

CURRENT LEGAL STATUS OF GM CROPS IN INDIA WITH SPECIAL REFERENCE TO INTELLECTUAL PROPERTY LAWS

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Abstract

India under the umbrella of the Constitution of India and international legal regime has evolved IPR laws with global compliance of all important treaties and legal instruments. They along with other laws regulate GM technologies related with the GM crops, seed and other propagule production, benefit sharing, preventing biopiracy, or foreign exploitation of natural resources. The present paper is an attempt to collate all the relevant laws and discuss the nuances related to it and to further see their effectiveness in light of the global scenario. Biotechnology like all other new technologies, also have some apprehensions and risks which causes unknown scare into the minds of people. The present paper tries to particularly traverse the intellectual property (IP) laws in India related to GM crops and also cover other laws and institutional framework available in India to regulate the effect or impact of transgenic or GM crops on environment, human health & biosafety.

Keywords: *IPR laws, GM technologies, GM crops, Biotechnology, Biosafety*

I. Introduction

The genetically modified crops (hereinafter GM Crops) are manmade biological product, developed by intentional alteration in genetic material by using biotechnological methods (Recombinant DNA technology) to get the desired characters or product in a plant species or any living organism. Though, biotechnology

is not a new phenomenon but its modern aspect emerged in recent past offers solution to the 21st century's greatest demand of food security.

An international legal instrument, the Convention on Biological Diversity (CBD) dealing with biological resources/biodiversity defines biotechnology under article 2 as “*Any technological application that uses biological*

systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.”¹

The biotechnological products range from classical products (fermentation technologies e.g., for beer, curd making, cheese making) to modern products like gene manipulation or GM crops development. Biotechnology includes traditional and local knowledge (TK) and its application in cropping practices, selection and breeding of plants and animals made by individuals and communities for millions of years.²

On the other hand, modern biotechnology refers to biotechnological techniques and their products obtained after the manipulation of organism’s genetic material by cutting, ligating (joining) and transferring to the cells beyond normal breeding barriers of plant species. This involves the application of tissue culture, genomic techniques and recombinant DNA technology (RDT). The first produced GM plant in the laboratory was tobacco in 1983.

¹ Convention on Biological Diversity UNEP. (2006). *Convention on Biological Diversity, Convention Text* https://www.cbd.int/convention/articles/default.shtml?_cbd-02

² Heinemann, J.A., Abate, T., Hilbeck, A., & Murray, D. (2009, January). *Agriculture at a Crossroads: The Synthesis Report of the International Assessment of Agricultural Knowledge, Science and Technology for Development*, <https://ir.canterbury.ac.nz/handle/10092/3774>

³ “Tomato, papaya, potato, sugarcane, sugar beet, field corn as well as sweet corn and rice have been genetically

Since then, the RDT gained momentum since the mid-1990s in various countries but focused on crops such as canola, maize, cotton, soybean etc³. Since then, the stupendous growth led to use of GM crop technology for 48% of the global plantings of these crops in 2014.⁴

But biotechnology like all other new technologies, also have some apprehensions and risks which causes unknown scare into the minds of people. The present paper tries to particularly traverse the intellectual property (IP) laws in India related to GM crops and also cover other laws and institutional framework available in India to regulate the effect or impact of transgenic or GM crops on environment, human health & biosafety.

II. GM Crops and Intellectual Property Rights Laws

India under the umbrella of the Constitution and international legal regime has evolved IPR laws with global standard compliance. They regulate GM technologies related with the GM crops,

modified to enhance either their yield, or size, or durability.”

⁴ Brookes, G., & Barfoot, P. (2018). Environmental impacts of genetically modified (GM) crop use 1996-2016: Impacts on pesticide use and carbon emissions. *GM Crops & Food*, 9(3), 109–139. <https://doi.org/10.1080/21645698.2018.1476792>,

Abbas, M.S.T. (2018). Genetically engineered (modified) crops (*Bacillus thuringiensis* crops) and the world controversy on their safety. *Egypt Journal of Biological Pest Control* 28, 52. <https://doi.org/10.1186/s41938-018-0051-2>

seed and other propagule production, benefit sharing, preventing biopiracy, or foreign exploitation of natural resources.

A. International framework for GM Crops and Intellectual Property Rights

The utility of GM crops is immense in present scenario but the environmental, health, economic and ethical issues of Genetically Modified Organisms (hereinafter GMOs) cannot be denied. Keeping this in mind, developed and developing countries have established domestic legal regulations on GM organisms under the umbrella of WTO-TRIPS agreement, the CBD and International Seed Treaty.

1. *WTO-TRIPS Agreement*

WTO is the key institution that regulates approximately 95% of current global trade.

