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From Biosafety to Liability: Examining India's Legal Framework for Regulation of Genetically Modified Organisms

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Regulation of GMOs in India is a mixed cocktail of science, environmental law, constitutional mandate, and socio-economic aspects. Whereas biotechnology gives rise to the possibility of enhancing agricultural output, food security and sustainability, while coping with a changing climate, on the other hand, it generates many other vital aspects of concern like bio safety, environment, public health and responsibility. In this research paper, an attempt has been made to critically examine the existing Indian legal regime for GMOs, more specifically, the progression from bio-safety aspects to the concept of liability measures. The paper will focus on laws such as the Environment Protection Act, 1986 and the Rules for Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989 and also upon various other legislations like the Biological Diversity Act, 2002 and the Food Safety and Standards Act, 2006. Further assessment is made in the research about the institutional involvement of GEAC and the judicial pronouncements affecting the regulation of GMOs. The issues concerning judicial apprehensions on biosafety procedures, transparency, and accountability of regulation are discussed through an analysis of landmark cases such as Aruna Rodrigues v Union of India and Gene Campaign v Union of India. The research further considers the inadequacy of a liability framework covering the damage inflicted by GMOs on humans and ecosystems.

Finally, reforms are recommended in the research on how India can regulate the genetic modification of organisms to comply with international obligations such as the Cartagena Protocol on Biosafety, but still maintain its ecological and constitutional interests.

Keywords: *genetically modified organisms, biosafety regulation, liability framework, environmental law.*

INTRODUCTION

Genetically Modified Organisms (GMOs) are among the most innovative endeavours that the field of modern biotechnology has witnessed. Manipulating the genetic makeup of organisms has helped certain traits to emerge in crops, such as tolerance to pests and drought, as well as the enhancement of nutritional value. For India, whose majority population depends on agriculture and has increasing food demands, the prospects offered by the GM technology are immense. However, the introduction of GMOs has also led to varied legal, ethical, and environmental concerns.

The Indian regulatory framework for genetically modified organisms is largely based on environmental law. The Environment Protection Act, 1986 (EPA) provides for a comprehensive set of rules for regulating activities relating to genetically modified organisms.[1] These regulations comprise a hierarchical system of regulation, wherein GEAC acts as the highest authority for granting clearances. Though there exists this regulatory mechanism, there are still questions about biosafety, risk assessment, and regulatory transparency. The licensing of genetically modified crops, such as Bt cotton, which is the only genetically modified crop licensed in India, has been a controversial issue. With the proposal for genetically modified mustard, there have been more controversies, leading to a split decision in the Supreme Court of India in 2024.

The core issue, however, extends beyond biosafety regulation but also involves the need for a liability regime concerning possible harm associated with GMOs. Although biosafety regimes focus on minimising harm via risk assessment and other precautionary measures, liability regimes focus on holding those causing harm liable for their actions. At present, there does not exist any legal liability regime in India concerning the environmental, health, and socio-economic impacts of GMOs. It is in an effort to fill this void that this research paper will focus

[1] Environment (Protection) Act 1986

on the development of GMO regulatory policies in India from a biosafety approach to a liability approach. The paper will demonstrate that without liability, the efficacy of biosafety regulations cannot be complete.

RESEARCH PROBLEM

When it comes to the main problem of research discussed in this paper, there are quite serious concerns with the operation of the liability regime in India. The current legal framework for the regulation of GMOs, which operates based on the Environment (Protection) Act, 1986 and Rules of 1989, is more focused on biosafety aspects, risk assessment for the environment, and obtaining prior permission, but fails to mention liability in case damage is incurred from GMOs after their release in the environment. In simple terms, the Indian legal framework is more concerned with ex-ante prevention regulation rather than ex-post remediation justice, which is concerned with who should be blamed in case of a certain harm occurring from genetic engineering. That is to say, whether seed manufacturers, biotechnologists developing genes, farmers cultivating the GM crops, or the regulatory agency that granted prior approval of release of genetic technology is to be blamed for potentially harmful side effects associated with GM crops and genes in question, is unknown. In fact, the lack of efficient liability mechanisms in such cases results in a legal vacuum that can adversely impact adherence to existing rules. The main research problem discussed in this paper is, therefore, exacerbated due to the dual nature of its problem as there are quite numerous overlapping legislative acts governing different fields (like environmental law, biodiversity legislation, food safety law) operating without a specific GMO liability legislation while on the one hand lack of clear statutory definition results in constant court interventions and conflicting interpretations, the result of which often leads to lack of predictability and ambiguity in determining liability issues, which tends to generate greater deficit of public trust.

