

THE INTRODUCTION OF GENETICALLY MODIFIED CROPS IN INDIA: THE NEED FOR AN EFFECTIVE LEGAL AND POLICY REGIME

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1. PURSUING THE LIABILITY DEBATE SURROUNDING GM CROPS IN INDIA: CHANGING PARADIGMS FOR INTELLECTUAL PROPERTY LAW

“With the technology that we now have available, and with the research information that’s in the pipeline and in the process of being finalized to move to production, we have the knowhow to produce the food that will be needed to feed 8.3 billion people by the year 2025.”¹

Amidst long lasting argumentative discourse surrounding the usage of genetically modified crops and its related legal and bio-centric contentions at multiple levels in India, the agricultural industry and its ancillary policy makers continue to a significant degree, to advocate the use of genetically engineered crops in the country.² Seen as a significant step forward in the apparently promising

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1 Norman Borlaug, *The Impact of Agricultural Research on Mexican Wheat Production*, Transactions of the New York Academy of Science, 20(1985), pp. 278-295.

2 Dr. Suman Sahai, *Genetically Modified Crops: Issues for India, Financing Agriculture*, Volume 35, Issue 4(2003), pp. 7-11.

path of technological advancement and its subsequent promise of a rise in productivity levels and national agricultural output, the process of policy experimentation of such an initiative has spanned over a few decades now³, with legislators and critics engaging in extensive debate over the use of genetically modified Brinjal, Potato, Cotton and Maize, amongst several others.⁴ While the traditional proponents of such crops advance arguments ranging from higher productivity⁵ to the decreased use of pesticides and herbicides,⁶ critics have often vehemently opposed their usage⁷, basing their arguments on the possibilities of such “novel gene combination”⁸ damaging environmental, health as well as legal interests of parties involved in the transaction of such crops. While on one hand, a significant portion of the farmer community has been seen as positively responsive to their usage (according to a 1997 survey conducted by the Economic Research Service⁹), a larger group of the public has remained very emotionally charged about their use, even in the face of the possibility of food security concerns being considerably alleviated,¹⁰ the skepticism arising mainly from issues related to trust and perceived risk.¹¹ This paper seeks to adopt a weighing balancing method of analysis, in order to deconstruct the possible legal reasons as to whether or not India is in a position to welcome the

3 Sachin Verma, *The Indian Bt Brinjal Controversy: Genetically Modified Food, Legal and Regulatory Framework*, Centre for Intellectual Property Law, Indian Institute of Technology, Kharagpur. (2008) pp. 45-58.

4 Colorado State University, *Transgenic Crops: An Introduction and Resource Guide*, (2010), pp. 21-42.

5 David Moeller, *GMO Liability Threats for Farmers: Legal Issues Surrounding the Planting of Genetically Modified Crops*, Farmers Legal Action Group (2001), pp. 89-98.

6 Kanchana Kariyawasam, *Legal Liability, Intellectual Property and Genetically Modified Crops: Their Impact on World Agriculture*, Pacific Rim Law and Policy Journal, (2010), pp. 1-27.

7 *Supra* n.6.

8 Felicia Wu and William Butz, *The Future of Genetically Modified Crops: Lessons from the Green Revolution*, (2004), pp. 11-48.

9 Robert Herdt, *The Politics of Precaution: Genetically Modified Crops in Developing Countries*, Economic Development and Cultural Change, Volume 51, Issue 3, (2003), pp. 783-785.

10 *Ibid.*

11 Ikechi Mgbeoji, *Adventitious Presence of Patented Genetically Modified Organisms: Is Intent necessary for Actions in Infringement?* Bulletin of the Science and Technology Society, Volume 27(2007), pp. 78-80.

usage of genetically modified crops.¹² The first section of the paper links issues relating to patent violations and farmer liability for GM contamination, followed by an examination of the manner in which the typically inadvertent Indian farming community is likely to be tangled in a web of liability. A portion of this section also examines the legal consequences of the often used binding arbitration clause contained in transaction agreements. The second section of this paper examines the possible international repercussions for India, which stem from the violation of internationally agreed environmental standards, through treaties, conventions as well as customary international law. The third and final section of the paper contains a concise analysis, which tries to attain a reasonable inference point, at least at the level of principle based policy making.

2. THE “MONSANTO” LIABILITY: LEGAL ISSUES SURROUNDING INDIAN PATENT LAWS, BINDING ARBITRATION CLAUSES AND THE “LEGAL LIABILITY WEB”

“It is true that intellectual property rights are not fully consistent with tangible property rights, but in the case of a farmer unintentionally acquiring a patented seed, intellectual property rights do not seem totally appropriate”¹³

In the year 1998, biotechnology tycoon Monsanto¹⁴ (who were responsible for developing the glyphosate resistant gene for the canola plant which would therefore be resistant to the Roundup herbicide brand), learnt that Canadian canola farmer Percy Schmeiser¹⁵ was growing a Round-up resistant crop and proceeded to obtain a license agreement signature from the latter. Refusing to pay a license fee and dismissing all allegations of patent infringement using the defense of accidental and unintentional use¹⁶, Schmeiser contended repeatedly

12 The weighing balancing method of analysis includes measuring the pros and the cons of a particular policy measure, which in turn reflects accurately upon the net pay off from any such policy perspective.

13 Stephanie Bernhardt, High Plains Drifting: Wind Blown Seeds and the Intellectual Property Implications of the GMO Revolution, *Northwestern Journal of Technology and Intellectual Property*, Volume 4, 2005, pp. 2-5.

14 *Monsanto Canada Inc v. Schmeiser*: 1 S.C.R 902, 2004 S.C.C. 34.