Presently, the WTO-TRIPS has pivotal role to the international trade of GMOs and asserts IPR on life form. The Agreement came into effect on 1st January, 1995. It contains provisions for patents, trademarks, copyright and related rights, geographical indications and layout designs etc. Under the TRIPS agreement, the application of sanitary and phytosanitary measures (SPS Agreement) is related to the international trade of GM organisms. Article 27 of the TRIPS Agreement determines the subject of the intellectual property related to GM crops.⁵

The major drawback with TRIPS agreement is that it promotes the private appropriation of benefits but has no explicit mechanism for acknowledging the role of traditional knowledge in the industrial use of genetic resources.⁶ India, being a party of TRIPS

⁵“Article 27.1 declares that ‘subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.’ The patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.”

“Article 27.2 says that Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or *morality*, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.”

“Article 27.3 says that Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical

methods for the treatment of humans or animals. (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement (WTO-TRIPS, n.d.)”

⁶ “But Article 1 of TRIPS agreement provides some flexibility, allowing domestic law to exceed minimum protection standards, a provision that could allow member nations to enact legislation to protect traditional knowledge. The Article 27.3(b) of TRIPS allows for the development of *sui generis* or unique IPR protection systems for plants, animals and essentially biological processes, creating an opportunity to develop alternative

Agreement, has enacted PPVFR Act 2001 to provide *sui generis* protection to new plant varieties and have made amendments (2002 and 2005) in Patent Act 1970.

2. *The Convention on Biological Diversity (CBD)*

Earth Summit was held in Rio de Janeiro in 1992, world leaders agreed on a comprehensive strategy for "sustainable development" and a key agreement adopted was the Convention on Biological Diversity.⁷

The Articles of CBD incorporates: principles relevant to GM crops; sovereign right of state over their biological resources; sustainable use of components of biological diversity; access to genetic resources and handling of biotechnology and distribution of its benefits. To ensure execution of the later principle, Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits

(ABS) has been brought. It is a supplementary legal instrument for biodiversity conservation concluded in Nagoya in 2010 and India is party to this protocol. The protocol gets its force from article 8(j) of CBD convention in which parties will be legally obliged to follow rules designed to prevent bio-piracy and provide benefits, including financial benefits, to other Parties when their genetic resources are accessed.⁸

Apart from this, The Bonn Guidelines have been made inconsonance with above protocol.⁹ To meet the goals of CBD, India has enacted Biological Diversity Act 2002.

3. *International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)*

The origin of this treaty is a voluntary agreement concluded in 1983, known as the International Undertaking on Plant Genetic Resources for Food and Agriculture

IPR regimes appropriate to the needs and conditions of traditional communities.”

⁷ “Convention on Biological Diversity UNEP. (2006). *Convention on Biological Diversity, History of the Convention*, <https://www.cbd.int/history/>. The convention establishes three main goals namely the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits originating from the use of genetic resources. India became a signatory to the CBD in December 1993 and ratified the convention in February 1994. CBD addresses issues like biodiversity conservation, habitat preservation, intellectual property rights, bio-piracy, bio-safety, and indigenous peoples’ rights.”

⁸ “Convention on Biological Diversity UNEP. (2018). *The Nagoya – Kuala Lumpur Supplementary Protocol on*

Liability and Redress to the Cartagena Protocol on Biosafety.” <http://bch.cbd.int/protocol/supplementary/>.

⁹ “Secretariat of the Convention on Biological Diversity (2002). Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization. Montreal: Secretariat of the Convention on Biological Diversity. <https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf>. Which tries to fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding”

(IUPGRFA). The agreement incorporated the philosophy that the genetic resources being the common heritage of humanity. But after this, the CBD came into existence in the year 1992 that brought historical change. It established that genetic resources present under the jurisdiction and sovereignty of a national government (state) can restrict the free flow of common heritage. Thereafter, it became necessary to get permission for access and utilization of bioresources for the purpose of agricultural-industrial development and food security. But there was need to bring a specialized legally binding Treaty to conserve and promote PGR associated specifically with food and agriculture.

To meet this need, the provisions of IUPGRFA were reshaped accordingly that gave birth to International Seed Treaty or better known as

ITPGRFA. The Treaty is instituted by Food and Agriculture (FAO) in 2001¹⁰ and come into force in 2004.¹¹ It is a legally binding and multilateral system that recognizes of the sovereign rights of states over their own PGR for food and agriculture on a complementary and mutually reinforcing basis.¹²

III. GM Crops and National Laws

A. GM and The Constitution of India

Though there is/are no explicit provision for GM organisms in the Constitution of India. The DPDP enshrined in the constitution can be interpreted to favour GM crops.¹³ The intent of this article gives mandate to the state for development of agricultural products or animal breeds including GM organisms, in the light of modern science.

¹⁰ FAO Resolution 3/2001, Adoption of the International Treaty on Plant Genetic Resources for Food and Agriculture and Interim Arrangements for its Implementation.

<http://www.fao.org/docrep/meeting/004/Y2650e/Y2650e01.htm#3>

¹¹ Cooper, H.D. (2002). The International Treaty on Plant Genetic Resources for Food and Agriculture *Review of European Community and International Environmental Law*, 11(1), 1-16.