RESEARCH OBJECTIVE

The research paper under consideration is developed with the purpose of conducting a thorough and critical examination of the regulatory framework in India concerning genetically modified organisms (GMOs). Namely, it focuses on how it has changed from the biosafety-oriented to the liability-oriented one. Initially, the research work aims to critically evaluate the currently applicable legal framework, which includes such documents as the Environment (Protection)

Act, 1986 and the Rules of 1989 in particular. Moreover, it will be necessary to pay attention to the ways in which the regulation of biosafety is performed through the risk assessment process, approval procedures, and institutional oversight in order to prevent negative effects on public health, biodiversity, and the environment. However, taking into account the fact that merely prevention may not be sufficient, the aim of the research paper should be to identify the gaps in the liability mechanism of the currently existing law and to discuss its implications for the governance of GMOs in India. Namely, the lack of a provision regarding responsibility and compensation in cases of damage will need to be analysed critically.

Another aim of the research will be to analyse judicial decisions regarding disputes over GMOs and their impact on Indian GMO governance. As such, it would be necessary to explore the role of judicial intervention in the development of principles of precaution and accountability and to analyse how it has impacted the current state of affairs in this respect. In addition, the compliance of domestic laws regulating GMOs with international norms in the sphere of biosafety is another goal of this research because the current state of international regulations will need to be examined as well. Thus, this research will aim to come up with reasonable reforms of the current legal framework with a focus on the introduction of liability mechanisms.

RESEARCH QUESTIONS

This paper seeks to answer the following key questions:

1. To what extent does India's existing legal framework adequately regulate biosafety concerns associated with GMOs?
2. What are the gaps in the current legal system regarding liability for harm caused by GMOs?
3. How can India develop a comprehensive liability framework to complement biosafety regulation and ensure accountability?

RESEARCH METHODOLOGY

The present study uses a doctrinal and analytical approach to carry out a systematic and extensive study and evaluation of the legal regime pertaining to genetically modified organisms (GMOs) under Indian law. The study is carried out about two specific legal areas- the first is concerned with the biosafety of genetically modified organisms and the liability for the damage

caused due to the use of GMOs; the second is concerned with defining the nature and extent of liability that will be attributable to the manufacturer of genetically modified organisms and the distributors, users, and handlers of genetically modified organisms. The doctrinal method involves a meticulous study of primary and secondary legal sources; primarily the Indian statutes (such as the Environment (Protection) Act, 1986, Biological Diversity Act, 2002, Food Safety and Standards Act, 2006) and regulations enacted under the Environment Protection Act, 1986, which essentially form the existing legal framework regarding GMOs in India. The analysis will also emphasise the interpretation of the legal provisions by Indian constitutional courts with respect to GMOs, filling in the regulatory gaps, and enforcing environmental protection standards.

This study examines the legal context using secondary resources, such as research articles on legislation and expert commentaries, as well as using secondary sources such as research articles, government reports and others to understand how to analyse the legal framework regarding biosafety at the international (global) level and also looking at countries attempting to establish an appropriate biosafety regime in conjunction with the implementation(s) of the Cartagena Protocol on Biosafety.

Another important aspect of the study looks at how historical and landmark judgments have been used to evolve and develop the judiciary's views on precautionary and liability-related principle(s) and the influence of the judiciary in developing the regulatory framework. Overall, the model or methodology employs a critical analysis and synthesis of legal norms, techniques and processes to identify areas of structural deficiencies in relation to liability, and propose coherent and practicable reforms to improve the effectiveness of the regulatory framework in India.

