Thus they advance a model that would be based on the decentralization of decision-making to local governments and communities, local- ization of economies (as opposed to globalization), and one that relies on more delibera- tive and participatory mechanisms of governance (e.g., Kothari, 2016).

To conclude, few would disagree that India's environmental quality has experienced sig- nificant deterioration, at least since the beginning of the economic reforms in 1991. This can be stemmed only with an approach that is open to experimenting with a variety of regulatory approaches and perhaps with alternative models of development where environmental protection is not inherently viewed as a trade-off with economic development.

SUMMARY AND CONCLUSION

The study focused on the evaluation of the functioning of the Pollution Control Boards (PCBs) with the goal of determining whether the regulatory system is effective in preventing environmental pollution in India. Since the market and the liability systems are unable to provide incentives to the polluter to reduce pollution, there is a need for the regulatory system to prevent, control, and abate environmental pollution in the country. The PCBs were established under the provisions of the Water, Air and EP Acts in order to fulfil the objectives of formulating environmental standards, monitoring them, issuing consents for the establishment and operation of industries, and advising the Courts and the Government on scientific and technicalities of environmental issues. Our study is based on primary and secondary data. The insights obtained from the data were used to prepare questionnaires that were then submitted to the officials of the PCB's to get their opinion on the functioning of the

PCBs. We have critically analysed the data and the opinions of the PCB officials in the light of the theory of the regulatory system to determine the role of an ex-ante system in abatement of pollution in the country. The study reveals that the role of the Board is of great importance in preventing, controlling, and abating environmental pollution in the country. The PCBs however, are ineffective in ensuring internalization of environmental concerns in the process of economic development. This is mainly because of the responsibilities of are manifold, inadequate technical and scientific staff, prevalence of uncertainty over resource base, presence of the influence of the interest groups, existence of jurisdictional problems, absence of punitive measures, non-existence of minimum sampling tests manual, lack of effective and efficient working culture, and non-disclosure of information about the activities of the hazardous industries. Thus, there is a need to introduce policies on restructuring of the existing PCBs, establish competitive environment, empower PCBs to impose fine against rogue industries, incentive mechanism for the personnel, reduce the revenue generation responsibility and provide financial assistance directly from the Ministry of Finance. Overall, the study emphasises the necessity of improving the functioning of the regulatory system by making necessary changes not only in substance of the law, but also in the working conditions of the PCBs so as to improve the environmental quality in the country. Regulatory bodies protect the environment by establishing and enforcing environmental laws, setting pollution standards, and ensuring compliance from industries through a system of clearances, monitoring, and penalties. They play a crucial role in conserving natural resources, managing waste, and promoting sustainable development by overseeing activities like pollution control, resource extraction, and biodiversity preservation. Key functions include issuing permits, conducting inspections, managing hazardous and e-waste, and creating policies to address climate change Studying regulatory systems in India involves a comprehensive look into the frameworks, institutions, and policies that govern the nation's diverse sectors. Fueled by post-1991 liberalization, this field has become critical for understanding India's shift from a state controlled economy to a regulatory state.

This includes analyzing the statutes, judicial decisions, and constitutional aspects that shape regulation in India. Central to this is the establishment of statutory independent regulatory agencies, which are accountable to Parliament but operate with a degree of autonomy from government ministries. Studying the specific roles, powers, and performance of key regulatory bodies in different sectors is essential. Prominent examples include India's pharmaceutical industry is regulated by multiple bodies at both central and state levels,

operating under the umbrella of the Drugs and Cosmetics Act of 1940. These organizations work together to ensure the safety, efficacy, and quality of medicines available in the country India's pharmaceutical regulation is a multi-layered system involving both central and state bodies. The CDSCO and IPC handle drug approvals and quality standards, while the NPPA controls drug pricing. State authorities are responsible for local enforcement and licensing, ensuring a decentralized yet coordinated approach to safeguarding public health The Water Act of 1974 established the Central Pollution Control Board (CPCB) and State Pollution Control Boards (SPCBs) to prevent and control water pollution, providing a formal structure for enforcement. In early 2024, the government introduced and passed an amendment bill to the Water (Prevention and Control of Pollution) Act, 1974 The amendment removed imprisonment as punishment for several violations, replacing it with monetary penalties ranging from ₹10,000 to ₹15 lakh. The main aim of studying an environmental protection act is to understand the legal framework and mechanisms for safeguarding and improving the environment The Central Pollution Control Board (CPCB) functions as the national authority for pollution prevention and control in India. Its key duties include advising the Central Government on pollution issues, coordinating with State Pollution Control Boards, and developing and implementing a nationwide program to control water and air pollution. The CPCB also conducts research, collects data, sets pollution standards, provides technical assistance, and runs public awareness campaign