¹² "International treaty on plant genetic resources for food and agriculture FAO, (2009). International Treaty on Plant Genetic Resources for Food and Agriculture. The key goals of the Treaty are the conservation and sustainable use of PGR for food and agriculture (to facilitate access to plant genetic resources) and the fair and equitable sharing of the benefits arising out of their use for sustainable agriculture and food security. The Treaty facilitates access to PGR for the purpose of utilization and conservation for research, breeding and

training for food and agriculture. The Treaty also makes provision to disclose all available passport data and non-confidential descriptive information subject to applicable law. The Treaty bars certain things under the ambit of access such as chemical, pharmaceutical and/or other non-food/feed industrial uses. The treaty ensures that access to PGR for food and agriculture protected by any intellectual and other property rights and shall be consistent with relevant international agreements, with relevant national laws as well as pursuant to a standard material transfer agreement (hereinafter MTA)" <http://www.fao.org/plant-treaty/overview/texts-treaty/en/>.

¹³ "Article 48 of the Constitution states that the state shall endeavour to organize agriculture and animal husbandry on modern and scientific lines and shall, in particular, take steps for preserving and improving the breeds, and prohibiting the slaughter, of cows and calves and other milch and draught cattle."

To promote such progressive scientific-technological work, the Constitution also puts duty that state shall endeavour to foster respect for international law and treaty obligations in the dealings of organized peoples with one another under article 51(c). Using such provisions, India has entered into many international treaties and conventions related to GM organisms. The TRIPS agreement, the CBD and the International Seed Treaty are some of the examples that aim to build better cooperation for GM organisms, IPR and related matters. The Seventh schedule (entry 49, union list) of the Constitution of India gives power to state to make laws related to patents (related to GM organism and Biotechnology), inventions and designs, copyright, trade-marks and merchandise marks. The states are also given power under entry 14 of state list.¹⁴ On the other hand, the fundamental duties enshrined under Article 51 (g) and (h) guides the citizens in this regard.¹⁵ These duties also compel for the inventions related to GM organisms and their

products. Reading all these provisions together gives a complete picture that for the welfare of human life, we must go for scientific upgradation like GM organisms simultaneously taking care of environment and human health.

India is dealing with intellectual property related to GM crops with legislations like the Indian Patent Act (1970), PVPFR Act (2001) and Biological Diversity Act (2002) have relevant provisions that seems sufficient to deal with GM crops.

B. Indian Patent Act (1970)

The Indian Patent Act contains provision for identifying what is not an invention and cannot be patented. To get a patent on GM crops, an invention must pass triple test namely novelty, inventive step and capable of industrial application and should not fall under any patentability prohibition listed under Section 3 of the Act.¹⁶ The relevant provisions related to GM makes direct link whereby patent can be denied for GM crops on three grounds.¹⁷

¹⁴ “To make laws on agriculture, including agricultural education and research, protection against pests and prevention of plant diseases.”

¹⁵ “That it shall be the duty of every citizen of India to protect and improve the natural environment including forests, lakes, rivers and wild life, and to have compassion for living creatures and to develop the scientific temper, humanism and the spirit of inquiry and reform Ministry of law & Justice, Government of India. *Constitution of India.*”
<https://legislative.gov.in/sites/default/files/COI...pdf>.

¹⁶ The Indian Patent Act, Chapter II Inventions Not Patentable – 3, 10 (Act No.: 39 of Year 1970 dated 19th

September 1970).
https://legislative.gov.in/sites/default/files/A1970-39_0.pdf

¹⁷ “a. **Contrary to public order/morality/environment:** An invention the primary or intended use or commercial exploitation of which could be contrary public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment. For example, terminator gene technology incorporated in GM crops.

b. **Medicinal, surgical, curative processes:** Any process for the medical, surgical, creative, prophylactic or other treatment of human beings or any process for a similar

But this section has exception, it grants patent to genetically transformed bacterium or microorganism. Methods of agriculture and horticulture were excluded from patentability under section 3(h) of Indian Patent Act 1970. IC is because the first link in the food chain is seed or propagule. They are treated as a common property resource (CPR) like a free air to ensure that farmers' inalienable right to save, exchange and improve seed is not violated. The Indian Patent Act also ensures that an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components that has direct or indirect link with GM seeds are not patented. For examples, traditional knowledge already in public domain for producing hybrid seed.¹⁸

Thus, though the provisions in the Patent Act generate a negative impression whereby what

treatment of animals or plants to render them free of disease or to increase their economic value or that of their products.

c. Agriculture or horticulture method: The plants and animals in whole or any part thereof including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals are not patentable. For example, GM glowing mouse containing GFP are not patentable.”

¹⁸ “The Indian Patent Act, Chapter XXI Revocation of Power patents – 64 (Act No. 39 of Year 1970 dated 19th September, 1970). https://legislative.gov.in/sites/default/files/A1970-39_0.pdf On the other hand, the patent Act makes it compulsory for patent applicant to disclose source and geographical origin of biological material used in invention (Indian Patent Act, 1970)¹⁸ and failure to disclose source and geographical origin of biological

cannot be patented is a ground on which patent can be revoked. Notwithstanding that patent can be granted to technologies including GM crops.