LEGAL FRAMEWORK GOVERNING GMOS IN INDIA

Environment Protection Act, 1986 and 1989 Rules: In India, GMOs are governed under the Environment (Protection) Act 1986 (EPA) as the primary legal basis for all environmental regulation in India, as a result of the Bhopal Gas Tragedy.[2] The central government was given broad powers to take action to protect and improve the quality of the environment and to prevent

[2] *Union Carbide Corporation Etc v Union of India Etc* (1991) 4 SCC 584

harm to human beings, other forms of life, plants, and property. The government then issued Rules under the EPA entitled Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells in 1989. These Rules constitute the principal regulatory framework in place for regulating GMOs. The regulations utilise the principle of precautionary action and the regulatory approach to regulating GMOs by classifying genetically-engineered organisms as hazardous and putting into effect a system of strict regulatory oversight of the various stages of research, development, field trials and commercialisation. The regulatory structure established by the 1989 Rules has a 3-tiered institutional framework, which is created to ensure appropriate scientific review, risk management, and regulatory compliance at each level of the entire regulatory framework.[3]

RDAC (Recombinant DNA Advisory Committee) monitors Biotechnology nationally and internationally to see that safety rules and bioethics are followed. RCGM (Review Committee on Genetic Manipulation) under the Department of Biotechnology inspects and looks after GM research, such as lab experiments, etc. For biosafety measures and approved usage in the environment. GEAC (Genetic Engineering Appraisal Committee) under the Ministry of Environment, Forest & Climate Change is the main regulatory decision-making committee regarding all GM organisms and gives approval to GM organisms for their release into the environment, large-scale field trials and to the commercialisation of biotechnology products. All biosafety information, impact assessments and management of risk are looked into by GEAC before giving a permit to the organism for the environmental release. As the regulation of GM organisms by such a layered system causes controversy in the biosafety and accountability aspect, many arguments are presented by critics, such as a lack of transparency, overlapping responsibility, bureaucratic impediments, lack of participation of the public.

Biological Diversity Act, 2002: The Biological Diversity Act 2002 has a specific relevance in the Indian regulatory regime over GMOS since it facilitates the conservation and sustainable use of biological resources.[4] It has been enacted with the purpose of providing the measures that are required by India in terms of commitment to the Convention on Biological Diversity (CBD) relating to access to biological resources and to knowledge relating thereto, and the fair and

[3] *Regulations and Guidelines for Recombinant DNA Research and Biocontainment* (Ministry of Science and Technology 2017)
[4] Biological Diversity Act 2002

equitable sharing of benefits arising from the utilisation of such resources.[5] Within this Act, regulation over GMOs is also included as genetic engineering usually requires the utilisation of indigenous biological resources, which include indigenous plant species, genes and other genetic material included in India's rich biodiversity, so a regulation over the utilisation of such resources carries a significant relationship with that over GMOs. Three levels of regulatory frameworks are formed under this Act, which include (1) National Biodiversity Authority (NBA) at the centre level, (2) State Biodiversity Boards (SBBS) at state levels, and (3) Biodiversity Management Committees (BMC) at the local level. These three levels monitor and regulate access to biological resources within their jurisdiction. Foreign access to biological resources requires the prior approval of the NBA, as does the transfer of research findings or intellectual property rights based on these biological resources.

In the context of creating biotech products, what is currently referred to as the developing countries' approach to ensuring compliance with this legislation is largely dependent upon multinationals and/or joint ventures having effectively met the requirements of the Agricultural and Crop Production Act within developing countries. In addition to protecting against biopiracy through compliance with these laws, there are also protections provided for the traditional knowledge associated with biodiversity through adoption of the Convention on Biological Diversity, which could be exploited during the development of genetically-modified products but not provided for through the use of these methods (e.g., there are no assurances that the traditional knowledge associated with biodiversity will remain protected).

