EVALUATING THE LAW ON REGULATION OF GENETICALLY MODIFIED CROPS IN INDIA

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1. Introduction

The debate over the coterminous effects of genetically modified organisms on the environment has been raging on in the recent years both in India and the international arenas. In the past decade alone, there has been a substantial rise in the number of groups that take a stand against the release of such organisms into the food chain. This opposition to the development and sale of genetically modified organisms has been, to date, successfully countered by the lobbying juggernaut of the major players in the genetic engineering industry who seek to capitalise on the established advantages of such organisms like higher yielding capacity and higher resistance to pests and diseases in the case of genetically modified agricultural crops.

The propaganda against and in support of genetically modified organisms is dangerous as it leads to the formation of an extremely reductionist view of the issue in the eyes of a layman who either sees the strictly against or staunchly for stance of the interest groups involved. Education regarding the existence of a common ground between the two stands needs to be imparted. It has become an imperative objective to inform the layman about the credible advantages and potential disadvantages of introducing a product of human intervention in the process of evolution and natural selection.

The primary objective of this paper is to present an overview of the law on regulation and release of genetically modified organisms. A brief discussion about the existing legislations has been attempted which is followed by a concise account of the functions of the regulatory committees on GMOs. An account of the associated liabilities and remedies that flow with the GMOs and transgenic products has also been provided. The precautionary principle which forms the backbone of the machinery deciding the deployment of precautionary action has also been elucidated. Lastly, with a forward looking perspective the merits and lacunae of the Biotechnology Regulatory Authority of India Bill has been explained with recommendations proposed for the emendation of the Bill.

India's current legislative framework with regard to genetically modified organisms is arguably panoramic with statutes spanning the fields of science and technology, environment and its preservation, agriculture and its advancement, food and health

and also the trade of GMOs. Almost all the frameworks dealing with the regulation of GMOs have been briefly discussed in the following part of the paper. The only exceptions worth mentioning are the Patent Act, Biological Diversity Act, and Plant Variety Protection and Farmers' Rights Act which are remotely linked to the issue at hand but do not have the machinery expressly concerned with the regulation and release of GMOs.

2. Framework of Legislations

The regulations pertaining to biosafety in India constitutes primarily of the biosafety rules and guidelines. However, the central legislative authority for biosafety regulations in the country is arguably the Environment (Protection) Act, 1986.[1] The sections 6, 8 and 25 of this Act jointly form the preamble through which all the currently existing biosafety regulations flow in India. Section 6 of the Act gives the authority to the Central Government to form the essential rules on the standard procedures, implement safeguards and place the necessary restrictions for handling of hazardous substances and outright prohibit the others. On the other hand, Section 8 of the Act imposes a prohibition on a person from handling any substances considered to be hazardous under the Act except when the procedures and safeguards have been complied to. Lastly, the Section 25 of the Act places the responsibility of stipulating the rules regarding procedures and safeguards for handling hazardous substances[2] on the Central Government. As a direct consequence of this, the general consensus in the Indian Judicial System is that the biosafety rules are of a statutory nature as their genesis lies in the abovementioned provisions of the Environment (Protection) Act. These abovementioned provisions have also lead to the promulgation of the 1989 Biosafety Rules by the Ministry of Environment and Forests.[3]

The 1989 Biosafety Rules apply to the products made from genetically engineered micro-organisms and other gene-technology produce and regulates their manufacture, storage and import. These Rules also cover the pre-release facet of genetically modified organisms, namely their research and development besides the large scale applications and trials. Hazardous organisms which are not genetically modified are also regulated by the 1989 Biosafety Rules. The Rule 8 of this statute mandates the requirement of an approval by the regulatory bodies prior to the discharge or even the production of

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[1] The Indian Environment (Protection) Act, 1986 (Act 29 of 1986).

[2] *Ibid.*

[3] Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/Genetically Engineered Organisms or Cells. (Rules 1989).

genetically modified organisms and cells. The Rules no. 10 and 11 necessitates the requirement of an approval for any such substances that contain genetically engineered organisms or even cells. However, the Rule 9 of this statute is the foremost in significance as it expressly prohibits the deliberate and/or unintentional discharge of genetically modified organisms (for experimental purposes) covered under its schedule, barring a situation where it has been approved as a 'special case' by the appropriate authority. The abovementioned schedule is a feature of the 1989 Biosafety Rules which classifies human and animal pathogens in terms of their risk profiles.

The 1989 Biosafety Rules have been augmented aptly by the Biotechnology Safety Guidelines which have been put into effect by the Department of Biotechnology.[4] The Biotechnology Safety Guidelines are the consequence of Rule 4(2) of the 1989 Biosafety Rules which mandates the requirement of guidelines manuals which are to be stipulated by the Review Committee on Genetic Manipulation. This committee is a departmental off-shoot of the, and serviced by the Department of Biotechnology. These guidelines are concerned with the assessment of biosafety levels of which it carries a detailed analysis. A detailed admonishment on recombinant DNA or rDNA related activities, experiments, shipments and quality control produced by genetic engineering is also provided. The Biotechnology Safety Guidelines, before reaching its current form and after being issued by the Department of Biotechnology in 1990 were revised and emended two times and finally amended in 1998 in accordance with the progressive strides made in the field of rDNA research.

