

Genetic Modification Technology and Environment Law

Arundhati Patra*

Abstract

The massive development of the field of biotechnology has ensured the increase of vast knowledge in the area of genetic modification. The rapid rate of progress has made it mandatory to regulate this field efficiently. Various international conferences have yielded regulations and rules that are to be mandatorily followed to ensure the safety of the environment. Taking inspiration from the international regulations there have been many developments in the field of the laws of genetically modified technology. The precautionary principle of environmental law is one of the basic principles that has been followed during the formulation of both the international as well as in Indian policies of genetic modification. This paper discusses the evolution of these laws through time and the decisions of the judiciary that impacted the regulations of genetic modification technology.

Keywords: Genetic modification, biotechnology, environment, environment law, genetic modification technology

INTRODUCTION

Biotechnology has developed significantly in the last few decades offering varieties of both benefits and risks. Genetic engineering has enhanced the production of food by reducing the vulnerability of plants to drought, frost, insects, and viruses and by allowing plants to compete more efficiently against weeds for the soil nutrients. It has also substantially improved the quality and nourishment of foods by altering their composition. It has provided a means to introduce genes into plants and organisms that are different in some respects from the classical breeding methods.

The process of alteration in the genetic makeup of an organism is known as genetic modification. This process has been in practice since ages by selective and controlled rearing and breeding of flora and fauna for beneficial domestic use. The modern developments in the biotechnology industry has further helped in the easier, faster and more precise alteration of the organism by genetically engineering its specific gene.

Genetically modified organisms or GMOs are defined as organisms other than human beings in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination [1]. GMOs have been widely used in medical researches, biotechnological researches, in the pharmaceutical industry for the preparation of drugs, for researches on experimental medicines and most commonly and extensively acclaimed agriculture industry.

*Author for Correspondence

Arundhati Patra
E-mail: arundhati.patra24@gmail.com

Student, National University of Study and Research in Law,
Ranchi, Jharkhand, India

Received Date: February 26, 2021
Accepted Date: March 30, 2021
Published Date: May 21, 2021

Citation: Arundhati Patra. Genetic Modification Technology and Environment Law. National Journal of Environmental Law. 2021; 4(1): 76–86p.

During the past several years, developments in the biomedical sciences relating to genetics have given rise to dramatic possibilities for human intervention in the basic genetic processes. Such intervention may be directed towards the reduction or elimination of disease of genetic origin. It may be directed towards the modification of the natural processes of evolution, the modification of the basic characteristics of living creatures, including humans. There has been a comprehension on the

part of the biomedical community that these developments will have a profound impact on society, and the biological community has undertaken to engage representatives of other disciplines philosophers, theologians, lawyers, ethicists, sociologists, etc. in speculations and discourse as to the social consequences of the use of the new genetic knowledge [2].

The recent discoveries in this domain have given rise to considerable amounts of concern and debate among all communities. The reasons for this apprehension regarding genetic modification are because of a number of issues, posing unique and erratic hazards to human life, to the environment and to agriculturally based economies. On the contrary, the benefits to the medical industry, agriculture industry and the environment counterbalance the detriments through it.

The rapid developments in this field give rise to legal issues as well in addition to the aforementioned issues. While the technical aspect comes under the intellectual property right law, its effect to the environment in general can be regarded as a very important part of environment law.

In fact, the legal controversy over bioengineered plants and foods is not new [3] rather there have been numerous lawsuits over the commercialisation and intellectual property rights attached to these techniques, but in recent times, awareness about environment and climate change has led to many environmentalists to look at its ecological effect so that it does not damage the environment.

ENVIRONMENTAL IMPACT OF GENETICALLY MODIFIED ORGANISMS

The development of genetically modified organisms has allied disparate groups concerned about food safety and the environment. Any new development or invention comes with both benefits as well as disadvantages especially if it directly affects the ecosystem. Experience gathered through years of environmental impact studies suggests that the impact on the environment due to new biological elements in the ecosystems may take many years to be understood, thus increasing the probability of causing adverse harm to the environment before the cause is discovered. The environmental impact of introduced genetically modified organisms can be either ecological or genetic [4].