This is especially critical from an ecological perspective, since the Biological Diversity Act works hand-in-hand with the Environment (Protection) Act by providing a regulatory mechanism that establishes biosafety measures to prevent erosion of populations of genetically-modified varieties and loss of native varieties as a result of converting these populations to genetically-modified organisms, and preventing degradation of overall ecological balance as a result of biomass of GMOs displacing native or sustainably-produced non-GM product (e.g., environmental sustainability).

To date, the Act provides little direction regarding how to establish appropriate legal liability for damage to biodiversity as a result of producing genetically-modified organisms; thus indicating

[5] Convention on Biological Diversity 1992

there is still a considerable void in the legislative framework governing biotechnology in India generally.

Food Safety and Standards Act 2006: An important piece of legislation relating to the regulation of GM foods in India is the Food Safety and Standards Act, 2006 (FSSA), which sets out a legal framework for the regulation of food and ensures it is safe and wholesome. It was enacted with the view to consolidate laws relating to food and establish an authority in India known as the Food Safety and Standards Authority of India (FSSAI). The FSSAI lays down standards of food, and it also regulates manufacturing, storage, distribution, sale and import of food products to be consumed by people. The FSSA establishes the need for the safety assessment of all food products derived from genetically modified organisms before being allowed in India for sale or importation. The FSSA also imposes certain labelling and disclosure requirements for all food products, including GM food products, that facilitate transparency and allow consumers to make informed decisions when they purchase GM food products. The importance of these provisions has been further realised by several judicial courts when they have stated that the Supreme Court has reiterated that labelling is required, and that strict compliance with the labelling requirements, safety standards and importation requirements of all food products, including GM food products, is to be strictly enforced.

The judiciary's concern for public health, consumer protection, and the need for regulatory accountability is reflected in this emphasis. On the one hand, the Act establishes an important framework regarding food safety and labelling; on the other hand, it fails to adequately address liability issues that could arise from GM foods' potential health effects, creating a significant "gap" in India's overall legal regime regarding GMOs.

Protection of Plant Varieties and Farmers' Rights Act 2001: The PPVFR Act 2001 represents a new and innovative area within the framework of laws relating to GMOs in India, as it aims to create a balance between the rights of breeders over new plant varieties, which are protected by IP law, and the traditional rights of farmers.[6] The Act provides a mechanism to protect plant varieties in accordance with India's obligations under TRIPS and establishes a sui generis system of protection for new plant varieties (breeders' rights) that provides breeders (which includes biotechnological companies developing GMOs) with exclusive rights to new

[6] Protection of Plant Varieties and Farmers' Rights Act 2001

varieties of plants which are distinct, uniform and stable. In addition, the Act is unique because it includes explicit provisions for the rights of farmers to conserve, enhance, use and exchange plant genetic resources. Farmers have the right to save, use, sow, resow, exchange, share and sell farm-saved seeds, including seeds of plant varieties protected under the Act, subject to specified limitations (i.e., may not sell brand-name seeds). The PPVFR Act is particularly important in the context of GM organisms, as it deals with the commercialisation and, broadly speaking, protection of genetically modified plant varieties, seeking to limit the monopolistic control by seed companies over those plant varieties. It also incorporates provisions for benefit sharing with the communities which have provided the resources with the aid of which the plant variety has been developed. The PPVFR Act also provides for compensation for the farmer for having planted the registered varieties where the registered varieties do not perform as represented under the specified growing conditions (percentages, geographical area). The PPVFR Act, however, also only offers limited provisions to deal with the problem of seed performance and farmers' rights and the broader liability issues which may be present regarding GM crops, with environmental and health concerns not explicitly covered. This leaves large lacunae in the overall regulatory environment regarding GMOs in India.