3. .Regulatory Committees

Typically, there are four stages of departmental structures involved in the life-cycle of a genetically modified organism or of a GMO based product. These are the pre-research, research, release and post-release stages. The pre-research stage is monitored by the Recombinant DNA Advisory Committee as it is the body which authorises and approves the research to be undertaken. The release stage in the life-cycle of a GMO is governed by the Review Committee on Genetic Manipulation and the Genetic Engineering Appraisal Committee. The RCGM reviews the procedure of research and experiment-based releases whereas the commercial discharge of GMOs directly or indirectly, is monitored by the GEAC. The occupants of the post-release stage are the Monitoring and Evaluation Committee, the State Biotechnology Co-ordination Committee and the District Level Committee. Although, these committees tend to overlap into the research stages as well through data-provisioning submitted to the

[4] Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation, 1998.

RCGM. Lastly, the Institutional Biosafety Committee implements the standard safeguards at the research and development sites under the headship of the RCGM, the SBCC and the DLC. A brief description of the undertakings of the respective committees is elucidated below.

Recombinant DNA Advisory Committee (RDAC)

The Department of Biotechnology is the parent body of this committee. The committee bears the responsibility of studying and reviewing the changes and developments made in the field of biotechnology at the national and international arenas. Consequently, it renders apposite suggestions to enhance safety regulations in the area of recombinant research and their applied utilities.

Review Committee on Genetic Manipulation (RCGM)

Just like the RDAC, this committee is also monitored and constituted by the Department of Biotechnology. However, this committee concerns itself with the safety and precautionary aspects of research in genetic engineering. In order to ensure the same, the committee has to stipulate the specific guidelines regarding the activities involving genetic engineering of organisms and their consequent use or release. The utmost importance is given to its prime objective which is to ensure environmental safety. It also bears the responsibility of monitoring the products, field experiments, production, sale and shipment involving even a fraction of genetically engineered organisms and cells which are classified as so in the schedule.

Institutional Biosafety Committee (IBSC)

The duty of constituting the IBSC lies with the institution which is conducting a research that includes the usage of even the smallest proportion of genetically modified organisms and even microorganisms that aren't natural to the local conditions. This committee needs to be comprised of the head of the parent institution directly invested in the research, the scientists hired by the institution for the genetic engineering of organisms, at least one medical expert and one nominee of the Department of Biotechnology. The parent institution is required to prepare an up-to-date emergency procedure(s) with the aid of the IBSC which conforms to the guidelines of the RCGM. It is also imbibed with the duty of providing the copies of such a contingency plan and procedure to the District Level Committee and the Genetic Engineering Appraisal Committee.

Genetic Engineering Appraisal Committee (GEAC)

The GEAC is constituted by the Ministry for Environment and Forests and grants the requisite approvals for activities or procedures involving large-scale commercial use and discharge of potentially hazardous microorganisms not excluding any such import comprising of GMOS and recombinant DNA. This committee has the authority to prohibit the production, sale, shipment or use of GMOs if it deems it a threat to the environment.

State Biotechnology Co-ordination Committee (SBCC)

The SBCC is constituted by the respective State Governments of India and acts as the State nodal agency monitoring and assessing the damages caused by the release of genetically modified organisms. The SBCC yields the power to enforce punitive action against the violations after it has conducted an appropriate investigation. This committee bears the additional responsibility of periodically reviewing the safety and control measures employed by the industries or institutions invested in the occupation of handling genetically modified organisms and hazardous microorganisms.

District Level Committees (DLC)

The DLC is constituted at the districts where biotechnology projects are to be undertaken. Its authority is subject to that of the SBCC. The head of the DLC is the District Collector and it is him who reviews and assesses the safety regulations employed by the industries or institutions engaged in the use of GMOs or hazardous microorganism. The committee's responsibilities include the checking of the institution's compliance with recombinant DNA guidelines and reporting the violations, if any, to the SBCC or the GEAC. It needs to coordinate the activities of the concerned institution or industry to the effect that it becomes easier to contain emergency situations caused from accidental or even intentional discharges.

Monitoring and Evaluation Committee

This committee has the duty of undertaking regular visits to the sites of experiment and recommend procedures in case any remedial measure is required to adjust any potential threat from discharges. The committee also aids the RCGM in tabulating and analysing primary data from the field so as to ascertain the comparative agronomic advantages of genetically engineered crops or plants.