C. The Plant Variety Protection and Farmers Rights (PVPFR) Act, 2001

The PVPFR Act was aimed to recognize and protect the rights of different stakeholders such as plant breeders, farmers, local communities and researchers for their contribution in conserving, improving and making available PGR for development of new plant varieties.¹⁹

As per Article 27.3 of the TRIPS Agreement, Member countries need to introduce an “effective system” for the protection of plant varieties either by patents or by an effective *sui generis* system or by combination thereof. India chose to adopt the *sui generis* system for

material used in invention would be good ground for opposing patent application (Indian Patent Act, 1970)¹⁸. It becomes an important ground for rejection of patent application as well as revocation of the patent includes nondisclosure or wrongful disclosure of the source of origin of biological resource knowledge in the patent application, an anticipation of knowledge or otherwise”¹⁹ “The Act accelerates agricultural development, stimulates investment for research and development for the development of new plant varieties, growth of the seed industry and ensures the availability of high-quality seeds and plant in material to the farmers. The Act was passed by both the houses and received the assent of the president of India on October 30, 2001. The Plant Variety Protection and Farmers Rights Act, 2001 (Act 53 of 2001, 30th October, 2001)” <https://legislative.gov.in/sites/default/files/A2001-53.pdf>

protection of variety (WTO, n.d.).²⁰ India has incorporated in this Act, the provision of national treatment with respect to new variety rights.²¹ The Act defines variety as a plant grouping of lowest botanical taxon, should be distinguishable from such other plant grouping and be able to act as propagating unit.²² There are four criterion laid down in the Act for protecting a plant variety namely novelty, distinctiveness, uniform and stable (NDUS).²³

The Act allows three types of plant varieties to be registered as

1. Any variety of such genera and species other than an extant or a farmer variety as specified under sub-section (2) of section 29, (New variety)²⁴
2. An extant variety²⁵
3. A farmer's variety²⁶

Essentially Derived Variety (EDV)²⁷. The Act gives differential treatment for the duration of protection for a registered plant variety such as trees and vines for 18 years, other field crops are for 15 years and extant/notified varieties for 15 years from the date of notification of that variety by the Central Government under the Seed Act, 1966.²⁸

Any person belonging from following four categories can apply for registration of a plant variety, first, the breeders or his successor or assignee; Second, the farmer, group of farmers, community of farmers (claiming to be breeder); third, authorized person from above two category and fourthly any institution, university or agricultural institution.²⁹ The Act makes provision and procedure for application for registration of plant variety. There is a form of application and every application made for

²⁰ "World Trade Organization. N.d. *Uruguay Round Agreement: TRIPS, Part II — Standards concerning the availability, scope and use of Intellectual Property Rights, Section 5: Patents, Article 27, Patentable Subject Matter.* https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm"

²¹ The Plant Variety Protection and Farmers Rights Act, 2001 (Act 53 of 2001, 30th October, 2001) <https://legislative.gov.in/sites/default/files/A2001-53.pdf>

²² *Id* at 7.

²³ *Id* at 11.

²⁴ "When a variety not in public domain in India earlier than one year before the date of filing or outside India or in the case of trees or vines earlier than six years or in any other case earlier than four years, it is called as new variety."

²⁵ "Extant Variety are those which is either notified under Seed Act, 1966, a variety about which there is common

knowledge or a farmer's variety or any other variety which is in public domain."

²⁶ "Farmers variety means a variety which has been traditionally cultivated and evolved by the farmer in their crop field or is a wild relative or land race of a variety about which the farmer possesses the common knowledge."

²⁷ "EDV are those variety which is predominantly derived from such initial variety or from a variety that itself is predominantly derived from such initial variety while retaining the expression of the essential characteristics that result from the genotype or combination of genotype of such initial variety and it is clearly distinguishable from such initial variety. An EDV conforms to such initial variety that results from the genotype or combination of genotype of such initial variety."

²⁸ *Id* at 15.

²⁹ *Id*, at 12.

registration of new variety/EDV shall be with respect to a variety; clearly state denomination; affidavit that it does not contain terminator technology or GURT; contain passport data about parent line, geographical location, contribution of farmer, villager or institution; description about NDUS; declaration that genetic material/parental material is lawfully acquired. A certificate is issued after registration by the registrar.³⁰

The Act also lays down certain condition for non-registration of a new variety, when variety is incapable of identification, liable to mislead on characteristic or identity, not different, hurt the religious sentiment, use as a name or emblem and solely or partially a geographical name.³¹ On the other hand, the Act takes care about the protection of traditional knowledge where it demands from breeder that he shall disclose in his application the information regarding the use of plant genetic material conserved by any tribal/rural families in the breeding or developing of such variety or not. If breeder fails to disclose, application rejected.³²

