# The Indian Journal for Research in Law and Management

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Editor-in-Chief – Dr. Muktai Deb Chavan; Publisher – Alden Vas; ISSN: 2583-9896




## GMO AND THE LAWS REGULATING IT: WHY WE NEED SOMETHING NEW


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**ABSTRACT**

The regulation of Genetically Modified Organisms remains a sore topic across International law. Biotechnology has seen great progress in the past decades. However, the laws and regulations governing it have failed to catch up with the momentum. This short article analyses the non-uniform regulations and highlights the need for a global and uniform framework. It also explores the new age risks with GMO, the existing legal frameworks and how they have created gaps that need to be addressed soon. The article concludes that we need transparent and uniform regulation and a robust international cooperation to implement them if we want to ensure sustainable scientific innovation, smooth international trade and protection of human health and the environment.



**Key words-** Genetically Modified Organisms | Bio-safety | Global governance | Biotechnology


### 1. INTRODUCTION

The Genetically Modified Organisms have become an integral part of the global economy. It has crossed borders and have given rise to debates about regulation, environment and fair trade practices. The laws and regulations governing GMO trade were developed in a time when technology was not this advanced. Hence, they often assume certification by traditional means, physical inspection, and national level oversight. These frameworks struggle to accommodate digital data flows, algorithmic risk assessments, and decentralized verification systems. This article explores the current legal landscape and the potential ways in which the system can be more efficient.

### 2. GMO AND THEIR USES

These are the organisms whose genetic material have been altered artificially via genetic engineering. In nature, the DNA of an organism doesn't mutate easily unless it has been exposed to any strong external agent like radiations and chemicals. Also, we can't guarantee that any such natural mutation will only produce desirable traits. This is where genetic engineering comes into play. It is usually done to introduce desired phenotypic and genotypic traits in the organisms. Crops have been genetically modified to increase yields as well as to increase their resistance to pests, unfavorable weathers and diseases. The most widely known example would be that of Bt cotton. It has been manufactured to express a toxin from the bacterium *Bacillus thuringiensis*, which provides the plant with insect resistance[1]. Moreover, we have seen the rise in the demand of Biofortified crops, as they have been specially built to provide multiple types of nutrients.

Apart from agriculture, GMO are mostly used in Medicine. A lot of modern medicines and vaccines are made by using and manipulating the genetic strains of certain organisms. They are used for production of relevant proteins and enzymes needed to make certain biological components. A good example would be the employment of such organisms to produce essential hormones like Growth hormone and Insulin, or using certain GMO to create vaccine for Hepatitis-B[2]. Many heavy industries are also known to use GMO to make advanced products which are sustainable in long run. e.g., in production of biofuel and enzymes for manufacturing of bioplastics[3]. Many such microorganisms are also used in degrading pollutants and restoring the destroyed ecosystem[4]. It has also been recorded that the GMO are now used to clean oil spills in the seas and near oil rigs, and in detoxifying hazardous wastes generated from factories and industrial outlets[5].

## 3. RISKS AND CONCERNS RELATED TO GMO

[1] C. Zhang, *Genetically Modified Foods: A Critical Review of Their Benefits and Risks*, 6 *Food Control* 1, 3–5 (2016).
[2] *Genetically Modified Organisms – Medicine, Research, and Applications*, Britannica, https://www.britannica.com/science/genetically-modified-organism/GMOs-in-medicine-and-research
[3] *Genetically Modified Organisms – Applications in Medicine and Industry*, National Geographic, https://education.nationalgeographic.org/resource/genetically-modified-organisms/
[4] *Genetically Modified Organisms – Environmental Applications*, U.S. Food and Drug Administration, https://www.fda.gov/food/agricultural-biotechnology/gmos-and-environment
[5] *Genetically Modified Organisms – Industrial Applications*, U.S. Environmental Protection Agency, https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/genetically-modified-organisms

In a broad sense, we can divide the risks into two types – scientific concerns and ethical concerns.

From a scientific point of view, the adoption of GMO comes with its own share of risks and concerns. Researchers have discussed about the potential gene flow from GMO crops to non GMO crops and pests developing more resistance[6]. Scholars are now debating about the long term health effects of consuming GMO foods as some studies suggest potential allergies or unintended side effects[7].