They may include:

Impact on Non-target Species

The population dynamics may be affected by the unintended effects in the receiving environment due to the impact on non-target species, which may occur directly by predation or competition, indirectly by changes in the farming patterns and the use of land.

A study by some scientists in the year 1999, revealed that pollen from an insect resistant corn had a negative impact on the larvae of Monarch butterflies thereby raising concerns and questions about potential risks to this specie due to genetic mutation. It was however cautioned that the particular study in question was conducted in a lab therefore to base this theory solely on this study would be inappropriate. Another study in 2001, concluded that the impact of the particular genetically mutated corn in question was negligible to this species of butterfly [5].

Unintended Effects on Biogeochemistry

The soil microbial populations that regulate the flow of nitrogen, phosphorus and other essential elements that lead to the unintended effects on the biogeochemistry of the ecology and the environment. Another concern over the use of genetically modified crops is their quality of insect resistance, which will lead to the decline of the insect population, thus affecting the biodiversity of the environment [6]. Therefore, to prevent this phenomenon from happening, it was required by the farmer to have a small portion of non-modified crops, so the insect population is not affected. Thus, the regulation of these crops was required so that the ecology is not affected.

Transfer of Inserted Genetic Material

Due to processes such as gene flow, through pollination, mixed mating, dispersal or microbial transfers, transfer of genetic material to other domesticated or native populations due to the interference of the genetically modified organisms. The genetically mutated crops have the potential to create new weeds by crossing with wild relatives, or simply by persisting in the wild. A ten-year study initiated in the year 1990 demonstrated that there is no increased risk of invasiveness or persistence in wild habitats for genetically modified crops and traits tested when compared to their unmodified counterparts. However, the researchers stated that the results “do not mean that genetic modifications could not increase weediness or invasiveness of crop plants, but they do indicate that productive crops are unlikely to survive for long outside cultivation” [7]. Therefore, the regulation of these genetically modified organisms is very important so that the environment does not face harm.

Biosafety Aspect of Genetically Modified Trees

The genetically modified trees are needed to be regulated because of the long generation time of trees, the very important roles of the trees in the ecosystem functioning and their ability for dispersal of pollen and seed in the long distance. It is essential to weigh the possibilities of the exploitation of large amounts of genetic variation in the forest trees that is generally untapped. Insect and virus resistance, herbicide tolerance and modified lignin content are the features that can be genetically introduced in trees and are generally found in such modified trees. The first reported trials with genetically modified forest trees are recorded in the year 1988 using poplar trees even though there has not been commercial-scale production of such trees.

Issues of Genetically Modified Fishes

Genetic modification technology has also been introduced in the fishery industry. The essential issues of such modified fishes focus on predation, competition and genetic pollution. These fishes may pose risk to the environment due to the increase in the rate of feeding on prey species, the wider environmental tolerances of these species allowing them to invade new territories and leading to a possibility of displacing the local native population as well as potentially genetically mixing with, and altering the compositions of the natural fish population. However, the researchers have claimed that these species of fishes shall be very domesticated and thus may not be able to survive in nature of long.

PRECAUTIONARY PRINCIPLE IN GENETIC MODIFICATION TECHNOLOGY

Precautionary principle is a guiding principle that helps to prevent the activity that posing threat or danger to the environment. It considers the harmful effects before they pursue their activities [8]. It is a notion which supports taking protective action before there is complete scientific proof of a risk, that is, action should not be delayed simply because full scientific information is lacking. It is mainly based on the concept of ‘prevention is better than cure’.

The earliest mention of this principle can be traced back to England in the year 1854 when Dr John Snow recommended the removal of a handle of a London water pump in order to stop a cholera epidemic [9]. Even though there was no substantial proof that it would help beyond reasonable doubt, yet this simple and relatively inexpensive measure very effectively helped in halting the spread of the epidemic. The origins of the official use of precautionary principle is said to be Germany where it was said to be one of the basic principles of environmental policy ever since the mid-1970s along with the cooperation principle and the polluter pays principle.