15 *Ibid.*

16 *Id.*

that a significantly larger interest of his “farmer’s property rights”¹⁷ would nullify the use of seeds which were accidentally thrown into his production area (probably by windborne seeds), contending further that he was not in any manner responsible for the unintended use of genetically modified elements and should therefore be absolved of all charges relating to patent infringement.¹⁸ Ultimately, the Supreme Court of Canada, in a 5:4 ratio held in favour of Monsanto, asserting that the “settled principles of the Patent Act”¹⁹, contained in Section 42 would show the acts of Percy as that which deprived Monsanto of the monopoly right that was legally vested in it, for the special canola plant, and that “Schmeiser knew or ought to have known that those plants were glyphosate resistant when he saved their seeds in 1997 and planted them the following year.”²⁰ Addressing the question of damages however, the Court disagreed with the Trial Court decision in the matter of compensatory damages, absolving Percy of such payment, on the grounds of no direct profit accruing to him from the invention of Monsanto.²¹ The implications of this case given exceptional situations cannot remain in isolated oddity from the Indian context.

The second amendment of the Indian Patent Act is a move which several critics suspect to be one which favors the interests of Monsanto, in an arbitrary fashion.²² With the amended clause (i) of Section 3 in the abovementioned Act²³, a plant modification has been brought within the purview of an “invention” which can therefore be patented, providing an extra element of patent violation probability for the Indian farming community. Moreover, Section 3(j) of the same Act (which excludes biological processes related to production and propagation from the purview of the word “invention”) does not provide a clear definition as to whether or not all modifications of plants or animals are essentially “biological”, thereby providing for a lacuna in the law, which may

17 Maria Lee and Robert Burrell, Liability for the Escape of GM Seeds: Pursuing the “Victim”? 65 Mod. Law Review 2002, p. 517.

18 Philippe Cullet, Farmer Liability and GM Contamination: Schmeiser Judgment, The Economic and Political Weekly, Volume 39, Issue 25, June 2004, pp. 2551-2554.

19 *Supran.* 14.

20 *Ibid.*

21 *Id.*

22 Section 3(i), Indian Patent Act 1970.

23 *Ibid.* Also see Eliot Marshal, Supreme Court to Review the Scope of Monsanto’s Seed Patents, Science, New Series, Volume 339, Issue 6120 (February 2013), pp. 639-714.

be exploited by biotechnology players, in order to further their interests. In fact, the spirit of Article 27.3(b) of the TRIPS²⁴ Agreement is what many believe has essentially been translated into Indian law²⁵. Considering how major a player Monsanto was, in the drafting and the structuring of the TRIPS Agreement in the first place, one might ordinarily give sufficient credit to the suspicions of those who doubt the fallouts of the second amendments to the Indian Patent Act.²⁶

3. POSSIBLE PATENT VIOLATIONS UNDER THE AMENDED PATENT ACT: WHOSE DUTY IS IT TO PROTECT FARMER'S RIGHTS?

The prohibition of unauthorized copying and replicating human intellectual efforts forms one of the core areas of debate related to the research and development of genetically modified crops.²⁷ An intellectual property law apart from recognizing the magnitude of human intellectual effort that goes into the conception of these crops also creates a limited monopoly in the organisms along with restricting access to GM technology.²⁸ A lawsuit may therefore lie in cases where a possibility of a patent infringement lies, in the form of copying a particular invention or by the sale of patented seeds without permission from the concerned patent owner.²⁹ The legal consequence of introducing these crops in India would be at multiple levels. Firstly, for an illiterate majority of the Indian farming population, the unintended acquisition or sale of patented organisms or seeds has been historically evidenced.³⁰ Considering that the mere possession of these crops can amount to an infringement, even when the farmers of non-genetically engineered crops, who enter a non-GM market area for sale of their crops, have unintentionally acquired genetically modified crops or

24 Article 27.3(b), The Agreement on Trade Related Aspects of Intellectual Property Rights.

25 *Supra* n. 6.

26 Deborah Whitman, Genetically Modified Foods: Helpful or Harmful? ProQuest Database, April 2000.

27 Brad Sherman, Biological Inventions and the Problem of Passive Infringement, Australian Intellectual Property Law Journal, Volume 13, 2002, pp. 146-149.

28 Roger McEowen, Legal Issues Related to the Use and Ownership of Genetically Modified Organisms, Washburn Law Journal, Volume 43, 2004, p. 611.

29 Dan Miller, Do GMO's Pay? The Progressive Farmer, 2011.

30 *Supra* n.6.

seeds, they may be held liable for intellectual property theft and patent violations.³¹ The question which arises, as a rebuttal to the abovementioned proposition, is how does this “unintended acquisition” take place? The answer to this is fairly uncomplicated. The commonly used terminology which is seen to be the root cause of farmer’s liability in the context of intellectual property rights, is “contamination”. This refers to the presence of genetically modified plants or plant parts in the production area or a part of the productive process of a crop that is intended to be GM free. Contamination can happen in various ways, the most common way including the spread of GM seed and pollen from one farm to the other³², thereby creating a liability for most inadvertent and unaware farmers who without bearing no mental element, incorporate these GM seeds into their own productive process. A positivist reading of the law and its subsequent stringent application therefore creates what critics call an “unfair legal liability web” which bears no weightage to the absence of intention and relevant knowledge of the socio economic backgrounds of Indian farmers, who in most cases are completely unaware of the legal consequences of contamination, so as to incentivize a greater degree of protection from it. Moreover, as was also observed in the case of *Monsanto v. Dawson*, “the inadvertent presence of contaminated crops does not protect the innocent possessor from infringement”.³³ Being a victim of such gene contamination, an inadvertent farmer often finds himself liable to the corporation whose intellectual efforts conceived the GM crop, for the offence of patent infringement, an issue which becomes one of paramount importance in the Indian socio-economic farming context.

As Ann Dorris observes, it has often been seen that contracts between seed companies and private owners contain a binding arbitration clause that mandatorily requires all conflicts arising from the use of the seed to be resolved only through arbitration. In a majority of such instances, there also remains a time period (usually 15 days from the first instance of the problem which the

31 Joan Font and Elias Mossialos, Are Perceptions of Risks and Benefits of Genetically Modified Food Independent? Food Quality and Preference, Volume 18, 2007, pp. 173-182.

32 Ken Belcher, Genetically Modified Crops and Agricultural Landscapes: Special Patterns of Contamination, Ecological Economics, Volume 53, 2005, pp. 387-398.