4. Legal Disputes

In the case of *Research Foundation for Science, Technology and Natural Resource Policy* v. *Union of India*[5], the petitioners alleged that the respondents had violated certain provisions of the Indian biosafety regulations. The alleged violations stemmed from genetically modified cotton seeds which were imported and had subsequently spread through trials which had been conducted on multiple sites in open environment. It was also alleged that the respondents were not adhering to the adequate measures for countering pollen flow or maintaining a safe distance. The Supreme Court barred any further field trials by issuing a temporary injunction against the respondents and concurrently directed them to make amendments which had the effect of securing against any potential threats to biodiversity, environment and human health. Accordingly, the Department of Biotechnology responded by authorising the Review Committee on Genetic Manipulation to conduct small-scale field trials. The petitioners aggrieved by this approached the appellate authority constituted under Rule 19 of the 1989 Biosafety Rules by challenging the approval of Bt Cotton. This appeal was dismissed and it was held that the approval of the Bt Cotton was granted after due examination of the biosafety and agronomic data collected via tests over a period of six years. The allegation directed against the permission granted by the Review Committee on Genetic Manipulation as being violative of the 1989 Biosafety Rules was dismissed as RCGM has the authority to permit restricted field trials to control and prevent the escape of GMOs into the environment. It was reiterated that in accordance with the Allocation of Business Rules, 1961, the Department of Biotechnology is the central department to monitor and regulate the import and shipment of genetically modified organisms.

A public interest litigation filed before the Supreme Court by Gene Campaign in 2004 is pending under the head of *Gene Campaign* v. *Union of India*.[6] The petition challenges the constitutional validity of the 1989 Biosafety Rules and attacks its utility and alleges that the rules are inconsistent with their intended objective of protecting the environment and public health guaranteed by the Article 21 of the Constitution of India. It is also alleged that the 1989 Biosafety Rules are not in conformity with the Biosafety Protocol of which India is a signatory and has ratified. The petitioners claim that the regulatory agencies under the 1989 Biosafety Rules lack technical competence, transparency, and public participation. It is further alleged that many important and legally established notions like the precautionary principle, inter-generational equity and polluter pays principle have not been accrued with due recognition under the rules.

[5](2005) 13 SCC 186.
[6] Writ Petition (Civil) No. 606/2007.

5. Genetically Modified Organisms and Associated Liabilities

Presently, there does not exist any specialised statute that deal with genetically modified organisms and the liabilities arising out of the misappropriate handling or use of such organisms in India. However, there exists effective legal machinery that ensures the awarding of appropriate legal remedies to the aggrieved persons. Instances where damage and injuries caused by the misapplication of genetically modified organisms and violation or oversight of any biosafety regulation can be discerned with the aid of specific legal provisions and precedents of the judiciary.

Specific GMO Liability Provisions

If a measure adopted by the defendants is found to be in contravention of the 1989 Biosafety Rules, then the section 15 of the Environment (Protection) Act, 1986 is attracted. Such a failure to concur with the Biosafety Rules is punishable by an imprisonment term extending to not more than five years or a fine not extending the amount of one Lakh rupees or both. An additional fine can be imposed if such a contravention of the Biosafety rules continues and this amount shall not exceed five thousand rupees for every day.[7] The court has the authority to take cognizance under section 15 of the Environment (Protection) Act, 1986 only on a complaint instituted by either the central government or an officer authorized on its behalf and even a person who has given a due notice of a minimum of sixty days in the prescribed manner to the central government or a authorised officer.[8] However, the general consensus regarding the liability provisions under the Act is that they are tenuous and time consuming.[9] Any genera or species that involve the use of 'any technology' which makes them potent to either the life or health of human beings, animals and plants cannot be registered under the Protection of Plant Varieties and Farmers' Rights Act, 2001.[10] The explanation of the sub-section clarifies that the term 'any technology' includes the genetic use restriction and terminator technology. The Environment (Protection) Act, 1986 deals specifically with the liability arising from the non-performance of a propagating material that is registered under the Act. The developers of such varieties are duty-bound to make a disclosure to the farmers about the expected performance under differential conditions. Upon the failure of the developers to do so, the aggrieved

[7] Punishment, which may extend up to seven years, is prescribed, if such failure or contravention continues beyond one year from the date of conviction.
[8] Sec. 19, The Indian Environment (Protection) Act, 1986 (Act 29 of 1986)
[9] R.K. Tyagi, Randhawa GJ, *et.al.* (eds.), *Transgenic Crops and Biosafety Concerns* (NBPGR, New Delhi, 2001)
[10] The Indian Environment (Protection) Act, 1986 (Act 29 of 1986), s. 29(3).

farmers can institute a suit for damages before the Plant Variety Protection Authority under the Act[11], which has the authority to award compensations accordingly.