The Act gives rights to breeder, farmers, researchers and local communities who has

anyways contributed to development, conservation or protection of wild species or relatives. The breeder or his successor or his agent or licensee gets exclusive right on registered variety to produce or reproduce, sale, distribute, stock, market and export-import the variety.³³ The farmers rights include right for registration of new variety, registration of own variety, recognition and rewards from national gene fund (NGF) for conservation of genetic resource of land race and wild relatives, save, use, share, sow, re-sow, sell his farm produce and compensation.³⁴ The only prohibition laid down by the Act that farmer is not entitled to sell branded seed. The researcher can use any registered variety for conducting experiment and research and can use variety as an initial source for the purpose of new variety creation.³⁵ The communities get right to obtain compensation when they are not given due share for their contribution and role in conservation of that species.³⁶

To consider the contribution made by any person or community in the development of new variety, benefit sharing arrangements have been made accordingly in the Act. The determination is done by PPVFR authority by

³⁰ *Id.*

³¹ *Id at 11.*

³² *Id at 21.*

³³ *Id at 16.*

³⁴ *Id at 21.*

³⁵ *Id at 18.*

³⁶ *Id at 21.*

giving due hearing to both parties (breeder and benefit claimer). The authority after considering following two key aspects namely the extent and nature of genetic material of claimant used as well as commercial utility and demand of variety, disposes claims and decides the amount to be given to benefit claimant.³⁷ The amount is deposited in NGF. The fund consists of benefit sharing received, annual fee, compensation and contributions used for payment of benefit sharing, compensation, conservation & sustainable use of genetic resources.³⁸

To ensure smooth, ample and continuous supply of propagating material, authority can make order for compulsory license after 3 years in certain circumstances such as when variety is not available in market or not available at reasonable price or when reasonable requirement of public is not satisfied.³⁹

Rights given by law to authorized person is infringed by a person who either is not being breeder/agent/licensee does prohibited acts or deceptively sells variety similar to registered variety that causes confusion in the mind of people in identifying registered variety.⁴⁰ Three

kinds of relief available under this Act as Injunction, damage or a share of the profits.⁴¹

The Act contains penal provisions that provides differential penalties such as, for applying false denomination, the imprisonment is not less than 3 month to 2 year and fine is 50 thousand to 2 lakh or both;⁴² for selling varieties to which false denomination is applied, imprisonment not less than 6 month to 2 year or fine of rupees 50 thousand to 5 lakh or both;⁴³ for falsely representing a variety as registered variety, imprisonment is not less than 6 month to 3 year or fines rupees 1 lakh to 5 lakh or both.⁴⁴ The penalty for subsequent offence is imprisonment not less than 1 year to 3 year or fine rupees 5 lakh to 20 lakh or both.⁴⁵

IV. GM Crops, Environmental Laws and Institutional Framework

The introduction of GM crops has brought new opportunities and challenges in the form of impact on livelihoods and food security, human health, poverty and hunger, free trade and international markets, and the environment, particularly biodiversity. Indian laws and institutional set up are being evolved and made

³⁷ *Id at 16.*

³⁸ *Id at 22.*

³⁹ *Id at 19.*

⁴⁰ *Id 27.*

⁴¹ *Id*

⁴² *Id at 28.*

⁴³ *Id at 29.*

⁴⁴ *Id*

⁴⁵ *Id*

to ensure that public and private interests are maintained. These are ensured in compliance with the global level legal framework such as the CBD and its Cartagena Protocol to which India is party.

A. International Legal Framework for GM crops, Environment and Biosafety

It contains two key legal instruments which has been adopted by India, one the CBD convention and other is its Cartagena Protocol.

1. The Convention on Biological Diversity (CBD)

Convention on Biological Diversity (CBD) was one of the key agreements adopted at the 1992 Earth Summit in Rio de Janeiro. which focuses on three crucial aspects.⁴⁶ Apart from the provisions regulating intellectual property, it also contains provisions for biodiversity and environmental conservation especially originating from genetically or living modified organisms GMO/LMOs.⁴⁷

The convention makes an important provision for the projects such as development of GM crops to have an impact assessment and adopt measures for minimizing adverse impacts on

environment, biodiversity and human health. It also emphasis the public participation in such measures that makes the project transparent.⁴⁸ Apart from these key articles, provisions for compensation for any damage arising from any project, incentive measures, research and training, public education and awareness, access to and transfer of technology, exchange of Information, technical and scientific cooperation pertaining to conservation of biodiversity are also included. The CBD convention contains Cartagena Protocol as supplementary legal frameworks to achieve the goal of convention.

Cartagena protocol

Under the CBD convention, the Cartagena Protocol on Biosafety was adopted in 2000. The Protocol became operative in July 2003. The protocol gets its force from Article 19 of CBD convention that talks about handling of biotechnology and distribution of its benefits.⁴⁹

The protocol is primarily concerned with trans-boundary movement of LMOs and provides a framework for countries to assess risks associated with LMO prior to authorizing

⁴⁶ “Conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits from the use of genetic resources.”