The protection of the North Sea can be counted among the first global level use and acceptance of the precautionary principle. This was discussed at a number of international conferences held in Bremen (1984), London (1987), The Hague (1990), Esbjerg (1995), Bergen (2002) and Gothenburg (2006) [10]. The word precaution was not used in the first conference, while at the second conference in 1987, the London Declaration mentioned the necessity of a precautionary approach that required an

action to control inputs of the most dangerous substances before the establishment of causal links through absolute clear evidences. The third conference in The Hague it was declared that the precautionary principle would be applied, thereby referring to the action to be taken in a way that potentially damaging impacts of substances that are persistent, toxic and have high chances of bioaccumulation can be avoided even when there is no scientific evidence to prove that a causal link between emissions and effects has been established [9].

In the Esbjerg Declaration at the fourth conference, the precautionary principle is applied in fisheries management policies. Bergen declaration was adopted in the fifth conference that stated that to achieve sustainable development, precautionary principle must be adopted in framing the policies. Environmental measures must anticipate, prevent and attack the causes of environmental degradation. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation [11]. The parties at the Gothenburg Conference in 2006 revealed that numerous issues that have been discussed at the various conferences are now being treated at different forums.

The London Convention in the year 1972, named Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter was of the view that when there was reason to believe that substances or energy released into the marine environment would likely cause harm, appropriate preventive measures have to be taken, even when there was no conclusive evidence to prove a causal relation between inputs and their effects [12].

The United Nations Conference on Environment and Development (UNCED) in the year 1992 also called the Rio Declaration in the year 1992 explicitly recognized and adopted the precautionary principle. The participating parties accepted that where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation [13]. In the United Nations Framework Convention on Climate Change, 1992, the parties came to the conclusion that to anticipate, prevent or minimise the causes of climate change and mitigate its adverse effects, precautionary measures should be taken. In case of serious and irreversible threats, lack of scientific research should not be used as a reason for postponing such measures, taking into account that policies and measures to deal with climate changes should be cost-effective so as to ensure global benefits at the lowest possible cost [14].

The European Union recognised that its well-being is inextricably linked at the sea [15]. Article 191 R para 2 of the Treaty on the functioning of the European Union (EU) aims to ensure a higher level of protection of environment through taking preventive measures in case of risk. It shall be based upon precautionary principle and polluter pays principle. The parties shall take provisional measures to safeguard the environment that shall be subjected to the inspection of the procedures of the community.

REGULATION OF GENETIC MODIFICATION TECHNOLOGY WORLDWIDE

Convention on Biological Diversity (CBD)

Convention on Biological Diversity in 1992 and the Cartagena Protocol in 2000 are among the major instruments that are internationally relevant in the field of biosecurity. The main objective and aims of this Convention are the preservation of biodiversity, sustainable use of its components and the fair and equitable allocation of the benefits arising out of the use of genetic resources. Biosafety is addressed in two Articles by the CBD, Article 8(g) and Article 19(3) and (4). Article 8(g) [16] states that *the Contracting party shall- establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.*

The Article 19(3) [17] states that *the Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity*. While Article 19(4) [17] states that *each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced*.

The Convention itself requires implementing legislation as it is non-self-executing. The Contracting Parties are guided by the in the implementation of the official documents that contain the Articles and the decisions of the Convention. The documents also mention a clause that the Contracting Parties shall periodically report on the implementation of the Convention in Article 26.

Cartagena Protocol on Biosafety to the Convention on Biological Diversity

The first international instrument legally binding to the living modified organisms was the Cartagena Protocol that was adopted in 2000. The basic purpose of this Protocol was to control the adverse effects by the genetically modified organisms that the transfer, handling and use of such organisms do not affect the sustainability and conservation of the ecology as well as risk human health. This Protocol is based on the precautionary principle as well as specifies the general measures for risk management and the criteria.