33 David Moeller, Farmer’s Guide to GM Crops, 2004, p. 21.

dispute is about) within which a farmer has to raise a dispute³⁴. Given such international norms and practices, the inclusion of such traditions in the Indian context may have a disastrous impact on our farmers given the fact that excessive litigation costs and the generally tedious judicial process significantly excludes the majorly illiterate Indian farmers from being able to compete on equal footing with powerful biotechnology players.³⁵ The increasingly low bargaining position of the farming community worldwide has also been well evidenced by the fact that contractual conditions between seed companies and farmers often include the farmer's acceptance of the seller's limited liability.³⁶ Dorris pertinently quotes a contract from a Monsanto company which read as "in no event shall the seed company or any other seller be liable for any incidental, consequential, special or punitive damages", in order to substantiate her contention.³⁷

To sum up the intellectual property debate, the introduction of GM crops jeopardizes the legal interests of farmers, both through the fallouts of "contamination" as well as through the amended Indian Patent Act. Moreover, taking into account the inevitability of genetic pollution, and the condition of 2% refugia in the GEAC³⁸ clearance is recognition of the legal leeway given to the likes of Monsanto to claim "intellectual property crime" through the current patent laws and the inevitability of farmers being caught in the liability web through the inevitable process of "contamination". The Indian legal system therefore favors a situation where plants and plant varieties are not patentable.³⁹ Also, moving beyond the written text of the law, there is very little jurisprudential guidance for judges to use and interpret, and to therefore balance the interests of the entity marketing the GM seed and the rights of those who "invented" it.⁴⁰ The development of a comprehensive liability framework in

34 David Kruff, *Impacts of Genetically Modified Crops and Seeds on Farmers*, The Agricultural Law Resource and Reference Centre, Pennsylvania State University, 2001, pp. 72-87. Also see Ann Dorris, *Monsanto Contracts: To Sign or Not to Sign*, *The Mississippi Farmer*, 2000, pp. 84-86.

35 *Supra* n.14.

36 *Supra* n.35.

37 *Ibid.*

38 The Genetic Engineering Appraisal Committee, Government of India.

39 *Supra* n. 18.

40 *Ibid.*

relation to biotechnology prevents India from welcoming the usage of GM crops, the subsequent advancement of which may permit their use at a later stage.⁴¹

4. INTERNATIONAL LEGAL ISSUES UNDER THE NAGOYA AND CARTAGENA PROTOCOLS: FURTHERING THE POLICY APPROACH DEBATE

One of the only broad universal agreements pertaining to the preservation of biodiversity across the globe is the Convention on Biological Diversity, along with its two supplementary agreements, namely the Cartagena Protocol on Biosafety and the Nagoya Protocol on Liability and Redress. This particular Convention, to which India is a signing as well as ratifying party, through Article 19(4) makes it explicitly known that contracting parties are to manage as well as regulate the risks associated with the use and the release of Living Modified Organisms (Hereafter LMO's), within the realms of domestic governance.⁴² The convention further mandates the adoption of an appropriate policy procedure in order to ensure that for projects which are likely to pose a threat to the interests of world biodiversity, an impact assessment is also carried out.⁴³ Given the changing face of customary international practice, the spirit of such international agreements is to ensure that ratifying Parties execute the safe transfer, handling and overall usage of such LMO's. India, being a ratifying party to the Convention and its principled ideology, has an international duty to uphold its spirit within domestic governance. Moreover, reaffirming the precautionary approach laid down in Principle 15 of the Rio Declaration, the Cartagena Protocol also addresses the issue of trans boundary movement, which in the commercial context of India, would be essential to address, should India decide to either import or export such crops.⁴⁴

The question here is not whether India willfully neglects her international commitments, but whether or not she possesses the required regulatory and liability framework to successfully carry such commitments out. The

41 *Ibid.*

42 Article 19(4), Convention on Biological Diversity.

43 *Ibid.*

44 Article 15, The Rio Declaration on Environment and Development.

environmental hazards posed by genetically engineered crops are suspected to be many, out of which the possibility of the introduction of a new gene in an existing crop negatively affecting the surrounding environment tops the list.⁴⁵ Moreover, the dangers of the gene transferring certain characteristics to either wild or domesticated varieties of the same species could also lead to the development of “super weeds”, causing a loss in the genetic diversity of crop species.⁴⁶ Some even suspect the possibilities of such crops upsetting the balance of entire ecosystems.⁴⁷ Therefore, in light of her international obligations, the authors propose a policy level rethinking of how to develop the required mechanisms to ensure that the spirit of the Biodiversity Convention is upheld within domestic governance, after which India may finally be in a position to open her gates for genetically modified crops.

Policy makers in India face a seemingly daunting task today, of choosing not to opt for the introduction of genetically modified crops in a bid to alleviate food security concerns. Although apparently rather promising, it is important for us to adopt a manner of deconstruction that looks at the Indian perspective in isolation from the rest of the world. Given the structure and scope of India’s current liability system, it is advisable to develop a comprehensive mechanism which is able to ensure the use of GM crops, while also ensuring that the interests of none of the parties to such commercial transactions, is sacrificed at any level. Until the country can comprehensively develop such a framework, the author continues to advocate that such crops must not be allowed to compete in the Indian market conditions.

5. HOW READY IS INDIA TO ACCEPT THE RECOMBINANT DNA TECHNOLOGY REGIME? A LEGAL ANALYSIS OF BTBRINJAL AND BTCOTTON

Genetically Modified crops are scientifically very different from any existing organism that has existed in nature. It is also very different from the higher yield crops created by cross-breeding within a single species. Through genetic engineering, we have been able to breach the divide between different species.