General Environmental Liability

The Articles 32 and 226 of the Constitution of India are the legal pathways through which the fundamental rights guaranteed under part III of the Constitution can be enforced by any qualified citizen or a legal person under certain cases. The Article 32 is invoked to move the Supreme Court and likewise Article 226 is invoked to move any particular High Court[12] under the jurisdiction of India. Both of these courts are clothed with the power to issue appurtenant writs for the enforcement of fundamental rights and as a remedial measure for their infringements. The apex court has by way of its pronouncements, which have had the effect of considerably relaxing the rule of *locus standi*, has onset a plethora of public interest litigations seeking to enforce the fundamental rights of the socially and economically handicapped who were previously inept to approach the courts. Furthermore, the increasingly broadening horizon of the interpretations under the head of Article 21 has brought to the fore previously unimportant rights like the right to a clean environment and the right to health. This has further enabled persons to approach the High Courts or the Supreme Court for the remedy of the violations of such rights. The remedial measures employed by the courts involve the closure of polluting establishments and mandatory requirement of caution deposits, following the final report of fact-finding commissions constituted by the respective courts. A number of judicial pronouncements have emphasized the requirement of establishing specialised 'environmental' courts across the nation to handle the complicated issues with expertise.[13] The environmental liability principles are primarily built up on Supreme Court judgments like the precedent of *M.C. Mehta* v. *Union of India*[14]. In this case, the apex court examined the absolute and strict liability of enterprises in the event of an accident particularly if the respondent is engaged in hazardous or inherently dangerous industry. The court also examined the rule laid down in the *Ryland* v. *Fletcher*[15] case and was of the opinion that this rule was archaic as it was promulgated in a period when science wasn't as developed and hence this precedent was inept for accounting the "present day economy and social structure". Consequently it was held that an enterprise that causes harm as a result of any accident

[11] The Indian Environment (Protection) Act, 1986 (Act 29 of 1986), s. 39(2)
[12] The jurisdiction of High Court is not limited to the protection of fundamental rights but also for other legal rights.
[13] Law Commission of India, 186th Report on Proposal to Constitute Environment Courts (September, 2003).
[14] 1987 SCR (1) 819
[15] (1868) UKHL 1.

is strictly and absolutely liable to compensate the affected. This liability[16] was held to not be subjected to the exceptions allowed under the *Ryland* v. *Fletcher* rule.

As regards the factor of accounting for the amount of damages to be paid by the violating enterprise, it has become an established practice to keep the amount payable to be directly proportional to the capacity and wealth of the violators. The objective for awarding a compensation of such a nature is to create deterrence among the enterprises handling hazardous substances. In *Union Carbide Corporation* v. *Union of India*[17] the Supreme Court dismissed the precedents set in the Oleum Gas Leak case as obiter dicta citing the fact that a conclusion about the status of the defaulting company under Article 12 of the Constitution was not drawn. However, the apex court adopted a different point of view while deciding in the matter of *Indian Council for Enviro-Legal Action* v. *Union of India*[18]. It was observed by the Hon'ble court that although the court hadn't directed any specific damages to be paid in the Oleum Gas Leak case, the bench had dictated that cases on the basis of the principle of absolute liability can be instituted. Therefore, the apex court in the Indian Council for Enviro-Legal Action case followed the principles of absolute liability in discerning the immediate issues of the matter. Concurrently, it was also observed by the court that damages based on the absolute liability principle must account for the costs of restoring the environmental degradation besides the compensation for the victims. On the other hand, in *M.C. Mehta* v. *Kamal Nath*[19], the perspective adopted by the Supreme Court was to view pollution as a tortious act against the 'community as a whole'. The court also awarded exemplary damages to be paid by the respondent. Thus, it can be reasonably inferred that the guilty party is liable to pay damages to the victims who have suffered loss and the same should also account for the restoration of the ecology and environment. A classification of different types of liabilities associated with pollution was attempted by the Supreme Court in the case of *K.M. Chinnappa* v. *Union of India*[20]. The court categorized the liabilities as follows: (i) criminal liabilities through which imprisonment sentences can be awarded; (ii) administrative sanctions; (iii) costs for clean-up of the pollution caused; (iv) civil liability based on the principle of strict liability; and (v) adverse publicity. In the case of *Research Foundation for Science Technology and Natural Resources Policy* v. *Union of India*[21], the polluter pays principle was further clarified by the Supreme Court.

[16] The Public Liability Insurance Act, 1991 (Act 6 of 1991).
[17] 1990 AIR 273.
[18] AIR 1996 SC 1446.
[19] (1997)1 SCC 388.
[20] AIR 2003 SC 724.
[21] (2005) 13 SCC 186.

It was held that this principle includes the costs for preventing and tackling any pollution caused by the polluter.

Liability under Law of Tort

The liability under law of tort, in majority of the cases, can be traced to the pernicious effects which result from mixing of genetically modified organisms with unmodified or 'natural' organisms[22] and even due to the supplanting of genetically modified plants as substitutes or volunteers. However, given that pollen transfer is a biological phenomenon, in order to determine liability, some discernable damage needs to be proved. To date, no specific precedents have been established in India. Thus, reliance can be made on analogical deduction from trends set in the United States and Canada. These trends show that suits have been instituted by non-transgenic plant growers against the developers of genetically modified plants or crops. The genetically modified crops hold an inherent potency of causing a genetic contamination that might onset claims of nuisance, negligence and strict liability against the farmers and the developers of the seeds.[23] Claims pertaining to trespass[24], and nuisance[25] based suits, have failed thus far in both the American as well as Canadian courts. However, suits resulting from negligence have found considerable success in establishing precedents and it has been held that it is reasonable to expect a duty of care from persons handling genetically modified organisms. A breach of that duty would invite liability on the basis of negligence. Any economic loss resulting from physical contamination caused by the adulteration of seeds by unapproved substances and loss of markets caused thereby are valid claims for instituting suits on tort of negligence, private nuisance and public nuisance as well.[26]