Article 6 of the Protocol [18] states about the transit and contained use of the genetically modified organisms, Article 7 as well as 8 states about the advance application as well as notification of the transfer of such organisms. Article 10(3) states that 270 days shall be provided in which it shall be decided whether to allow the parties and what conditions shall be imposed on the grant of such permission. Article 20(1) states that a Biosafety Clearing-House is to be established as part of the clearing-house mechanism. Article 17(1) states if a party becomes aware about any accidental movement of such modified organisms across borders and such movement may lead to “have significant adverse effects on the conservation and sustainable use of biological diversity” including risk to human health, then the party shall be obligated to notify the affected countries, the relevant international organisation and the established Biosafety Clearing-House. Article 18 states that it must be ensured that relevant measures shall be taken so that there is proper handling, packaging as well as safe movement of the genetically modified organisms in addition to the containment of all documentation during its shipment. Improper transmission of Genetically Modified Organisms across borders does not hold any specific penalties according to the Protocol. Article 25 states that the parties *shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements on violation of the provisions of the Protocol and such cases must be reported to the Biosafety Clearing House*.

The Protocol thus creates an enabling environment for the environmentally sound application of biotechnology, making it possible to derive maximum benefit from the potential that biotechnology has to offer, while minimizing the possible risks to the environment and to human health [19].

Nagoya-Kuala Lumpur Supplementary Protocol

This protocol was adopted in the year 2010 after years of negotiations over issues of liabilities arising out of genetically modified organisms. René Lefeber, who was one of the co-chairs while facilitation of negotiations of the text of this Protocol stated that “*since adverse effects may occur in spite of risk-management measures or as a result of the failure to identify the risk of adverse effects, the allocation of the costs of such effects should be anticipated and regulated*” [20]. The basic aim of

the Supplementary Protocol is “to contribute to the conservation and sustainable use of biological diversity, taking also into account risks to human health, by providing international rules and procedures in the field of liability and redress relating to living modified organisms” [21]. This Protocol is based on the polluter pays principle and also states in Article 11 [22] that it does not affect “the rights and obligations of States under the rules of general international law with respect to the responsibility of States for internationally wrongful acts”. It also provides that domestic laws can be used by the Parties as rules and procedures and to establish the time and limits of liability for costs incurred in response to damages [23] caused by such genetically modified organisms as well as in case of establishing civil liability laws for the regulation of the genetically modified organisms to apply to their existing general laws [24].

WTO—Sanitary and Phytosanitary Measures Agreement

The Sanitary and Phytosanitary Measures Agreement or the SPS Agreement is supervised by the World Trade Organisation and Article 1(1) in the Agreement provides a common approach to the different sectors in the biosafety field by application in a sanitary and phytosanitary measures that affect international trade either directly or indirectly [25]. Article 2(3) states that such measures must not be “arbitrary or unjustifiably discriminate between member states” and that would lead to restrictions on international trade in disguise. The Agreement elucidates what factors shall be considered while considering the involvement of risk in the genetically modified organisms. Article 5(2) elucidates that while considering the risk assessment “available scientific evidence” as well as “relevant economic factors” [26] must be taken into consideration. Article 5(7) in the Agreement [24] provides flexibility for the adoption of the regulations in case the scientific evidences are insufficient. This Agreement is a non-self-executing legal instrument and is subject to revision of regulations for the compliance with the international standards. This Agreement is referred to and applied when a biotechnological product is a potential risk to human, animal or plant health.

WTO—Technical Barrier to Trade Agreement

This Agreement monitored by the World Trade Organisation is a modified version of the Tokyo Round code that had been negotiated in 1973-79 and it tries to ensure that regulations, standards, testing and certification procedures do not create “unnecessary obstacles to international trade” [27] and be “more trade-restrictive than necessary” in the hopes of achieving their “legitimate objective, taking account of the risks of non-fulfilment” as stated in Article 2.2 [28]. This agreement comprises of technical regulations that require mandatory compliance as well as standards that are non-binding set rules. It is applicable to a wider range of domestic health and environment regulations. The basic aim of this Agreement was to conform the national regulations to the international standards while also ensuring that domestic industries do not suffer unfairly due to the foreign industries and the foreign industries do not face barriers to international trade especially with respect to genetically modified organisms.