INSTITUTIONAL MECHANISMS AND REGULATORY AUTHORITIES

India's system of regulating genetically modified organisms (GMOs) is complicated, with several kinds of institutions working together. In fact, this multi-layered institutional system includes the following (but is not exhaustive of all institutions): RDAC, RCGM, BSC, SBCC, DLC, and GEAC, each with varying functions, from advisory, supervisory, monitoring field-work, and final approval of GMOs. Although this regulatory system allows for each stage of the development and application of a GMO to be reviewed by distinct entities, it has led to overlap and duplication of responsibilities, fragmented regulation and procedurally inefficient working. Agency coordination is weak, and decision-making becomes time-consuming. Inconsistent biosafety standards are applied inconsistently, whereas this type of multiple-agency structure has been criticised because accountability is unclear and the regulation is not effectively overseen. The apex regulatory body in the framework is the GEAC (under the Ministry of Environment, Forest and Climate Change), responsible for the approval of large-scale field trials and commercial release (final release into the system of distribution) of GM crops. This committee evaluates bio-safety data, analyzes risks posed to the environment and forms risk management procedures before granting consent for release

into the environment, and although the GEAC occupies an apex regulatory status it is still largely criticized in relation to transparency, independence and public accountability; for example, there is insufficient release of scientific data into the public arena, a lack of sufficient opportunity for the public to engage in decision-making procedures and possible inclusion of commercial and political influences in the committee's decision-making practices. Because the GEAC is not an independent statutory institution, the committee's independence and credibility come into question. Moreover, the limited ability for effective post-approval monitoring and enforcement hinders the system from monitoring GMOs' long-term effects in the environment. Therefore, despite a seemingly structured institutional system, practical problems of implementation are evident.

BIOSAFETY REGULATION: PRINCIPLES AND CHALLENGES

Biosafety regulation in India is part of the framework of law on GMOs to avoid any threat or damage to human beings, life and nature. In India, there is a case-by-case risk assessment, and all GMOs (such as genetically modified food crops) are analysed and approved on the basis of individual analysis and assessment for field trials or commercial use. Indian environmental principles, such as the Precautionary Principle, which says that in the event of risk or uncertainty, the burden of proof that a certain act or product is safe lies with those who want to perform such act or sell such product; the principle of sustainable development, requiring that economic activities need to take into account the needs of the generation of the future; and the principle of intergenerational equity, have an important role to play in assessing biosafety and approving GMOs. In its observations on several GMO-related cases, the Supreme Court has underlined that if proper and adequate biosafety assessments are not carried out for genetically modified food crops, then there can be harm to the environment, and the rights of future generations may also be violated.

JUDICIAL INTERVENTION AND CASE LAW ANALYSIS

Judicial intervention has played a crucial role in shaping the regulatory discourse on genetically modified organisms (GMOs) in India, often moving in to address gaps, ambiguities, and deficiencies within the existing legal framework. In Aruna Rodrigues v Union of India (2012),[7] the judiciary of India has been faced with problems in relation to the environmental release of

[7] *Aruna Rodrigues and Ors v Union of India and Ors* (2012) 5 SCC 331

GM crops and concerns of risk of release of GM crops like Bt brinjal, including the sufficiency of the existing biosafety regulatory frameworks. Because of potential risks of GMOs and the absence of robust and transparent regulatory systems, the Supreme Court opted for a precautionary principle and put stress on pre-release testing, through a more objective, transparent and independent manner. More importantly, the court set up a Technical Expert Committee (TEC) with scientists independent from any agency to scrutinise the regulatory framework and biosafety protocol. The recommendations made by the TEC, calling for more careful risk assessment, long-term studies, and improved transparency, showcased required reforms for the system of GM governance in India and pointed toward the need for an active role of the judiciary in protecting the environment and human health. Subsequently, in Gene Campaign v Union of India (2024),[8] the Supreme Court dealt with the contentious issue of the approval of genetically modified mustard (DMH-11). The case ended in a split verdict, indicating sharp divisions among the judiciary on whether or not the biosafety data presented to them was enough to allay doubts, on the role and responsibility of the regulatory bodies and on finding a balance between technological progress and environmental security. One judgment supported the regulatory process, whereas the other voiced strong concerns about the opacity of the process, inadequate testing and possible environmental risks. More recently, in Kritesh Oswal v Union of India (2025),[9] the Rajasthan High Court addressed the issue of genetically modified food products entering the market without adequate regulatory oversight. A conspicuous regulatory void concerning imports, labelling, and safety assessments of GM food has also been noted by the Court, which insisted that "a legal regime that would have to be coherent and binding". The cumulative judgments also clearly showed how courts are being called upon more and more to compensate for legislative and regulatory gaps, "upholding principles like precaution and transparency in the management of biotechnology" and "enhancing accountability of GMOs Governance". But again, the limits of adjudication without proper statutes were clear.