As many as five instances can be anticipated in United States of America and Canada based disputes where genetically modified organisms related liability might come to the fore. They are as follows: (i) damages arising from the admixture of GMOs with conventional crops; (ii) damages originating from the loss of premium for a traditional commodity or food products without GMOs; (iii) an admixture rendering the registered identity of the product as lost; (iv) damage caused due to the loss of markets and (v)

[22] A permissible limit of GMOs in non-GM grains is fixed in India by the GEAC.
[23] Drew L. Kershen. 'Of Straying Crops and Patent Rights' 43 *Washburn L.J.* (2004)
[24] Stuart J. Smyth and Drew L. Kershen, 'Agricultural Biotechnology: Legal Liability Regimes from Comparative and International Perspectives' 6 *GJA* (2006)
[25] *Ibid.*
[26] Stuart J. Smyth and Drew L. Kershen, 'Agricultural Biotechnology: Legal Liability Regimes from Comparative and International Perspectives' 6 *GJA* (2006).

damage from inability of a farmer to plant a crop due to the proximity of transgenic crops.[27]

GMOs and Product Liability

The genesis of the liability arising from products causing injury lies in the House of Lords decision of *Donoghue* v. *Stevenson*.[28] It was held that the manufacturer of a product owes a duty of care towards the consumer when he has the knowledge that there does not exist any intermediate mechanism for the examination of the manufactured product and that an omission of reasonable care on his part towards the product can cause injury to the consumer's life or property or both.[29]

The Consumer Protection Act, 1986

The central objective behind the promulgation of this Act was to promote and protect the consumer's rights in the market. The consumer rights include but are not limited to the right to be shielded from the marketing of potentially hazardous goods; right to be informed about the quality, quantity, purity, standard and price of goods and the right to consumer education. Under the Act, all movable properties with the exception of actionable claims and money bills are considered goods.[30] Therefore, genetically modified organisms based products are also considered as goods under the Act. The Act also provides for a consumer[31] to file a complaint[32] against a trader[33] for defects in the goods sold or for the deficiency in service accompanying the sale of goods. Thus, actions against defective GMOs or the inept services accompanying them are maintainable under the Act. Suits[34] can also be instituted against the malpractices of excessive pricing, offering sale of hazardous or potentially hazardous[35] goods and services. Restrictive trade practices[36] that could lead to the manipulation of prices and unfair conditions of delivery, which in turn can cause unjustified costs and restrictions for the consumer, are also covered by the Act. Fraudulent or bogus claims aimed at deceiving the consumer by misrepresenting goods and services, fall within the ambit of

[27] *Ibid.*
[28] (1932) UKHL 100.
[29] *Ibid.*
[30] The Section adopts the definition in the Section 2(7) of Sale of Goods Act, 1930 (Act 3 of 1930).
[31] Sec. 2(1) (d), The Consumer Protection Act, 1986 (Act 68 of 1986)
[32] Sec. 2(b), The Consumer Protection Act, 1986 (Act 68 of 1986)
[33] Sec. 2(j), The Consumer Protection Act, 1986 (Act 68 of 1986).
[34] Sec. 2(c), The Consumer Protection Act, 1986 (Act 68 of 1986)
[35] The trader in such cases could have known with due diligence that the goods offered for sale are unsafe.
[36] Delay in the agreed delivery time leading to a price rise and any trade practice which requires the buying of any goods or hiring or availing of any service as a condition precedent for buying other goods and hiring or availing other services', are restrictive trade practices.

the Consumer Protection Act, 1986. Such a contrived representation of the standard, grade and composition of genetically modified organisms are considered to be unfair trade practice. Therefore, the marketing of GMOs without the labels indicating their grade and composition, especially when a legal requirement to label the GMOs exists, tantamount to a fallacious and bogus representation and is consequently an unfair trade practice prohibited by the Act.