Codex Alimentarius Commission

The Codex Alimentarius international food standards, guidelines and codes of practice contribute to the safety, quality and fairness of this international food trade [29]. The Codex commission primarily addresses the aspect of food safety in genetically modified organisms. The main aim of this Commission was the protection of consumer health, monitoring practice of fair trade and promotion of the global standards of food laid down by the international organisations. The year 1993, saw the beginning of discussions for labelling guidelines for genetically modified organisms and opposed by many countries at that time. However, several years of disagreements and discussions finally yielded result when in the year 2011 voluntary adoption of genetically modified food product labelling was agreed to and the labelling guidelines were adopted by the participating countries.

International Plant Protection Convention (IPPC)

The purpose of the International Plant Protection Convention or IPPC is to secure common and effective action to prevent the spread and introduction of pests of plants and plant products, and to

promote measures for their control [30]. The main areas of work for the IPPC are protection of wildlife as well as wild and cultivated flora in addition to direct and indirect damage from pests and weed, thereby ensuring the conservation of natural resources as well as biodiversity in plants and animals. Article I(4) of the IPPC text states that it regulates “any organism, object or material capable of harbouring pests or spreading pests that affect plants or plant products” [31]. The areas of work for the IPPC have a broad applicability, they include the regulation of genetically modified organisms and living modified organisms that could directly or indirectly impact the biodiversity.

REGULATION OF GENETIC MODIFICATION TECHNOLOGY IN INDIA

The framework for the regulation of biosafety in India is governed by two main regulatory bodies, Department of Science and Technology and Ministry of Environment and Forest. Genetic Engineering Appraisal Committee setup under the Ministry of Environment and Forest implements the decisions based on the State Biotechnology Coordination Committees and the District Level Committees that are set up by the respective Ministry. Other such committees that are involved in the implementation of guidelines are the Institutional Biosafety Committees and the Review Committee on Genetic Manipulations. The National biosafety framework is mainly involved with the regulation of processes related to the genetically mutated organisms in all states to ensure their safety as well as the safety of the ecology and humans.

A few biosafety legislations in India are mentioned below:

Environment (Protection) Act, 1986

This legislation was implemented as a means to provide a universal structure for the improvement and protection of the ecology. The Ministry of Forest and Climate Change laid down the “Rules for manufacture, use/import/export & storage of hazardous microorganisms/genetically engineered organisms or cells, 1989 [32]” on the basis of Section 8 and 25 of the Environment (Protection) Act, 1986 [33]. The laid down rules are essentially very broad in range covering entire sets of activities in relation to genetically modified organisms and relating product including new gene technology apart from genetic engineering. Biosafety safety measure is provided in the Rules, 1989 [31], its violation and non-compliance of these rules lead to penal action under the EPA, 1986 [32]. The exclusions related to genetically mutated organisms provided under this rule are:

- No person shall import, export, transport, manufacture, process, use or sell any genetically modified organisms, substances or cells except with the approval of the Genetic Engineering Appraisal Committee.
- Use of pathogenic organisms or genetically modified organisms or cells for research purpose shall only be allowed in laboratories or inside laboratory areas notified for this purpose under the EPA, 1986.
- Any person operating or using GMOs for scale up or pilot operations shall have to obtain permission from Genetic Engineering Appraisal Committee.
- Experiments for the purpose of education involving GMOs can be undertaken with the oversight of Institutional Biosafety Committee.
- Deliberate or unintentional release of GMOs not allowed.
- Production in which GMOs are generated or used shall not be commenced except with the approval of Genetic Engineering Appraisal Committee. All approvals shall be for a period of 4 years at first instance renewable for 2 years at a time.
- GEAC shall have powers to revoke approvals in case of:
 - i. Any new information on harmful effects of genetically mutated organisms.
 - ii. Genetically mutated organisms cause such damage to the environment as could not be envisaged when approval was given.
 - iii. Non-compliance of any conditions stipulated by Genetic Engineering Appraisal Committee.