45 Neil Hamilton, *Legal Issues in Biotechnology*, American Law Association, 2000.

46 *Ibid.*

47 *Id.*

Genes from one species can be now inserted in another very different species to 'enhance its quality'. Here comes the catch—this is a gross tinkering with the evolutionary process and our limited knowledge of biological and evolutionary processes ensure that we do not know the outcome of this mixture of genes we have produced. This creates ecological, environmental, social and ethical issues. Dr. George Wald, Nobel Laureate in Medicine, said:

“Recombinant DNA technology [genetic engineering] faces our society with problems unprecedented not only in the history of science, but of life on the Earth. It places in human hands the capacity to redesign living organisms, the products of three billion years of evolution. Such intervention must not be confused with previous intrusions upon the natural order of living organisms: animal and plant breeding.. All such earlier procedures worked within single or closely related species... Our morality up to now has been to go ahead without restriction to learn all that we can about nature. Restructuring nature was not part of the bargain... this direction may be not only unwise, but dangerous. Potentially, it could breed new animal and plant diseases, new sources of cancer, novel epidemics”.⁴⁸

As the above suggests, GM crops, having characteristics of many different species may often be unstable and have unintended effects. In any case the consequences of cross-species genetic transfer is extremely difficult, if not impossible, to predict. J. R. Pillarisetti and Kylie Radel in their study have enumerated certain problems related to GM crops:⁴⁹

- (i) unnatural gene transfers between completely unrelated species may create new toxins or 'rogue genes';
- (ii) These unpredictable behaviour of new genes created can have health impacts;
- (iii) This may create new allergens and toxins and introduce them into food cycle. For instance- genetically modified corn 'StarLink'—meant

48 George Wald, *The Case Against Genetic Engineering*, *The Recombinant DNA Debate*, Jackson and Stich, (eds.) Reprinted from *The Sciences*, Sept./Oct. 1976, pp. 127, 128.

49 J. R. Pillarisetti and Kylie Radel, *Economic and Environmental Issues in International Trade and Production of Genetically Modified Foods and Crops and the WTO*, *Journal of Economic Integration*, Vol. 19, No. 2, Developing Countries in the WTO Regime: Selected Issues, June 2004, pp. 332-352.

for livestock feed, entered human food chain and acted as a human allergen, causing reactions like rashes to breathing problems.

- (iv) These GMOs and genetically altered hormones have potential to impact negatively on livestock or the environment. For example- a GM milk hormone, the recombinant Bovine Growth Hormone (rBGH), which was meant to increase dairy production by 10 was found to be dangerous to cattle as it created udder infections, painful, debilitating foot disorders, and reduced life span in cows.
- (v) The GM herbicide-resistant crops, in some instances, have been found to be resulting in the increased use of chemicals in the medium to long term. In one instance, a record number of complaints about spray-drift was recorded at the time of cultivation of these crops. This busts the myth that GM crops are beneficial for environment.
- (vi) Ethical concerns have been raised regarding GM crops,⁵⁰ especially for religious people and vegetarian groups, regarding the unnatural gene transfers from completely unrelated and potentially toxic species such as transfers from arctic flounder fish to tomatoes, and genes from the cholera toxin to alfalfa.
- (vii) The pest-resistant GM crops can pose a threat to organic agriculture and natural plant species “through cross contamination, cross pollination and creation of pests resistant to natural *Bacillus thuringiensis* (Bt) toxins.”
- (viii) Many of the GM crop patents are thought to involve ‘biopiracy’— theft of the indigenous knowledge and plants used by many local communities for centuries.
- (ix) There is wide concern that GM crops can act as invasive species and destroy the biodiversity existing among several species of crops.

50 Ron Epstein, *Redesigning the World: Ethical Questions about Genetic Engineering, Ethical Issues in Biotechnology*. Richard Sherlock and John D. Morrey (eds). Lanham, Boulder, New York, Oxford: Rowman and Littlefield, 2002, pp.47-70.

- (x) One of the documented case of GM crops is the Golden Rice—a variety of GM rice with higher levels of beta-carotene which is converted into Vitamin A and it is touted as the solution for Vitamin A deficiency (and consequent illness and blindness etc.) in children in developing countries. However there are many dark aspects of the Golden Rice. Golden rice is made from genetic material from bacteria and viruses which are associated with diseases in plants and from other non-food items such as cauliflower mosaic virus (CaMV) which increases unintended metabolic affects. One of these genes is linked to antibiotic resistance marker gene and hence there is concern that horizontal gene transfers from Golden Rice could spread antibiotic resistance genes to bacterial pathogens, and create new disease causing viruses and bacteria. Further can be noted that Vitamin A deficiency can be met more efficiently by consumption of more diverse organic diet and which will encourage biodiversity.
- (xi) Competition in Global Agricultural Market and consequent deregulation may lead to a situation where GM crops will drive out other crops and only a few high yielding monoculture GM crops will exist, at the cost of sacrificing bio-diversity and increasing risk to environment.

In a report of the Ecological Society of America, the risks of Genetically Modified organisms were clearly underlined.⁵¹ It explained how GMOs can cause risk to the environment in the following ways. Firstly, it may proliferate and persist without human intervention; Secondly, genetic exchange may be possible between a GM organism and other non-domesticated organisms, thereby creating unintended environmental impact; Thirdly, if they are released to environment, the enhanced traits of GMOs may confer it an advantage over native species, thereby displacing it and reducing biodiversity. For example-fast-growing transgenic salmon that escape from aquaculture net pens might seriously jeopardize native fish species. Fourthly, it may creating new or more vigorous pathogens or making the existing pests more resistant through

51 A. A. Snow, D. A. Andow, P. Gepts, E. M. Hallerman, A. Power, J. M. Tiedje and L. L. Wolfenbarger, *Genetically Engineered Organisms and the Environment: Current Status and Recommendations*, Ecological Applications, Vol. 15, No. 2, Apr., 2005, pp. 377-404.

hybridization; Fifthly, it may harm non-target species, such as soil organisms, birds, and other animals and thereby have disruptive effects on biotic communities; and Finally, cause irreparable loss in species diversity or genetic diversity within species.⁵²

Therefore the report recommended subjecting GMOs to greater scrutiny than organisms produced by traditional techniques of plant and animal breeding, especially in light of their novel characteristics and lack of experience in breeding, releasing and monitoring them.⁵³ This scrutiny should involve well designed tests by ecologists, evolutionary biologists, agricultural scientists, molecular biologists and other disciplinary specialists carrying out research over a range of spatial and temporal scales.

It further recommended evaluating the environmental benefits and risks of GMOs relative to “appropriate baseline scenarios, with due consideration of the ecology of the organism receiving the trait, the trait itself, and the environment into which the organism will be introduced”.⁵⁴ It strongly recommended a cautious approach in releasing GMOs into the environment and preventing release of GMOs about which scientific knowledge about possible risks is inadequate or of there is chance of serious environmental or health impacts.