LIABILITY ISSUES IN GMO REGULATION

Liability is one of the least developed areas in India's legal regime on GM crops, even though there are fairly well-developed biosafety rules to ensure against harm. The present regime mostly

[8] *Gene Campaign and Anr v Union of India and Ors* (2024) INSC 545
[9] *Kritesh Oswal and Ors v Union of India and Ors* (2025) RJ-JP:31237-DB

addresses the issue of risk assessment and regulatory approval in a pre-approved sense rather than its actual implications when harm has occurred. This has implications for liability in multiple counts.

Environmental Damage: Unwanted gene flow, biodiversity loss, development of resistance, or disturbance in the ecological balance resulting from the introduction of GMs, the harm from which can be irreversible and extends beyond the point of initial release.

Health Risks: This relates to the potential long-term or unforeseen effects of GM foods on humans, which might be impossible to detect early on.Economic Losses to Farmers: This may arise when the GM crop is unable to perform to the expected standards, when seeds and other inputs are exorbitantly priced due to its modified nature.

Contamination of Non-GM Crops: Through cross-pollination or accidental mixing during handling and storage, organic and other traditional farmers would be harmed, and thus contract or certification liability might arise. These forms of liability often overlap, which complicates matters. In the absence of a specific statutory regime for addressing such issues, reliance is placed on common law principles of tort and public liability under environmental law. It appears that victims of harm due to GM crops may seek remedies based on negligence and even strict liability (based on judicial pronouncements).[10] Also, environmental jurisprudence in India includes the doctrine of 'polluter pays', and the same principles might theoretically be applicable for GMs also.[11] However, these are not enough in practical scenarios. This includes the challenges of causation as it is scientifically difficult to prove a link between a specific GM and the harm, and that they develop over time. Lack of GMO-specific provisions that specify liability standards or define who, amongst developers, companies, farmers and regulators, bears responsibility under the law also weakens it. Lack of a written strict liability regime increases the burden on the victim to prove negligence or fault, which, in the face of an advanced technology like GMOs, is nearly impossible.

[10] *Rylands v Fletcher* [1868] LR 3 HL 330
[11] *Indian Council for Enviro-Legal Action Etc v Union of India and Ors Etc* (1996) 3 SCC 212

EXISTING LEGAL MECHANISMS

At present, the remedies available to redress damage arising out of GM crops are limited to Torts (Negligence and Strict Liability) and Public Liability under Environmental Law. None of these provisions has been tailored to meet the emerging and diverse risks arising out of modern biotechnology. Under the provisions relating to Tort (Negligence and Strict Liability), a claimant can sue for damages if he is able to demonstrate the existence of a duty of care owed to him by the defendant, a breach of this duty and damage as a direct consequence thereof. Strict liability can be imposed in cases of inherently risky operations without proof of fault by the defendant.[12] This mechanism presents insurmountable difficulties in cases relating to GM crops, especially since proving causality is exceptionally difficult, as it is technologically impossible to establish the correlation between a specific GM crop and damage to the environment or health, especially over long periods of time or where many factors may have contributed. The provisions of Public Liability under Environmental Law, which flow from the statute, viz. Environment (Protection) Act, 1986, and the principle of 'polluter pays' may provide a remedy for environmental damages and hold the polluter liable for environmental pollution and ecological damage. These provisions technically include GM crops and environmental damage caused thereof, but the standards to be met have not been clarified specifically for Biotechnology stakeholders, viz. Developers, companies and farmers have a proper strict liability regime absent in respect of GM crops.