Plant Quarantine (Regulation for Import into India) Order 2003

This order [34] has been passed under the Destructive Insects and Pests Act, 1914 and is regulated by the Ministry of Agriculture & Farmers Welfare. It covers the regulation of germplasm/GMOs/transgenic plant material for research purpose. The order mainly regulates the import of such organisms for the purpose of research. Consignments containing such material are not allowed to be imported into India for research or experimental purpose without valid permit [31]. A number of measures have been laid down in the order to ensure the safety of the ecology such as restriction of import of some species, proper experiment as well as quarantine facility certified by the authority so that the environment is not affected, proper safety and testing facilities along with proper facilities for their supervision.

Biological Diversity Act, 2002

The National Biodiversity Authority implemented the Biological Diversity Act, 2002 that regulate the use of biological resources that include genes used for the improvement of crops and livestock through genetic intervention. The preamble for this act provides for the *“conservation of biological diversity, sustainable use of its components and equitable sharing of the benefits arising out of the use of biological resources”*.

The Supreme Court has held that the Convention on Biodiversity has been accepted by India and is obligated to implement it. It was said *“India is a signatory to CBD, which also mandates the contracting parties to develop and maintain necessary legislation for protection and regulation of threatened species and also regulate trade therein [35]”*. It was held by the Apex Court that *“it is settled law that the provisions of the Treaties/Conventions which are not contrary to Municipal laws, be deemed to have been incorporated in the domestic law [36]”*. The Apex Court has held that the Biological Diversity Act, 2002 states that *“bio- diversity and biological diversity includes all the organisms found on our planet i.e. plants, animals and micro-organisms, the genes they contain and the different eco-systems of which they form a part” [37]*.

The most important elements of the Biological Diversity Act, 2002 are:

- To transfer genetic material outside the country and to claim intellectual property right over it, approval of the Indian Government is required.
- Measures have been put in place through this act to claim as well as share benefits from the use of biodiversity, transfer of technology, returns of a monetary nature, research and development, ownership, etc.
- It provides Measures for conservation and sustainable use of biological resources, along with habitat and species protection, assessment of the impact on environment projects, inclusively integrating biodiversity conservation into the plans, policies as well as programs of different sectors.
- Integration of local communities and requirement of their knowledge and say for the utilisation of the indigenous and traditional resources.
- Regulations for the use and utilisation of genetically modified resources.

Food Safety and Standards Act, 2006

This Act is monitored by the Food Safety and Standards Authority of India and it regulates the manufacture, storage, distribution, sale as well as import of food which includes genetically modified food. This Act is based on a few aspects of the Prevention of Food Adulteration Act, 1954 and the international legislations and the guidelines of the Codex Alimentarius Commission, thus conforming it to the international trends regarding food standardisation. It delegates responsibility to the manufacturers by providing provisions to recall food. In cases where the food business operator is of the knowledge that the processed, manufactured or distributed food does not comply with the provisions of the Act, he is entitled to recall such food from the market only after information is provided to the consumer regarding the reasons for such withdrawal [38]. Section 34 of the Act also

gives the designated officer power to exercise the imposition of emergency prohibition notice against health risk in respect of food businesses [38]. The existing legislation does not have any appropriate procedure to deal with the damages caused by the transboundary trade of GM foods or remains silent towards incorporating the procedures relating to emergency response measures [39].