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3. “They are largely born by the regulatory agency, which has the task of formulating, monitoring, and enforcing standards”. See, for instance, Anthony I. Ogus, Regulation: Legal Forms and the Economic Theory, Oxford, Clanrendon Press, 1994; 155.
4. “They are the capital expenditure on equipment and adoption of plant to meet the standard”. Ibid.

5. "They fall under the category of productive inefficiency, the inhibition of technology, and allocative inefficiency. The assessment of indirect costs is problematic because relevant effects which are widespread and data is difficult to obtain". Ibid.
6. C. D. Kolstand et. al., "Ex-post Liability for Harm vs. Ex- ante Safety regulation substitutes or complements? 80, American Economic Review, 1990; 888.
7. R. Ellikson, "Alternatives to Zoning: Covenants, Nuisance, and Fines as Land Use Controls", University of Chicago Law Review, Vol. 40, Summer, 1973; 681-781.
8. Supra note 1 at p. 257.
9. Under the provisions of the Articles 251 and 254.
10. The Water (Prevention and Control of Pollution) Act, 1974 was enacted by the Parliament after consent resolutions were passed by 12 State Legislatures.
11. The Bhopal Disaster of 1984; December, 3.
12. Water is a subject in the State List under the Constitution (Entry 17, List II, Seventh Schedule). So the Act was enacted by the Parliament after consent resolutions passed by 12 State Legislatures under Article 252 (1) of the Constitution.
13. One chairman; 5 members the representatives of government; 3 members from industry, agriculture and trade; 2 members from the PSUs; and a Member Secretary- all are nominated by Central Government.
14. They are at Lucknow, Bhopal, Shillong, Kolkata, Vadodara, and Bangalore.
15. Under the provisions of the Water and the Air Acts, 1974 and 1981; respectively.
16. Under section 25 of the Environmental Protection Act, 1986; The State Pollution Control Board (SPCBs) must take into the consideration these standards while issuing consents to the industries.
17. Santhosh Illendula, Sindhuja PL, Suresh ChV, Rao, KNV. A novel validated RP-HPLC method for the estimation of remdesivir in bulk and pharmaceutical dosage form. Int J Adv Res Med Pharm Sci., 2023; 8(1): 58–67.
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19. In a study (Inventorisation of Hazardous Waste Generation), the CPCB found that the hazardous wastes generation in 8 states (Gujrat, J&K, Punjab, Kerala, Andhra Pradesh, Madhya Pradesh, National Capital Region and Orrissa) accounted for 19 lakh tpa.

http//www.nic.in/envfor/cpcb/cpcb.html.

20. Section 25 and 26 of the Act provides for refusal or withdrawal of consent by the Boards. Section 33 of the Act empowers the Boards to make an application for directions to the Court of a Judicial Magistrate, where the Boards apprehend pollution. Section 33- A (53 of 1988) further empowers the Boards to direct the closure of polluted industries by regulation of supply of electricity, water or other sources.
21. The Water (Prevention and Control of Pollution) Act., 1974; (Amendment, 1988).
22. Under the Water (Prevention and Control of Pollution) Cess Act, 1977.
23. Under the Air (Prevention and Control of Pollution) Act, 1981; (Amendment, 1987)- Noise Pollution has been added as an air pollution in 2000.
24. Chairman of the Board may convene a meeting whenever there is urgency- Section 8 and 10 of the Water and the Air Acts, respectively Section 21 and 26 of the Water and the Air Acts, respectively.
25. Section 33 (A) and 31 (A) of the Water and the Air Acts, respectively. However, the industries can approach Appellate Tribunal and even go up to Apex Court of India in order to get remedial measures against disputed closure orders passed by the Board.
26. Section 25 and 21 of the Water and the Air Acts, respectively.