These risks associated with GM crops suggest that if GM crops were to be allowed they must be done on a case-by-case basis. Further, they must be subjected a stringent risk assessment process which can correctly identify the risk they pose and the benefits that might accrue from them, thus allowing policymakers to decide whether to allow them or not. This method of risk assessment is discussed in subsequent section.

The GEAC cleared BtBrinjal for commercialization on October 14th 2009, following which significant furore was created in the country, across the farming and the anti GM community in particular. This ultimately resulted in an official notification by the Government on February 9th, 2010, saying that it needed more time and evaluation before it could give the green signal to the

52 *Ibid.*

53 *Id.*

54 *Id.*

commercialization of BtBrinjal. While on one hand, proponents of the commercial use and cultivation of this transgenic crop advance arguments as to how beneficial such crops shall be to small scale farmers, because they are proved to be of greater productivity and increased resistance to insects, a different proponent group advocate their use because it shall turn out to be cost effective and will have minimal environmental impacts. However, its adverse impact on human health, Biosafety, livelihood of persons and its adverse impact on biodiversity also constitute a significant portion of debate today. Therefore, in the absence of scientific consensus and the general opposition to it by the public, the stand taken by the government may not be beneficial to the immediate commercial market for such transgenic crops, but addresses the fact that India is obligated to follow the precautionary principle, laid down in international law.

6. ASSESSING SAFETY AND RISKS OF GMCROPS: PRECAUTIONARY PRINCIPLE VERSUS SUBSTANTIAL EQUIVALENCE UNDER THE LEGAL RUBRIC

In the last few decades, the 'Precautionary principle' has emerged as the key principle in International Environmental Law for environmental impact assessment⁵⁵ for any kind of activity that might affect the environment adversely and this principle has found support in major Environmental declarations and conventions.⁵⁶ Especially in case of food law and food safety, the European Parliament and of the Council in 2002 laid down general principles and requirements of food law, established the European Food Safety Authority

55 James Cameron and Juli Abouchar, *The Precautionary Principle: A Fundamental Principle of Law and Policy for the Protection of the Global Environment*, 14 B.C. Int'l & Comp. L. Rev.1 (1991).

56 See the instances of Precautionary principle in: Vienna Convention for the Protection of the Ozone Layer, 1985, 1513 UNTS 323; 26 ILM 1529 (1987); Montreal Protocol on Substances that Deplete the Ozone Layer, 1522 UNTS 3; 26 ILM 1550 (1987); Bergen Ministerial Declaration on Sustainable Development, 1990; The Convention on the Protection and Use of Transboundary Watercourses and International Lakes, 1992, 1936 UNTS 269; 31 ILM 1312 (1992); Convention on Biodiversity, 1992, 1760 UNTS 79; 31 ILM 818 (1992); UN Framework Convention on Climate Change, 1992, 1771 UNTS 107; S. Treaty Doc No. 102-38; U.N. Doc.A/AC.237/18 (Part II)/Add.1; 31 ILM 849 (1992).

and laid down procedures for food safety.⁵⁷ It approved the precautionary principle for risk analysis and food safety.⁵⁸ Precautionary Principle is based on the adage ‘better safe than sorry’ and ‘it is better to err on side of caution’ and is considered integral aspect of sustainable development thesis.⁵⁹ Precautionary principle allows and mandates taking protective action (such as ban of particular activity) even before there is complete scientific proof of a risk—no longer can the preventive action be delayed simply because full scientific information is lacking.

Most importantly this principle is recognized and affirmed in Cartagena Protocol on Biosafety, Article 11.8 states:

“Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.”

This protocol tries to regulate and ensure safe trade, cross border transfer, handling and use of living modified organisms that may have adverse effects on the biological diversity and human health.

According to WTO, this principle is widely accepted to be applicable in case of fields of food safety, plant and animal health protection.⁶⁰ This principle is

57 Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, European Union: Regulation (EC) No. 178/2002.

58 Article 6 & 7, Regulation (EC) No 178/2002.

59 World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), The Precautionary Principle, (2005) available at <http://unesdoc.unesco.org/images/0013/001395/139578e.pdf>, accessed on 12-07-2014).

60 World Trade Organisation, Precautionary Principle, SPS Agreement Training Module, available at http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c8s2p1_e.htm, accessed on 12/07/2014.

recognized in the Sanitary and Phytosanitary Agreement (SPS) concluded in the framework of the World Trade Organization (WTO). This agreement while re-affirming that every state has the right to adopt or enforce measures necessary to protect human, animal or plant life or health, tries to ensure this does not become an excuse for arbitrary or unjustifiable discrimination. Article 3.3 of the SPS Agreement leaves space for states to adopt precautionary approach by permitting them to adopt SPS measures which are more stringent than measures based on the relevant international standards. Article 5.7 of this agreement, relating to assessment of risk, allows a state to provisionally adopt "sanitary or phytosanitary measures on the basis of available pertinent information" when the available relevant scientific evidence is insufficient. However, in Beef Hormone dispute case, the Appellate panel of WTO held that precautionary principle as reflected in Article 5.7 could be invoked provisionally in cases where scientific knowledge is insufficient. However States' direct invoking of 'customary norm' of precautionary principle without invoking Art. 5.7 and by stating that import prohibition was not a provisional measure, was a violation of the agreement. It further held that Article 5.7 does not override obligations under articles 5.1 and 5.2.

The precautionary principle may be invoked only when these preliminary conditions are met: 1. when a phenomenon, product or process may have a dangerous effect, 2. identified by a scientific and objective evaluation, 3. if this evaluation does not allow the risk to be determined with sufficient certainty.⁶¹ In case of the European Legislation, this principle has been used to put the burden of proof back on producer and manufacturer to show that the food product poses no danger.⁶²

It can be seen that considering the threats GM crops pose and the status of this principle as customary international law,⁶³ they must be subjected to

61 Europa Summaries of Legislations, *The precautionary principle*, Available at http://europa.eu/legislation_summaries/consumers/consumer_safety/l32042_en.htm, accessed on 12-07-2014.