CONCLUSION

Genetic modification technology can be defined as the technique by which genetic material can be transferred from one organism to another that cannot occur naturally by mating or natural recombination. This technology gained worldwide acclaim after several successful researches that ensured positive developments in the field of crops and food development. Genetically modified technology has many benefits that have been well established after several researches, these benefits include higher nutritional value, tolerance to herbicides and pesticides, resistance to viruses and bacteria, tolerance to factors such as climate, increased shelf life and thus ultimately leading to the resolution of the problems of security of food and issues of nutrition security. Like any other new technology genetic modification technology also stems a number of ecological concerns, mainly from the inability to control such technology after releasing them in the society.

There are a number of positive as well as negative aspects of genetic modification technology which is why it is essential to regulate such technology. Various efforts have been made both in the national as well as international forum to regulate this technology. The basic principle of such regulations is the precautionary principle stating action should not be delayed for the reason that there is lack of complete scientific proof regarding it. A number of international treaties, negotiations and commissions took place for the purpose of regulating this technology. The most important one being the Cartagena Protocol on Biosafety, of which India is a signatory as well. It was the first discussion in the international forum regarding genetically modified organisms. It further influenced the legislations for the subsequent discussions in the international forum. The protocols and treaties in the international forum have influenced the formation of legislations in the domestic and national forum. Regulatory bodies were formed in India in the basis of the discussions in these protocols and it also prompted the formation of legislations such as Environment (Protection) Act, 1986 that was the first legislation to mention the regulation of genetically modified organisms. It is important to periodically revise and review such decisions and legislations so that it is in cooperation with the scientific developments and experts. While regulations have been formed regarding genetically mutated technology, India along with the world requires more research as well as legislations in this field so that both scientific development in addition to the rule of law can be effectively regulated and promulgated.

Conflicts of Interest

The author declares no conflict of interest.

REFERENCES

1. Verma C. A Review on Impacts of Genetically Modified Food on Human Health. (2011) 4 The Open Nutraceuticals Journal 3 <https://benthamopen.com/contents/pdf/TONUTRAJ/TONUTRAJ-4-3.pdf>.
2. Green HP. Genetic Technology: Law and Policy for the Brave New World. (1973) 48 Indiana Law Journal 559.
3. Weiswasser ES, Egan KK and Calia KG. Genetically Modified Foods Raise New Legal Issues. (2001) 22 The National Law Journal 1 <https://www.cov.com/-/media/files/corporate/publications/2001/06/oid6070.pdf>.
4. GMOs and the Environment. (GMOs and the environment) <<http://www.fao.org/3/x9602e/x9602e07.htm>> accessed April 5, 2020.
5. Hellmich RL and Siegfried BD. Bt Corn and the Monarch Butterfly. [2001] Genetically Modified Organisms in Agriculture 283.