INTERNATIONAL FRAMEWORK: CARTAGENA PROTOCOL ON BIOSAFETY

India is a signatory to the Convention on Biological Diversity, and also to the Cartagena Protocol on Biosafety, a supplementary agreement thereto, that guides the international dimensions of GMO regulation.[13] Adopted to ensure the safe handling, transport and use of living modified organisms (LMOs) which may have adverse impact on biological diversity and human health, the protocol has a strong emphasis on the precautionary principle and sets a procedure for advanced informed agreement (AIA), risk assessment and risk management that requires the approval of countries on the environmental and health risks that are likely to be associated with a genetically modified organism before it is allowed to be imported or released. India's domestic regulatory regime under the Environment (Protection) Act, 1986, and the Rules of 1989 contains

[12] *M C Mehta and Anr v Union of India and Ors* (1987) 1 SCC 395
[13] Cartagena Protocol on Biosafety to the Convention on Biological Diversity 2000

various aspects of these issues as well, particularly emphasis on prior approval, scientific risk assessment and environmental safeguard, and the Supreme Court of India has on more than one occasion reiterated the need for India to adhere to international obligations undertaken under the Protocol on biosafety standards and transparent regulation. However, in the areas of liability and redress, which are important parts of the Cartagena Protocol and its supplemental protocol on liability and redress, India is significantly lacking as per international guidelines of the protocol. The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol provides a basis for parties to have domestic procedures for compensation and rehabilitation in cases where damage is incurred due to genetically modified organisms,[14] which in the Indian context does not exist as no dedicated laws are implemented for these purposes, and thus questions on defining damage caused by GMOs, procedures on claim for compensation and tracing out liability to various actors remain unanswered, which will certainly come into play while regulating the cross-border movement of genetically modified materials.

REGULATORY GAPS AND CHALLENGES

Though the regulation framework of genetically modified organisms (GMOs) in India is multi-layered, there are a lot of gaps and problems in its working and modification according to developing biotechnologies: Absence of a Comprehensive GMO Law remains one of the most fundamental issues. There is no sole, singular law in India that explicitly pertains to the regulation of GMOs. The regulation is fragmented across several pieces of legislation, such as the Environment (Protection) Act, 1986, Biological Diversity Act, 2002, and Food Safety and Standards Act, 2006. The lack of a specific law creates conceptual and operational problems relating to authorisation, control after release, responsibility, etc. This leads to a regulatory system which is merely reactive, not coherent and futuristic. Closely related to this is the problem of a Fragmented Regulatory Framework, where multiple authorities operate at different levels with overlapping jurisdictions and unclear lines of accountability. Many of these institutional structures (e.g., GEAC, RCGM and state-level authorities) lack functional coordination between them, which leads to duplication of effort, delays in decision making and non-uniform application of the biosafety rules. Another major concern is the Lack of Transparency in decision-making processes, particularly in relation to the approval of GM crops and disclosure

[14] Nagoya–Kuala Lumpur Supplementary Protocol on Liability and Redress 2010

of biosafety data. On the other hand, regulatory authorities have come under criticism for their lack of public access to scientific evaluations, inadequate involvement of relevant stakeholders and obscure processes. This issue is further compounded by Weak Enforcement Mechanisms, as even where regulations exist, their implementation at the ground level remains inadequate. There are generally poor implementations of field trials surveillance, fulfilment of safety conditions, and regulation of unauthorised planting or import of GM crops; largely owing to a lack of institutional capacity, trained manpower and coordination between the centre and states. Additionally, the framework suffers from Inadequate Liability Provisions, as there is no clear statutory mechanism to address harm caused by GMOs, whether in terms of environmental damage, health risks, or economic losses to farmers. Legal solutions under tort law and principles of environmental law are not designed to cover the specific characteristics of biotechnology, which have created both compensation and responsibility vacuums. All the problems mentioned above are compounded by the rapid pace of development of newer genetic technologies like gene editing and synthetic biology, and our legal system has yet to adapt. Many have been calling for a modernisation of Indian regulation to address the challenges of new biotech.