6. **Procedure for Large Scale Field Trials and Risk Assessment**

If the volume of the product to be assessed contains GMOs and exceeds twenty litres, then the trial is said to be on a 'large-scale'. There are standard procedures and safeguards prescribed by the law for regulating large-scale field trials of genetically modified organisms. The host organism (which contains GMOs) and the genetically modified organism itself should not be pathogens and should not have a nature similar to pathogens. The vector chosen for the experiment should be secured enough to be contained and safe. For the execution of an environmental release, the geographical position of the site, the dimensions of the area, the expected effects on the ecosystem in the proximity of the site, the method and quantity of the release and contingency plans need to be made out prior to the release. Assessment of the risks associated with the release needs to be made on a case-by-case basis before the release.[37] The Genetic Engineering Appraisal Committee bears the duty of handling and monitoring all large-scale operations involving GMOs.[38] The applicant has to submit his operational details on the management and disposal of harmful wastes before the GEAC. The evaluation of the genetically modified organism in a laboratory, growth chamber and an atmosphere stimulating greenhouse conditions is a pre-requisite to the field trials. Secure measures need to be employed so as to guarantee the safety and to prevent an accidental discharge of the GMOs. It is a reasonable expectation that the enterprise conducting the field trial either destroys or neutralises the bio-wastes before disposing them into the environment. The maintenance of a safe isolation distance, growth of any incompatible crop beyond the isolation distance to asses pollen transfer, growth of a few layers of a similar and preferably the same non-transgenic crop beyond the isolation distance as a neutralizer for escaped pollen are a few more prescribed measures to ensure safety of genetically modified plants testing. Following the harvest of such GM plants, the destruction of any vegetative parts or any plants generated from the GM seeds is a

[37] Recombinant DNA Safety Guidelines, 1990.
[38] The GEAC, polices Biosafety Research Level 11 (BRL11) trials

standard recommended practice. To further ensure the absence of any leftover, viable genetically modified cells, cultivation on that land is prohibited for a year.[39]

Risk Assessment for Releases into the Environment

In order to properly asses the risks before the release of GMOs into the environment, certain factors need to be considered. These include the nature of the GMO, the particulars of the organism's modifications, its genetic stability for its long term survival, and the details of the organisms targeted by the GMOs. Also accompanying should be the knowledge of the known and expected effects of the genetically modified organism. An experimental field use permit needs to be obtained from the Genetic Engineering Appraisal Committee. The GEAC will audit and evaluate the safety control measures and monitor the controlled large scale releases[40]. The GEAC will subsequently submit the information to the Review Committee on Genetic Manipulation[41]. In order to ascertain the possible risks associated with the release, factors like the characteristics of the donor organism, the vector, the transgenic insert, the genetically modified organism and the method of modification would be considered[42].For the evaluation and management of risks associated with limited releases, the maintenance of an isolation distance[43] (which will prevent fertilization), prevention of the plant developing buds by human intervention and through biological means are advised. Other additional suggestions include the destruction of volunteer plants and isolating the allergen properties of the GMO, drafting of emergency plans[44] and documentation of prior information.[45]

Precautionary Principle and Precautionary Approach

The precautionary principle is a heuristic doctrine through which pragmatic resolutions can be made in situations of scientific uncertainty. There are four primary objectives of the precautionary principle: (i) enforcement of preventive measures in situations of scientific uncertainty; (ii) transpose the burden of proof on the exponents of an inherently harmful activity; (iii) probe for the alternative procedures to achieve the same goal and (iv) involve the invested participants in the decision making process.[46]

[39] Recombinant DNA Safety Guidelines, 1994.
[40] Safety, risks and accidents related with environmental release.
[41] Recombinant DNA Safety Guidelines, 1990.
[42] Protocols for Food and Feed Safety Assessment of Genetically Engineered Crops, 2008.
[43] Guidelines for the Safety Assessment of Foods derive from Genetically Engineered Plants, 2008.
[44] *Ibid.*
[45] Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation, 1998
[46] David Kriebel *et.al*., 'The Precautionary Principle in Environmental Science', 109 *Environ Health Perspect* 871 (2001).

However, the practical projections of the principle's objectives remain controversial due to their varied interpretations.[47] Numerous versions of the principle continue to exist and essentially two formulations of the principle exist in International law- the precautionary approach and the precautionary principle.

Principle 15 of the Rio Declaration, 1992 states regarding this principle: "in order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall be not used as a reason for postponing cost-effective measures to prevent environmental degradation." The articulation of the approach is similar to that of the principle and the only variance exists in that firstly, the Rio Declaration recognises that there may be differences in local capabilities to apply the approach and secondly, that it appeals for the accounting of economic and social costs.[48] It is a general consensus that this 'approach' is a dilution of the more stringent 'principle'

Precautionary Principle in International Law

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity has promulgated one of the most robust references to the precautionary principle in contemporary international law. The protocol is the first of its kind to expound the precautionary principle outside of its preamble i.e., delineate the principle in its operational titles. As a consequence of this the Protocol has been credited with "propelling the precautionary principle to the forefront of international environmental law".[49]

The precautionary principle firstly dictates the requirement of a minimum level of risk that warrants the application of precautionary action. Enterprises that deal with even remotely risky yet economically profitable activities often employ "higher risk-triggering levels". The Rio Declaration requires the existence of both threats of serious and of irreversible damage to onset a precautionary action. Whereas, the level of risk established by the Protocol is "potential adverse effects", which tends to be significantly lesser than the levels established in the Rio Declaration. Thus, the inference that precautionary action is much easily justified under the Protocol than the Rio

[47] Anne I. Myhr, 'The Precautionary Principle in GMO Regulations', T. Traavik and L.C. Lim (eds.), *Biosafety First* Chapter 29 (Tapir Academic Publishers, 2007)
[48] S.M. Garcia, 'The Precautionary Principle: its Implications in Capture Fisheries Management' 22 *Ocean Coast Manage* 99 (1994).
[49] David J. Schnier, 'Genetically Modified Organisms and the Cartagena Protocol' 12 *Fordham Envtl. L.J.* 377 (2001).