⁴⁷ “such as States have the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities

within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.”

⁴⁸ *Id.*

⁴⁹ Cartagena Protocol. (18 May, 2021). *About the Protocol.* <http://bch.cbd.int/protocol/background/>.

importation. It seeks to ensure: “An adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on trans-boundary movements”.⁵⁰

B. GM Crops, Environmental laws and Institutional Setup in India

India started taking step to ensure safety at all levels sensing the importance of environmental risks, the research, product development and commercial release involving GMOs, hazardous microorganisms and trans-boundary movement of the living modified organisms (LMOs).

There are three key Acts executed by Parliament of India for regulating at development, release and commercial approval

of GM crops.⁵¹ India started regulating GMOs and products thereof by first enacting the Environmental Protection Act (EPA) 1986. Though, the Act does not describe specifically GMOs and GM crops, but it lays down provisions to regulate hazardous substances.⁵²

V. Evolution of Regulatory Framework for GM Crops in India

➤ The National Biotechnology Board was set up and a set of biotechnology safety guidelines were issued in 1983 to undertake biotech research in laboratory.

➤ The National Biotechnology Board was converted into Department of Biotechnology (DBT) in 1986 under the Ministry of Science and Technology (MOST) and got role of monitoring, development of safety guidelines and promotion of biotechnologies in country.

Later on, biotechnology (GMOs/LMOs) related work was reallocated to Ministry of Environment and Forest (MoEF).

⁵⁰ “Two key concepts, biosafety and precaution, form the basis for the framework developed in the Protocol. Biosafety is based on the concept of precaution and implies minimizing the risk to human, animal and environment health. It includes a range of measures, policies and procedures to minimize potential risks. The precautionary approach has been specifically incorporated in the Protocol that allows governments on the basis of precaution to prohibit the import of a GMOs, even where there is insufficient scientific evidence about potential adverse effects.”

⁵¹ “Environment Protection Act 1986 (implemented by MOEF); the Seed Act 1966 & the Seeds (Control) Order

(implemented by Ministry of Agriculture (MOA) and the Food Safety and Standard Act 2006 (implemented by the Ministry of Health and Family Welfare).”

⁵² “Hazardous substances have been defined as “any substance or preparation which, by reason of its chemical or physicochemical properties or handling, is liable to cause harm to human beings other living creatures, plants, microorganism, property or the environment.” The Environmental Protection Act, 1986. Chapter II General Powers of The Central Government - 3(2), (vii), 3. (Act No. 29 of 1986, 23rd May, 1986.) <https://legislative.gov.in/sites/default/files/A1986-29.pdf>

- The Environmental Protection Act (EPA) 1986, was enacted by the Parliament of India. biosafety, risk assessment and risk management related aspects of GM crops to DBT.
- MoEF drafted and notified the rules for the manufacture, use, import, export and storage of hazardous microorganisms, genetically engineered organisms or cells in 1989 or the EPA Rules 1989 under ‘hazardous substances’ section 3(2)(iv) of the EPA 1986. These rules to regulate GMOs and GM crops come into force on 13 September 1993. The applications of biotechnology in agriculture as GM crops or their products is being dealt with by above said three different Ministries/Departments in India and have six competent authorities as outline in figure herein:
- The Seed Act 1966 & the Seeds (Control) Order by Ministry of Agriculture (MoA) and the Food Safety and Standard Act 2006 by the Ministry of Health and Family Welfare (MOH&FW) were also brought to regulate GM crops.⁵³

Under such rules GM crops, GMOs and the products of genetic engineering were *de facto* categorized as ‘*inherently harmful*’ in the same manner as hazardous substances that cause harm to human beings or other living creatures, property or the environment. The Rules also makes provisions for appointment of competent authorities and composition of such authorities for handling of various aspects of GMOs. To ensure inter-ministerial coordination EPA rules 1989 was used that involves the DBT for its experience and expertise by assigning the

⁵³ Bhagirath, C., Godelieve, G., Jeroen, B., Piet, M. & Sylvia, B. (2014). Regulatory options for genetically

modified crops in India, *Plant Biotechnology Journal*, 12, 135–146.