62 *Ibid.*

63 Owen McIntyre and Thomas Mosedale, *The Precautionary Principle As a Norm of Customary International Law*, *Oxford Journal of Environmental Law* (1997) 9 (2): 221-241 doi:10.1093/jel/9.2.221; Agne Sirinskiene, *The Status of Precautionary Principle: Moving Towards a Rule of Customary Law*, *Jurisprudence* 4.118 (2009): pp. 349-364.

precautionary principle in their risk assessment. However the rising concept of 'substantial equivalence' advocated by GM food companies has sought to lower the risk assessment standards. The principle of substantial equivalence assumes that if it has been established that the GMO or any new food or food component is found to be substantially equivalent to an existing food or food component, it can then be assumed that there is no reason for the product to be more hazardous than those existing food and thus can be treated in the same manner with respect to safety.⁶⁴ However substantial equivalence principle overlooks that GM food have some entirely new dormant characteristics which cannot be observed during the regulatory scientific tests and it fails entirely to account for unanticipated side effects that GMOs might have. Many incidents and tests have proved that this principle is inadequate in assessing safety of novel food like GMOs.⁶⁵ For instance, in 1989 Showa Denko K.K. marketed a food supplement which had components of genetically engineered bacteria. However this led to thousands of consumers being ill, of whom, 1500 were permanently disabled and 37 died.⁶⁶ Another instance was Monsanto's genetically engineered Soy, which was declared 'substantially equivalent' with natural soy and was approved for human consumption. However, when hamsters were fed on it in three generations, they developed slower growth, fertility and high mortality.⁶⁷ Other researches have shown that that lab rats fed with GM potatoes spliced with lectin suffered damage to internal organs.⁶⁸ Instances can be multiplied.⁶⁹ Royal Society of Canada has led a scathing attack

64 Joint FAO/WHO Expert Consultation on Biotechnology and Food Safety. Rome, Italy, 30 September to 4 October 1996 p. 4.

65 Matthew Stilwell and Brennan Van Dyke, Codex, Substantial Equivalence and WTO Threats to National GMO Labeling Schemes, Center for International Environmental Law—Geneva, Available at http://www.ciel.org/Publications/CODEX_Substantial_Equivalenceand_WTO.pdf, accessed on 12/07/2014; Inadequate safety assessment of GE foods, Available at <http://www.psrast.org/subeqow.htm>, accessed on 12-07-2014.

66 John Fagan, The Failings of The Principle of Substantial Equivalence In Regulating Transgenic Foods, Available at <http://online.sfsu.edu/rone/GEessays/FAILINGSSUBSTANTIALEQUIVALENCE.html>, accessed on 12-07-2014.

67 Inadequate safety assessment of GE foods, Available at <http://www.psrast.org/subeqow.htm>, accessed on 12-07-2014.

68 *Supra* n. 49.

69 *Supra* n. 63.

against this principle and has declared “substantial equivalence does not function as a scientific basis for the application of a safety standard, but rather as a decision procedure for facilitating the passage of new products, GE and non-GE, through the regulatory process”.⁷⁰

This substantial equivalence test, advocated by WTO and GM companies, has to be viewed in suspicion and discarded in favour of the precautionary principle and a higher deep scrutiny test. This test merely allows GM companies to easily introduce the GM food. To use a criminal law analogy, GM foods should be presumed dangerous until proven otherwise beyond reasonable doubt. Even if substantial equivalence test, it should be used a preliminary test in a series of more rigorous trials, not as a determinative test.⁷¹ Thus the countries should lobby at international level for change of this norm.

Therefore the researchers suggest that precautionary principle must inform these tests for approval of GM food. As Hartmut Meyer notes, decision making in such environmental decision making has for too long suited to enable expedient decision making.⁷² Rather more holistic approach must be adopted and models accounting for complex environmental factors should be developed. Meyer has recommended to expand the scope of GMO risk assessment and include socio-economic aspects and to apply Strategic Environmental Assessment (SEA) developed by OECD, the Convention on Biological Diversity (CBD) and the European Union (EU), while using an ecological and approach and having precautionary principle as its baseline.⁷³ We fully agree with these recommendations.

7. INDIAN LEGAL POSITION ON GM CROPS

It is interesting to examine Indian legal framework in this regard. The precautionary principle has been acknowledged to be a part of Customary

70 The Royal Society of Canada, *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*, Ottawa, p.182 (April 2001).

71 A. A. Snow, D. A. Andow, P. Gepts, E. M. Hallerman, A. Power, J. M. Tiedje and L. L. Wolfenbarger, *Genetically Engineered Organisms and the Environment: Current Status and Recommendations*, *Ecological Applications*, Vol. 15, No. 2 (Apr., 2005), pp. 377-404.

72 Hartmut Meyer, *Systemic risks of genetically modified crops: The need for new approaches to risk assessment*, *Meyer Environmental Sciences Europe* 2011, 23:7.

73 *Ibid.*

International Law by the Indian Supreme Court and has been applied in environmental matters as a principle flowing from sustainable development, right to clean and safe environment and Article 21 of the Constitution and is held have three facets: First, Government must anticipate, prevent and attack the causes of environmental degradation; Second, lack of scientific certainty is no ground for postponing preventive measures to protect environmental degradation and third, the onus lies on the developer/industrialist to show that his action is environmentally benign.⁷⁴ As per the stated position of Ministry of Environment and Forest itself, in context of decision imposing moratorium on introduction of BtBrinjal, a cautious and precautionary principle based approach must be adopted while dealing with the ecologically important and vexing issue of GM Crops.⁷⁵ Recently the Supreme Court had constituted a technical expert committee to examine the issue of field trials of GM Crops and the committee recommended a ten year moratorium on such field trials till the safety and regulatory aspects are clarified.⁷⁶ Pursuant to this recommendation the Supreme Court has sought Union Government's response as to why should such field trials not be suspended in interim.⁷⁷ This shows Apex Court's concern about the environmental fallouts of GM crops and bolsters out thesis that GM Crops cannot be introduced in India now without further examination as to their different ecological and other impacts. Having accepted the precautionary principle in India and having commitment to biodiversity any attempt at introducing GM Crops must be subjected to strict scrutiny.