Declaration holds true. Secondly the Protocol makes an allowance to the responsible party during a period when precaution is triggered by making a "decision as appropriate with regard to import in order to avoid or minimize such potential adverse effects". More importantly, the Protocol does not seek any considerations for the profits of an activity or its economical quality. By doing so, the Protocol allows for the focus on the potential harmful impacts on the biodiversity. Thirdly, and in stark contrast to the Rio Declaration's requirement of "lack of full scientific certainty", the Protocol only demands the "certainty" for the conjuring of the precautionary principle. This renders the need for scientific consensus before the invocation of precautionary principle mute. Furthermore, the Protocol also necessitates the need for subjecting the decisions made to the assessment of risk.

Article 15(3) of the Protocol states that parties may ask the exporters to carry out the requisite risk assessments which will consequently enable the developing economies of the world to promulgate measures constituted on the precautionary principle, even in a situation where they do not possess the administrative machinery to perform those risk assessments themselves.

Although the Protocol does not mandate the requirement of scientific knowledge and consensus for taking precautionary action, this should not be construed as the existence or non-existence of a risk. Notwithstanding such articulation in the Protocol, risk assessments are to be conducted on a case-by-case basis and in a manner that conforms to the principles and laws of the associated science.

In postlude it can be summarised that the Precautionary Principle has an ambiguous language which makes it difficult to discern the acceptable levels of risks, how such potentially harmful trade-offs should be addressed, and what measure of scientific evidence is adequate in deriving at decisions.

Precautionary Principle in India

The precautionary principle is not promulgated by any explicit statutory authority in India. The resulting lacunae in biosafety regulations is however supplanted by judicial pronouncements of the Supreme Court which has adopted the matrix of the principle in adjudicating legal disputed regarding genetically modified organisms. In *Vellore Citizens' Welfare Forum* v. *Union of India*[50], the polluter pays principle and the precautionary principles were held to be indispensible parts of promoting sustainable development in India. The precautionary principle from the perspective of municipal

[50] AIR 1996 SC 2715

law would suggest that: (i) authorities have to 'anticipate, prevent and attack the causes of environmental degradation'; (ii) no postponement of cost effective measures in the face of scientific uncertainty and irreversible consequences; and (iii) the proponent bears the burden to prove that a proposal is environmentally friendly.[51]

The apex court was of the opinion that even though the principle is not promulgated by any Articles of the Constitution of India or any other of the several environmental legislations, it can be incorporated into the domestic law as a cardinal principle of international environmental law which is not contrary to municipal laws and should be taken into account for deciding cases by the judiciary.[52]

In another case[53] it was held by the Hon'ble court that reversal of the burden of proof, good governance and principle of intergenerational equity are indispensible ingredients of the precautionary principle. The Supreme Court while deciding the case of *Narmada Bachao Andolan* v. *Union of India*[54] held that the precautionary principle needs to be followed in all cases of uncertainty of ecological effects. Conversely, if the effects are certain or are known, mitigating steps should be employed to contain the harmful quality as much as possible. It was also established that a mere change in the ecology[55] should not be equated with an ecological disaster and that to counter such a claim, the defendant will need to prove the inert nature of the activity.

7. Recommendations on BRAI Bill

The Government of India has in conformity with the provisions of the Cartagena Protocol, of which it is a signatory, proposed the promulgation of National Biotechnology Regulatory Authority through the Biotechnology Regulatory Authority of India Bill which will, subsequent to its establishment, be the supreme authority on regulations and policies that flow with the genetically modified organisms in India. The Bill proposing BRAI is yet to be passed by the parliament. However, it has met with severe oppositions from the farmers and non-governmental organisations like Greenpeace India due to several of its questionable provisions that encroach upon the legal rights of the farmers and the consumers generally. It is submitted that these

[51] *Ibid.*

[52] It was reiterated that the principle is a customary rule of international law status of the principle and part of the Indian law {*Research Foundation for Science Technology National Resource Policy* v. *Union of India,* (2005) 13 SCC 186}. ·

[53] *A. P. Pollution Control Board* v. *Prof M. V. Nayudu*, 1999(2) SCC 718.

[54] AIR 2000 SC 3751.

[55] Here the activity was the construction of a large dam. The Court refused to equate dams with a nuclear establishment or polluting industry, by commenting that there has been an environmental upgradation with the construction of a dam.

conflicting provisions of the Bill be emended and alternate measures be taken to ensure the prevention of such gross violation of constitutional and legal rights. A brief account of the controversial provisions and their repercussions has been discussed below.