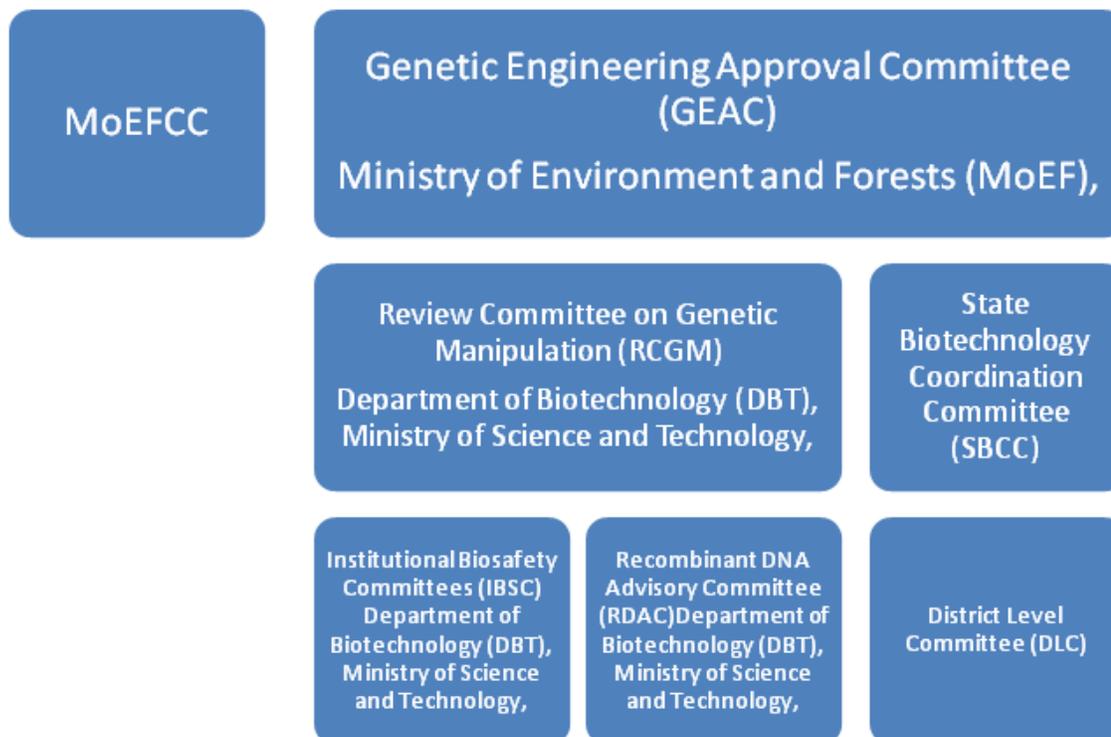


Fig.: Institutional framework for GM crops regulation in India

VI. Judicial Approach

As the matter of GM crop is bit technical in nature so court has not pronounced any direct decisions. After grant of first GM crop in India in 2002, activist filed public interest litigation (PIL) in Supreme Court (SC) of India against GM crops in 2005. Later on, a panel was appointed by SC to suggest moratorium on GM field trials.⁵⁴ The panel in an interim report recommended an indefinite moratorium for the next 10 years on field trials of GM crops and complete ban on the commercial release of GM

crops to the Supreme Court in October 2012.⁵⁵

The panel submitted a final report in July 2013 with one dissenting vote that supported release of GM crops.

CASE LAWS

Diamond v. Chakrabarty (1980)

It is a landmark judgment on life forms delivered by the US Supreme Court. It held microorganisms as patentable subject matter. In this case, the scientist Anand Mohan Chakrabarty, who was working for General Electric (GE) invented a genetically modified bacterium (microorganism) containing

⁵⁴ *Aruna Rodrigues v. Union of India*, 1944/2005/SC/PIL

⁵⁵ Kumar, S., Bhatnagar R. K., Kranthi, K. R., & Datta S. K. (31 January 2014). The legal battle over field trials of

GM crop. <http://www.natureasia.com/en/nindia/article/10.1038/nindia.2014.14>, doi:10.1038/nindia.2014.14.

modified plasmids. The microorganism was capable of degrading crude oils which had potential application in clean-up of oil spill. The patent was filed in 1972 but got rejected by patent examiner. The reason given that ‘living things’ were not patentable as subject matter under Section 101 of Title 35 U.S.C. The Board of Patent Appeals and Interference also agreed with reasoning of Patent examiner. The petitioner moved to US Court of Customs and Appeals which overturned the case decision that led to appeal in Supreme Court. The Supreme Court in a 5-4 ruling, held in favor of Chakrabarty as “a live human-made microorganism is patentable subject matter and it constitutes a “*manufacture*” or “*composition of matter*” within those statutes. It was also clarified that newly discovered products of nature are not patentable.⁵⁶

The judgment led to settling the dispute what is patentable and what is considered. The judgment opened the door for more biotechnology-based research by using genetic resources to create GMOs of plant, animal or microorganisms.