If we talk from legal and social viewpoint, there are a lot of ethical and regulatory concerns about GMO. The first issue is that there is no mandatory and uniform legal framework which is applicable worldwide to GMO creation, trade or patenting. As there is no synchronization of regulations, laws and interpretation of the said laws across the jurisdictions of different countries, implementation becomes difficult. It often ends up in commercial barriers with no clear understanding on liability when GMO traits migrate from one country to another or into non GMO domains[8].

The second issue is about rich corporations potentially exploiting poor farmers. GM seeds are subject to Intellectual Property rights. The patent to these seeds are mostly in the hands of rich corporations. It means that if the farmers were to plant those seeds, they need to purchase those seeds from those specific companies even if the companies raise the price[9]. This exclusivity granted by the Intellectual Property Rights creates seed monopolies, which severely limits the farmers' traditional seed-saving privilege.

The third issue is about potential use of GMO in producing next generation bio-weapons. Despite having international treaties and regulations to check the production and deployment of bio-weapons, we cannot simply rule out the possibilities of countries researching about it or having already developed such weaponry. There are also other possibilities. What if the

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[6] X. Hui, *Understanding the Societal Dilemma of Genetically Modified Foods*, 2 *Sustainable Food Systems* 1, 4–6 (2024)

[7] A.S. Bawa, *Genetically Modified Foods: Safety, Risks, and Public Concerns*, 1 *Food Control* 1, 2–3 (2012).

[8] B. D. Bulchandani , *Genetically Modified Crops: A Reality Check and Present Global Scenario*, International Journal of Global Science Research Vol. 4, No. 1, April 2017, pp. 516-537

[9] de Melo-Martín I, Meghani Z. Beyond risk. A more realistic risk-benefit analysis of agricultural biotechnologies. EMBO Rep. 2008 Apr;9(4):302-6. doi: 10.1038/embor.2008.39. PMID: 18379579; PMCID: PMC2288773.

manufacturer is a non-state entity? The current regulations simply do not explicitly cover the mechanisms to hold such entities accountable[10].

## 4. LEGAL LANDSCAPE OF GMO

Different countries have different regulations. In the USA the regulation is managed by three agencies. They are the US Department of Agriculture, the Environmental Protection Agency, and the Food and Drug Administration. The regulations are based on the *Coordinated Framework for the Regulation of Biotechnology*, which was established in year 1986. It focuses more on the product of the genetic modification rather than the process by which the gene was modified[11]. The European union's legislation on GMO includes directives that govern the approval, cultivation, and labeling of such organisms. It also emphasizes on ensuring safety of both environment as well as of human health[12].

Internationally, the regulation of GMO is influenced by the WTO Agreement on the Application of Sanitary and Phytosanitary Measures, the WTO Agreement on Technical Barriers to Trade and the Cartagena Protocol on Bio-safety. The SPS agreement says that any law or regulation made by any country for trading of food and agricultural products, must be backed by reasonable scientific evidences and proofs. The agreement also explains that the regulations should not discriminate or place any hidden restrictions on the trade. Similarly, Cartagena Protocol on Bio-safety was enacted to ensure that the alive GMO are safely handled, transferred and used[13]. This protocol gives great importance to assessment of risks and even encourages the public to voice their opinions and actively participate in decision making processes about GMO. Emerging trends indicate a shift towards more reasonable regulatory approaches. Some countries are considering deregulating certain GMO, particularly those developed using newer techniques like gene editing, which do not introduce foreign DNA. For instance, Japan has developed guidelines stating that gene edited plants and food can be sold

[10] The Future of Bioweapons: Analyzing Emerging Threats and Trends, August 10, 2024 by Military Dispatches Editorial The Future of Bioweapons: Analyzing Emerging Threats and Trends - Military Dispatches

[11] SGS Digicomply Editorial Team, *Comparative Analysis of Regulation of GMO Products Worldwide*, SGS Digicomply (June 14, 2024), https://www.digicomply.com/blog/comparative-analysis-of-regulation-of-gmo-products-worldwide

[12] European Commission, *GMO Legislation*, Food Safety, https://food.ec.europa.eu/plants/genetically-modified-organisms/gmo-legislation_en

[13] *Cartagena Protocol on Biosafety To the Convention On Biological Diversity,* cartagena-protocol-en.pdf

to consumers without safety evaluations as long as the techniques involved meet certain criteria[14].