BRAI is abrogating the powers of the State Legislature

Section 2 of the bill avers that the Union or the parliament alongside the central government has the authority to take actions pertaining to the regulation of genetically modified organisms and associated products. In addition to Section 2 of the bill, Section 81 reinforces the stance of the former by stating that even if such an empowerment of the Union is found to be in conflict with any previously existing legislation, the law under the Section 2 will prevail. Such provisions are explicitly against the Constitution. The Constitution expressly states that the parliament cannot legislate on matters enumerated in the State list without prior authorisation by the State Legislative Assemblies.[56] Item 14 of the State List (List II) provides for the state legislative assemblies to deal with matters concerning agriculture and plant diseases.[57]

This goes to show that matters pertaining to the regulation of genetically modified foods and products and their mass cultivation should be monitored by the state legislature. Therefore, the provisions of the BRAI Bill are in contravention with the Constitution as they override the powers of the state legislature.

Infringement of the Right to Information

Section 27(1) of the BRAI Bill states that the information pertaining to the research and development of genetically modified organisms and transgenic foods and products shall be confidential and will not be revealed in the public sphere. This is in direct contravention to the Right to Information Act. The Right to Information Act, 2005 was passed with the intention[58] of keeping the citizens of India informed about the machineries of the government and to counter corruption. This Act is a vital part of a democracy as it promotes transparency and acts as a catalyst to hold the governments and their agencies accountable to the public.

Legal Lacunae

Section 3 of the BRAI Bill[59] states that the provisions of the Food Safety and Standards Act, 2006, would no longer be applicable to the genetically modified organisms and associated products covered by the Bill. This can lead to an extremely dangerous

[56] Art. 249(1), The Constitution of India.
[57] No. 14 of State List (List II): Agriculture, including agricultural education and research, protection against pests and prevention of plant diseases.
[58] The Right to Information Act, 2005 (Act 22 of 2005).
[59] Schedule II, Part II of the National Biotechnology Regulatory Bill, 2008.

situation as the Food Safety and Standards Act provides for the explicit labelling of genetically modified foods.

This oversight of an essential requirement can be catastrophic as there would no longer be any legislation affirming the need for labelling genetically modified foods. This would lead to a dire situation where the consumer, who will most likely be a layman, would be rendered inept in differentiating between transgenic and organic food and associated products. This is to be understood in the context of 'labelling' being the operative part of the consumer's 'right to choose'.[60]

Cognizance of Offences and Lack of Jurisdiction

According to Section 70 of the Bill, all courts are universally barred from taking cognizance of any offence punishable under the Bill except when a complaint has been instituted by an authority or an authorised person under the Bill. Therefore, the department set up by the Bill cannot be challenged unless the authority feels so, ergo, they are answerable to themselves. In addition to this, the BRAI also establishes that does not have the jurisdiction with respect to any matter which the appellate tribunal under the Bill is empowered to decide.[61] Further, no injunction can be granted by any court in respect of any action taken under the Act.[62] These provisions make the BRAI Bill almost unimpeachable as very limited space is provided for interventions and the conventional mechanisms have been completely dismantled. These issues are further amplified by the free leash provided to the adjudicatory board to be established through the Bill that will not be subject to the provisions of the Code of Civil Procedure, 1908[63] or the Indian Evidence Act, 1872[64]. It is proposed that the board be regulated in accordance with the principles of natural justice.[65]

8. Conclusion

India is a signatory to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. According to this protocol, all signatories of the convention must enact an explicit law dealing with the regulation and release of genetically modified organisms. Keeping in conformity to this direction of the protocol, the Government of India proposed the BRAI Bill which would most likely be the future of the legal and administrative aspects of genetically modified organisms in India. However, as

[60] Yves Bertheau (ed.), *Genetically Modified and non-Genetically Modified Food Supply Chains: Co-Existence and Traceability*, (Oxford: Wiley-Blackwell, Oxford, 20th edn., 2013).
[61] Sec.77, National Biotechnology Regulatory Bill, 2008.
[62] *Ibid.*
[63] Sec. 56(7), National Biotechnology Regulatory Bill, 2008.
[64] Sec. 56(3), National Biotechnology Regulatory Bill, 2008.
[65] *Ibid.*

elucidated in the preceding section of this paper, such a governing body would be extremely autocratic and almost unimpeachable. This conflict between the Bill and the consumer's rights has given rise to an undesirable situation; the resolution of which lies in amending the aforementioned provisions of the Bill before it is passed by the parliament. However, this prospective resolution is weakened considerably by the lobbying forces of big industries that are heavily invested in transgenic technologies which would exponentially benefit from the provisions of the Biotechnology Regulatory Authority of India Bill. In such a situation, the farmer groups and anti-GMO activists have approached the courts for recourse. While the suits against the Bill are pending, it is submitted that such a piece of legislation should be declared ultra vires of the provisions of the Constitution of India and a Bill which is more in line with the welfare of the consumers and which conforms to the spirit of the Constitution be promulgated.