Nuziveedu Seeds Ltd. v. Monsanto Technology Llc (2018)

In this case Monsanto developed transgenic Bt II cotton seed by inserting the Cry2Ab gene into the cotton genome and secured process patent rights. Later on, Monsanto licensed seeds (doner seeds) of the cotton to seed companies, including Nuziveedu. The companies then introgress the traits from the ‘donor seeds’ into local plants to develop hybrid cotton plants having Cry2Ab and paid royalty to the Monsanto. Later on, Monsanto terminated the agreement with Nuziveedu due to issues concerning the payment of royalties but company continued to use the seeds. Monsanto filed a suit claiming that its patent rights were being infringed but Nuziveedu resisted by saying that Monsanto claim was invalid on two grounds one, the Patents Act bars patent on a living organism (transgenic donor seeds) and second, Monsanto has been granted process patent. Thus, the issue before the Court was whether the process patent granted on Monsanto’s claim which is resulting in donor transgenic Bt II seeds, was covered by the exclusion under section 3(j) of the Patents Act. The court affirmed positively and held that transgenic plants are excluded from protection under the Patents Act and can be registered

⁵⁶ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) <https://supreme.justia.com/cases/federal/us/447/303/>

under the PPVFR Act. The case is presently under appeal in the Supreme Court of India.⁵⁷

VII. Conclusion

The introduction of GM crops has brought new opportunities and challenges in the form of impact on livelihoods and food security, human health, poverty and hunger, free trade and international markets, and the environment,

particularly biodiversity. Indian laws and institutional set up are being evolved and made to ensure that public and private interests are maintained. The current legal cum institutional framework is quite encouraging. However there lies a scope for improvement and expansion with respect to enhancing the existing framework for streamlining the GMO patenting and commercialization.

Table 1. List of GMOs grown around the world

(Source: ISAAA. 2019. Global Status of Commercialized Biotech/GM Crops in 2019. ISAAA Brief No. 55. ISAAA: Ithaca, NY)

S. NO.	NAME OF COUNTRY	TRANSGENIC CROPS
1	India	Cotton
2	Canada	Canola, Maize, Sugar beet, Soyabean, Alfalfa, Potato
3	USA	Canola, Maize, Sugar beet, Soyabean, Alfalfa, Potato, Cotton, Papaya, Squash, Apple
4	Portugal	Maize
5	Spain	Maize
6	China	Cotton Papaya
7	Vietnam	Maize
8	Bangladesh	Egg plant
9	Myanmar	Cotton
10	Pakistan	Cotton
11	Indonesia	Sugarcane
12	Philippines	Maize

⁵⁷ *Nuziveedu Seeds Ltd. v. Monsanto Technology Llc*, 2018(74) PTC12(Del) 2018 MANU/DE/1388/2018=MIPR2018(2)179,

12	Australia	Cotton
Latin America		
14	Mexico	Cotton
15	Costa Rica	Cotton, Pineapple
16	Honduras	Maize
17	Columbia	Cotton, Maize
18	Brazil	Cotton, Maize, Soyabean, Sugarcane
19	Bolivia	Soyabean
20	Chile	Maize, Canola
21	Argentina	Soyabean, Maize, Cotton, Alfalfa
22	Uruguay	Maize, Soyabean
23	Paraguay	Maize, Cotton, Soyabean
Africa		
24	Nigeria	Cotton
25	South Africa	Cotton Maize, Soyabean
26	Eswatini	Cotton
27	Malawi	Cotton
28	Ethopia	Cotton
29	Sudaan	Cotton

Table 2: Different categories of transgenic crops developed by genetic engineering:

S.NO.	NATURE OF GM CROPS	AIM	GENES/PROTEINS	CROPS
	Herbicide tolerant	Developed to kill weeds that grows along with agronomically useful crops by use of selective & non selective herbicides.	glyphosate oxidoreductase (<i>GOX</i>), glyphosate acetyltransferase (<i>GAT</i>)	Maize, Argentine canola, soybean, potato, carnation, rice,

				sugar beet, wheat.
	Insect resistant	To control the harmful insects attacking economically important crops	<i>cry</i> gene, and <i>vip</i> gene	Maize, cotton, potato, soybean, rice, sugarcane, poplar, brinjal, tomato/ canola, Chickpea, alfalfa, Tomato
	Abiotic stress tolerant	To provide tolerance against abiotic stress like heat, salt, temperature,	<i>betA</i> , <i>cspA</i> <i>cspB</i> , and <i>Csp3</i> genes (cold shock protein gene) transcription factors (TFs)	maize, sugarcane and soybean.
	Disease resistant	To provide protections from pathogens like virus, bacteria and fungi	Coat protein (<i>cp</i>) genes, By gene silencing mechanism	potato papaya, squash bean, plum, sweet pepper and tomato
	Nutritional improvisation	Provide Vitamins as supplement along with food such as Vit-A	<i>psy</i> gene, <i>crtl</i> gene	Rice
	Modified oil/fatty acid	To provide transfat free oil, increased shelf life and increase the content of PUFA	genes to produce high levels of omega-3 long-chain polyunsaturated fatty acids (PUFAs)	Argentine canola, safflower, and soybean

	Essential Amino Acids	To supplement the essential amino acid	seed storage protein from <i>Amaranthus</i> <i>hypochondriacus</i> in cereals <i>cordapA</i> gene	maize
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(Source: Kumar, K., Gambhir, G., Dass, A., Tripathi, A. K., Singh, A., Jha, A. K., Yadava, P., Choudhary, M., & Rakshit, S. (2020). Genetically modified crops: current status and future prospects. *Planta*, 251(4), 91. <https://doi.org/10.1007/s00425-020-03372-8>