## 5. LEGAL GAPS

There are a lot of legal issues prevalent in this field. Firstly, we don't exactly have a uniform regulation. Every country is having their own set of laws. And this ultimately leads to a fragmented global regulatory landscape. Countries with multiple agencies are being criticized for making implementation complicated as their departments are not cooperating with each other and are stuck with outdated approaches, which doesn't fit well with the new age technologies. On the other hand, many countries are being excessively cautious when it comes to such regulations and are possibly hindering the innovation[15]The Cartagena Protocol's provisions are often criticized for lacking the clarity and ability to enforce them, particularly regarding liability and redressal mechanisms[16]. As there is no uniformity in the regulations worldwide, any effort to implement international GMO regulations becomes really complicated.

This gap ultimately leads to trade disputes. What may be acceptable in one country might violate regulations in another, which will give rise to WTO-based trade disputes. Without any internationally binding regulation, we have no way to prevent such mishaps.

In India,the GMO are governed by the *Environment (Protection) Act, 1986*, under which the "*Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells, 1989*" are notified[17]. Just like many of our other laws, the rules are there and their implementation has been inconsistent, leading to regulatory uncertainties. The Genetic Engineering Appraisal Committee responsible for approving GMO, has faced criticism for delays in decision making and lack of

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[14] International Service for the Acquisition of Agri-biotech Applications (ISAAA), *Updates on Global Regulatory Landscape for Gene-Edited Crops*, ISAAA Blog (Jan. 24, 2024), https://www.isaaa.org/blog/entry/default.asp?BlogDate=1%2F24%2F2024

[15] Hilbeck, A., Meyer, H., Wynne, B. *et al.* GMO regulations and their interpretation: how EFSA's guidance on risk assessments of GMOs is bound to fail. *Environ Sci Eur* 32, 54 (2020). https://doi.org/10.1186/s12302-020-00325-

[16] Liu, A. (2025). Toward the effective implementation of the Biosafety Protocol. *PMC*. https://pmc.ncbi.nlm.nih.gov/articles/PMC12133087/

[17] Department of Biotechnology, Ministry of Science and Technology, Government of India, *Regulation of Emerging Gene Technologies in India*, 2016, https://ges.research.ncsu.edu/wp-content/uploads/2016/08/Regulation-of-Emerging-Gene-Technologies-in-India.pdf

transparency[18]. This institutional incoherence ends up causing delays and uncertainty regarding the regulations. Also, India's approach to gene editing and techniques like CRISPR, remains underdeveloped. The absence of a dedicated regulatory body has made the existing issues worse. The concerns had resurfaced in the recent Supreme court Judgment in *Gene Campaign and others vs The Union of India*[19].

## 6. THE WAY FORWARD

The current legal issues cannot be overlooked. The judicial proceedings and arbitration are not only time consuming, but also costly. It is adversely affecting the trades, as well as the innovation and investment in biotechnology. We need harmony in GMO regulations to ensure smooth international trading, consistent safety standards and to avoid trade disputes with other countries.

Internationally, a lot of reforms are being proposed. Some scholars suggest to establish an International regulating body under WHO or WTO, who would set global safety standards, monitor the risks, and guide the labeling and traceability of the GMO[20]. It is also suggested that on a regional level, neighboring countries can come up with agreements regarding the same. Many policymakers are proposing new methods to keep track of the new technology so that they can make more clear guidelines for new technologies. This will eventually make the process somewhat more transparent. Moreover, patenting laws need to be revisited too.

What we need are not stricter laws, but more transparent regulations and their proper implementation. The academia, industry and the lawmakers need to come together to address this situation. Without cooperation at the international level, solving this issue will be really difficult.

## 7. CONCLUSION

Biotechnology will continue changing the space of agriculture, medicines and industry. But we as humans, will not be able to reap the benefits of this technological revolution if our laws and

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[18] Genetic Literacy Project, *India: Animals - Global Gene Editing Regulation Tracker*, 2020, https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/india-animals/.

[19] Gene Campaign & Anr. v. Union of India & Ors., (2024) INSC 545

[20] *International Policies and Global Trade of GMO/NGTS,* Darwin, 09/06/2025 https://darwin-ngt.eu/news-events/international-policies-and-global-trade-of-gmo-ngts

regulations continue to create difficulties. Not having a uniform regulation not only slows down the trade, but also chokes the scientific innovation. Hence, it should be our moral responsibility to achieve a balance between biosafety and innovation. Adoption of uniform laws on GMO is a great way to achieve this equilibrium.

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