6. Pocket K No. 4: GM Crops and the Environment. (GM Crops and the Environment | ISAAA.org) <<https://isaaa.org/resources/publications/pocketk/4/default.asp>> accessed April 6, 2020.
7. Plant Products Division, Plant Industry Directorate, Agriculture and Agri-food Canada, 1994. Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits. Ontario: Government of Canada.
8. Wibisana AG. Three Principles of Environmental Law: the Polluter-Pays Principle, the Principle of Prevention, and the Precautionary Principle, by Andri G. Wibisana. (Chapters January 1, 1970) <https://ideas.repec.org/h/elg/eechap/3946_3.html> accessed April 7, 2020.
9. Harremoës Poul. Late Lessons from Early Warnings: The Precautionary Principle 1986-2000. (European Environment Agency 2001).
10. The Precautionary Principle, World Commission on the Ethics of Science Knowledge and Technology (COMEST), 2005. United Nations Educational, Scientific and Cultural Organization. UNESCO, Paris.
11. Bergen Declaration. Fifth International Conference on the Protection of the North Sea. (2002) http://www.ospar.org/html_documents/ospar/html/bergen_declaration_final.pdf.
12. Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter, London Convention. (1972) <<http://www.unep.ch/regionalseas/main/legal/london.html>>.
13. United Nations Conference on Environment and Development (Rio Earth Summit) [1992] UN Doc. A/CONF.151/26 (vol. I), 31 ILM 874.
14. United Nations Framework Convention on Climate Change, United Nations [1992] FCCC/INFORMAL/84, GE.05-62220 (E) 200705.
15. Axel Luttenberger, Maritime Governance as the Environmental Driver, 22nd International Congress Energy and the Environment, Opatija (2010).
16. Unit B. Convention Text. (Convention on Biological Diversity March 30, 2007) <<https://www.cbd.int/convention/articles/?a=cbd-08>> accessed April 13, 2020.
17. Unit B. Convention Text. (Convention on Biological Diversity November 2, 2006) <<https://www.cbd.int/convention/articles/?a=cbd-19>> accessed April 13, 2020.
18. (Cbd.int) <<https://www.cbd.int/doc/legal/cartagena-protocol-en.pdf>> accessed 16 April 2020.
19. Yadava, R., Ram, H. H. (2007). Genetic Resources and Seed Enterprises: Management and Policies. India: New India Publishing Agency.
20. Rene Lefebvre. The Legal Significance of the Nagoya-Kuala Lumpur Supplementary Protocol: The Result of a Paradigm Evolution. (2012) SSRN <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2151282> accessed 20 April 2020.
21. Article 1, Nagoya-Kuala Lumpur Supplementary Protocol. (Convention on Biological Diversity) <<https://bch.cbd.int/protocol/nkl/article1/>> accessed 20 April 2020.
22. Article 11, Nagoya-Kuala Lumpur Supplementary Protocol. (Convention on Biological Diversity) <<http://bch.cbd.int/protocol/nkl/article11/>> accessed 20 April 2020.
23. Article 6-7, Nagoya-Kuala Lumpur Supplementary Protocol. (Convention on Biological Diversity) <<http://bch.cbd.int/protocol/nkl/article6/>> accessed 20 April 2020.
24. Article 12, Nagoya-Kuala Lumpur Supplementary Protocol. (Convention on Biological Diversity) <<http://bch.cbd.int/protocol/nkl/article11/>> accessed 20 April 2020.
25. WTO. Sanitary and Phytosanitary Measures - Text of the Agreement. (Wto.org, 2020) <https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm#top> accessed 18 April 2020.
26. E.A. Evans. Understanding the WTO Sanitary and Phytosanitary Agreement, IFAS extension. [1999] FE 492.
27. N. Alexandrova, K. Georgieva and A. Atanassov. Biosafety Regulations of GMOS: National and International Aspects and Regional Cooperation. (2005) 19 Biotechnology & Biotechnological Equipment.
28. WTO. Agreement on Technical Barriers to Trade. (Wto.org, 2020) <https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm> accessed 19 April 2020.
29. CODEXALIMENTARIUS FAO-WHO. (Fao.org) <<http://www.fao.org/fao-who-codexalimentarius/about-codex/en/>> accessed 19 April 2020.

30. The State of Food and Agriculture, 2003-04 (Food and Agriculture Organization of the United Nations 2004).
31. International Plant Protection Convention. (Ippc.int, 2011) <https://www.ippc.int/static/media/files/publications/en/2013/06/06/1329129099_ippc_2011-12-01_reformatted.pdf> accessed 20 April 2020.
32. Rules for manufacture, use/import/export & storage of hazardous microorganisms/genetically engineered organisms or cells 1989, G.S.R. 1037 (E).
33. Environment (Protection) Act 1986, Parliament Act no. 29 (India).
34. Plant Quarantine (Regulation for Import into India) Order 2003.
35. T N Godavaram Thirumalpad v Union of India [2003] AIR SC 724.
36. Vellore Citizens Welfare Forum v Union of India [1996] 5 SCC 647.
37. Centre for Environmental Law, WWF-I v Union of India [2013] 8 SCC 234.
38. Food Safety and Standards Act 2006, s 28.
39. SK Balashanmugam. Liability Aspects Related to Genetically Modified Food under the Food Safety Legislation in India. (2015) 9 IJSBEEBIE 3964.