TOWARDS A LIABILITY-BASED REGULATORY FRAMEWORK

To address the structural deficiencies of the existing Indian regime on GMOs, there is an urgent need to transition to a liability-based regulatory framework by supplementing biosafety regulation with clearly defined accountability provisions. Primarily, there is a necessity to Enact Dedicated GMO Legislation, since the current regime, lacking a singular statutory framework for GMOs, presents several shortcomings, including a fragmented and nebulous approach. A Dedicated GMO legislation is essential to encompass all stages of GMO regulation from R&D to release to monitoring and liability into a single comprehensive legal provision. It would provide greater certainty to institutional mandates, standardised protocols for risk assessment and approval procedures, and, most importantly, embed strict liability and remedy provisions. In addition, a dedicated law on GMOs would also facilitate synchronisation with international law and newer scientific developments, thereby creating a favourable environment. Secondly, it is imperative to introduce Strict Liability for GMO-Related Harm so that those institutions that are developing, commercialising, or distributing GMOs can be made legally responsible for any damage they cause without requiring a victim to prove negligence on the part of those

institutions. Given that there are risks and scientific uncertainties in the use of biotechnology, it may not always be feasible to require victims to establish negligence. A strict liability provision will place a greater onus on developers and firms, thereby encouraging a more cautious approach to safety, due diligence and risk assessment. Closely aligned to this aspect is the need to Establish Compensation Mechanisms for the affected victims, including farmers and local communities, who should be compensated efficiently and effectively, possibly through the creation of separate compensation funds, mandatory insurance schemes for biotechnology firms, or legal provisions that permit recovery of damages. The establishment of these provisions will increase public confidence in the regulatory system and ensure justice to victims. Furthermore, it is crucial to Strengthen Regulatory Institutions. Any legal framework is as good as its execution, and thus the institutional mechanism, including the GEAC and other regulatory bodies, must be equipped with enhanced capability, impartiality, transparency and accountability. This includes greater emphasis on scientific knowledge, clear lines of institutional responsibility and robust mechanisms for monitoring and enforcement at all levels of government. Lastly, the need to Enhance Public Participation in the GMO regime is also critical since GMOs pose risks not only to the environment, but to human health as well as livelihood; all aspects need to be considered during their assessment. The process of assessing GMOs needs to be more open, transparent, and participative, with access to biosafety data, opportunities for public consultation, and incorporating perspectives of diverse stakeholders, including farmers, scientists, civil society organisations, consumers, etc. A greater degree of participation will not only lead to a more democratically legitimate outcome, but also facilitate identifying the possible threats and concerns that may be overlooked otherwise.

CONCLUSION

In conclusion, India's existing legal regime on GMOs adopts predominantly a biosafety-oriented approach which promotes precaution, environmental protection and pre-release risk assessment at the expense of liability and accountability. The legislation under the Environment (Protection) Act, 1986 and the Rules of 1989 has thus put in place the fundamental building blocks for regulating the development, testing and commercialization of GMOs, but it is primarily a deterrent and does not offer any remedial recourse against damages, creating an imbalanced regulatory framework in the process where damages emanating from environmental degradation, health risks, or socioeconomic harm do not correspond to the assignment of legal

responsibility or the receipt of compensation for damages incurred. The increasing dynamism of biotechnology in a rapidly developing context that involves novel genetically modified organisms and the broad applications across multiple sectors will therefore further highlight the frailties of the existing legal regime. Judicial actions will, undoubtedly, play a part in highlighting these lacunae with the courts applying principles like precaution, transparency and intergenerational equity, sometimes stepping in to implement interim orders, or to insist on thorough assessment. But, there can be no substitution of an effective regulatory response with judicial activism in terms of the long-term governance structure. Courts will only be able to apply and interpret limited gaps. The absence of legal statutes defining responsibility results in ambiguity, unpredictable jurisprudence, and public distrust among different categories of stakeholders, such as farmers and consumers directly impacted by GMO-related risk factors. The step from a bio-safe centric approach to a hybrid liable approach is not only appropriate, but crucial to a fair and just legal framework for GMOs; one that contains clear standards for liability, both in terms of compensatory mechanisms, and effective enforcement in all phases of GMO development. This regulatory system should not only comply with standards like the Cartagena Protocol on Biosafety, but should also be responsive to the aspirations of the Indian Constitution concerning the environment, human health, and sustainable development.