74 *Vellore Citizens Welfare Forum v. Union of India and others*, AIR 1996 SC 2715; *M.C. Mehta v. Union of India*, (1997) 2 SCC 353; *Karnataka Industrial Areas Development Board v. C. Kenchappa and Ors.*, AIR 2006 SC 2038.

75 Ministry of Environment and Forests, Report to People on Environment and Forests 2009-10, Government of India.

76 Chetan Chauhan, SC committee says no to GM crops for time-being, Available at: <http://www.hindustantimes.com/India-news/NewDelhi/SC-committee-says-no-to-GM-crops-for-time-being/Article1-1096481.aspx>, accessed on 15-09-2014.

77 PTI, Supreme Court seeks Centre's response about open field trials of Genetically Modified crops, Available at: http://articles.economictimes.indiatimes.com/2014-04-22/news/49318877_1_open-field-trials-s-paroda-anti-gm-activists, accessed on 15-09-2014.

8. REGULATORY INABILITIES OF THE CURRENT LEGAL FRAMEWORK IN INDIA: EXPLORING POSSIBLE LEGAL PROBLEMS

The trial of transgenic crops, even after it receives approval from the Genetic Engineering Appraisal Committee, has been the topic of substantive debate across multiple contours in the country. Recently, Mr. Prakash Javadekar, Union Minister for the Environment, was petitioned by farmers of the Swadeshi Jagran Manch, requesting him to take appropriate action in order to prevent the trial of such crops, on multiple grounds. While Aruna Rodrigues' 2005 petition to the Supreme Court on the grant of a moratorium for GM crops is still pending, it is important to appreciate that as battle lines sharpen over the GM crops debate, we must examine whether or not the current legal framework in India is well suited to ensure that the process is adequately regulated. Beginning April 2014, the Technical Expert Committee called for the strengthening of the current regulatory mechanism before more field trials could be conducted. The shift of the GEAC from an approval committee to an appraisal committee is well founded in the statements of the Environment Minister of the country, when he contends, rather dubiously, that the GEAC (which he fails to understand that it's a part of his own ministry) is the body statutorily enabled to take policy decisions regarding GM crops and was not a "government decision" as such. In his parliamentary clarification coming in July 23, 2014, the Minister also explained how in view of safety and agronomic concerns, there would be a detailed evaluation process before field trials could be conducted. It is in that context that it is submitted that the working of the GEAC does not enable this regulatory process to be very effective, especially considering the fact that India's international obligations impose a duty to ensure that the interests of the Indian farming and general population's interests are given greater weightage than that given to powerful corporations.

In India, all activities related to GMOs are regulated by "Rules for the Manufacture/Use/Import/Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989" under the provisions of the Environment (Protection) Act, 1986 and is administered through Ministry of Environment and Forests, Department of Biotechnology (DBT), Ministry of Science and Technology. These rules set up the Genetic Engineering Approval Committee (GEAC) as the authority to regulate and approve the GM Foods. Other authorities such as the Recombinant DNA

Advisory Committee (RDAC); the Review Committee on Genetic Manipulation (RCGM); Institutional Biosafety Committees (IBSC); State Biosafety Coordination Committees (SBCC), and; District Level Committees (DLC) also help implementing the rules and play a role in approval and monitoring of GM Crops. However the Government of India is the final authority deciding these issues.⁷⁸

Meanwhile The Food Safety and Standards Act, 2006 (FSSA, 2006) has come to place which empowers the Food Safety and Standards Authority of India (FSSAI) to regulate genetically modified (GM) foods. Although notifications have come to exempt GM Food from the 1989 rules and place them under FSSAI regime, they are not yet in force.⁷⁹

The FSSAI has establish the Office of GM Foods and the GM Food Safety Assessment Unit (GMFSAU) which is tasked with preparing the Safety Assessment Report that summarizes the information that was taken into account during the safety assessment and states the decision of the GMFSAU as to whether the GM product may be considered as safe as its conventional counterpart in its use as food. The GMFSAU will comprise of a multi-disciplinary team of scientists trained in GM food safety assessment and will include molecular biologist; biochemist; immunologist; food allergenicity specialist; toxicologist and nutritionist.⁸⁰

FSSAI will also establish an expert committee on GM Foods, tasked with overseeing a public consultation process, considering and responding public consultations feedback and recommend conditions to be stipulated for product approvals keeping in view the safety assessment report by GMFSAU.

78 Food Safety and Standards Authority in India, Operationalizing the Regulation of Genetically Modified Foods in India, Available at http://www.fssai.gov.in/Portals/0/Pdf/fssa_interim_regulation_on_Operatonalising_GM_Food_regulation_in_India.pdf, accessed on 12-07-2014.

79 MoEF Notification No. S.O. 1519(E) exempted “*food stuffs, ingredients in foodstuffs and additives including processing aids derived from Living Modified Organisms where the end product is not a Living Modified Organism*” from Rule 11 of the Rules, 1989. However, the FSSAI was yet to publish rules that described how GM food stuffs would be regulated under the FSSA, 2006 and consequently MoEF published a series of additional notifications that have kept Notification No. S.O. 1519(E) in abeyance so that GM foods could, as an interim measure, continue to be regulated under Rules, 1989.

80 *Supra* n. 88.

It is to be noted that India does not have specific guidelines or parameters on how to assess safety of GM products, expect the GMFSAU directive to find if GM product is “as safe as its conventional counterpart” which seems like adopting substantial equivalence test.

In our opinion, India would do well to restructure these authorities and give them greater powers, like those enjoyed by European GM regulatory authorities and lay down explicit legislation and guidelines on line of the EU 2002 legislation, and not merely rely on recommendation of an expert body. Further, the Precautionary Principle should be the fundamental guiding principle behind these mechanisms and Strategic Environmental Assessment tests must be undertaken before approving GM foods. Independent tests undertaken by independent Research Institutions and laboratories must also be duly considered before giving any approval to any GM product. Even after approval, it must be ensured that it, as far as possible, remains isolated from the wild and farmers using it do not get unintentionally enmeshed in trappings of IPR law. Strict monitoring must be done to see if there is any unexpected or unintended environmental, biodiversity or health impact of such GM crop/food. If any such impact is found then the product should be roll backed immediately

9. GM CROPS AND FOOD SECURITY: EXPLORING ISSUES OF EFFICIENCY, INFERTILITY AND TRANSPARENCY IN GOVERNANCE

One of the prime reasons given for GM crops is it will ensure food security for millions of under nourished and mal nourished persons in the world. Altruistic as the reason may sound, it is actually hollow upon closer scrutiny.

International food security necessitates that nations must achieve a level of self-sufficiency in provided exclusively by countries like US may breed unhealthy dependency on these countries which may endanger food security besides compromising sovereignty. The WTO norms which endanger self-sufficiency of local agricultural markets must be renegotiated.⁸¹

81 *Supra* n. 49.

A further issue which should be noted is the extent of control of GM crops and food by few organizations. It is estimated that the top five biotechnology companies are controlling more than 95 percent of patents and gene technology transfers, while Monsanto's seeds alone account for 94 percent of the global transgenic crop area.⁸² Further, these companies have introduced 'terminator technology' which renders the seed infertile in second cycle—thereby rendering farmers dependent on these MNCs forever and the IPR regime relating to it paves way for legal exploitation of poor farmers. In this way it is argued, GM crops increase poverty and inequality of assets, breed dependency and thus undermining food security and contributing to food insecurity of nations.⁸³

Actual evidence also shows that Globalisation and GM crops are not a miracle way for expanded food production. One study reports that liberalization and globalization in third world is leading to reduction in global food production and fostering food insecurity by wiping out small efficient family farms. The large multi-national agribusiness corporations have failed in increasing food production.⁸⁴

This raises an important aspect of North-South debate.⁸⁵ The GM crops can be seen as to benefit and enrich the North (MNCs and agribusiness) at the cost of small farmers and governments of South.⁸⁶ It is worth recalling Senator McGovern's statement: "Food security in private hands is no food security at all."⁸⁷ This is eminently true because private corporations do not ensure food security out of altruistic motives, but do so because of profit.

Therefore it is not surprising at all that developing countries, which are supposed to be the prime beneficiaries of GM-crop-induced food security are at the fore front in opposing it. Paalberg's conclusion that GM food's introduction into developing world is stalled mainly due to politicization of national biosafety

82 *Ibid.*

83 Globalization Research Centre, 2003.

84 Hossein Azadi, Peter Ho, *Genetically Modified And Organic Crops in Developing Countries: A Review of Options For Food Security*, Centre for Development Studies, Faculty of Spatial Sciences, University of Groningen, The Netherlands, 2009.

85 Arenson, Patricia, *Enemies of Life in the Name of Life: Seed Patents, GM Crops, and the Global South*, 2011.

86 *Ibid.*

87 *Id.*

screening processes,⁸⁸ therefore misses the larger picture—that this politics is founded on very real concerns which have been scientifically validated.

Besides, GM crops need not always increase yields. For example- In 1997, 30,000 acres of herbicide resistant cotton in the Mississippi failed. Similarly, up to two thirds of a crop of insect-resistant 'New Leaf' potatoes failed in Georgia and the herbicide glyphosate-resistant soybeans has 4-10% losses compared to conventional soybeans.⁸⁹

The natural question which arises is that of an alternative to ensure food security. One alternative is Organic Farming. Environmental friendly it is but many have raised concern about its ability to increase food yield.⁹⁰ However documented evidence shows that at least in certain conditions it can increase yields.⁹¹ Pillarisetti in his study has documented cases of East African nations like Ethiopia, Madagascar and others which have increased 60-70% yields by organic farming.⁹² Countries like Sri Lanka, Cuba have also demonstrated the success of organic farming.⁹³

However admittedly, organic farming may not be the one-stop solution for food security. Other alternatives must be explored. However the researchers believe the alternative of GM crops is beset of other concerns and therefore should be avoided and be treaded carefully.

GM crops have also raised other ethical and moral issues about humans tinkering ill-advisedly with evolutionary processes of nature. While some have sought to defend it by saying it is not different from existing cross-breeding of crops, we believe it is fundamentally different as the recombinant DNA technology allows to create mixture of completely unrelated species.

88 Robert L. Paarlberg, *The Politics of Precaution: Genetically Modified Crops In Developing Countries*, Baltimore: Johns Hopkins University Press, International Food Policy Research Institute, 2001.

89 *Supra* n. 49.

90 Hossein Azadi, Peter Ho, *Genetically Modified and Organic Crops in Developing Countries: A Review of Options for Food Security*, Centre for Development Studies, Faculty of Spatial Sciences, University of Groningen, The Netherlands, 2009.

91 *Ibid.*

92 *Supra* n. 49.

93 *Ibid.*

Other issues include Right of Consumers to know what they consume, what they eat. Recently compulsory labeling of GM foods in Europe have led to an uproar among GM companies with US considering such practices as 'discriminatory'.⁹⁴

It is amusing to note GM companies' resistance to higher scrutiny of GM foods and their labeling. If the GM crops are truly as safe as they are touted by their makers, why have such resistance to further deep scrutiny? Their reluctance to accept this casts shadow over the reliability and safety of GM crops in the minds of consumers and thereby challenges their credibility.

10. CONCLUSION

There are multiple and cross cutting issues which from the policy centered debate around the introduction of genetically modified crops in India. While on one hand, the interests of large and powerful corporations may very well have substantively valid grounds for advocating the use of GM Crops, it is the duty of the policymakers in this country to ensure that the public is not adversely affected by the introduction of any such policy. It is therefore submitted that the current regulatory and legal framework relating to intellectual property rights, including patent rights, as well the current environmental laws both on the domestic and international front, mandate India to act in a particular manner. Now, unless and until conclusive reserahc and scientific experiments can prove beyond doubt that India's legal obligations shall not have to be sacrificed, along with the interests of the public at large, we may adopt a policy that allows for the commercialization of these crops Until then, India must get ready for it, and not adopt its use without knowing exactly what it entails for the system.

94 *Supra* n. 49.