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# GENETIC ENGINEERING THE INTERLOPER OF THE ENVIRONMENT: LEGAL, SOCIOLOGICAL AND ENVIRONMENTAL CONSIDERATIONS

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ABSTRACT

*The advancement in technology has made earlier impossible tasks possible. Accelerating desire for technological excellence has pushed India into an intricate conveyor of the research and development industry (R&D), giving rise to the novel technique of "Genetic Engineering" (GE). This paper sets a discourse on the expansion of methods used in genetic engineering such as altering genes (Gene modification) in humans , selective breeding (GMOs) to recombinant deoxyribonucleic acid (rDNA), human germline, and the CRISPR/Cas9 technology. With bacterial genome editing becoming old hat, researchers have turned to various agricultural operations, genetically modified babies, and therapeutic advantage of the technology. The underpinning object of altering and manipulating the genes points toward the scientific avenue of receiving the desired traits in humans which would have been impossible naturally. The dialogue space for using advanced agricultural practices and technologies in the past few years has been regarded as an intense debate on the adoption of Genetically Modified (GM) crops becoming one of the most contentious issue. The introduction of Genetic engineering technique in humans, though used for treating the illness falls short on ethical grounds. Hence, by dint of this paper, we have expatiated on the environmental hazards associated with GE in crops and humans, "Ethical guidelines" consigned by ICMR (Indian Council of Medical Research), and its effects. Further, the legal position of India as one of the early birds to have absorbed and introduced the concept of GE in comparison to other countries has been outlined. In conclusion, we have recommended suggestions for policy makers to strike a balance between the risks and benefits of this technique.*

Keywords: Genetic Engineering, CRISPR, Genetically-Modified Crops, Ethical Guidelines, rDNA



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## STEPPING INTO NEO-DIGITALIZATION

"*Genetic engineering has never been about saving the world; it's about controlling the world*".[1]

The advent of technology in leaps and bounds makes inconceivable tasks possible. The continuous spurring of technology forms a cornerstone for debate on contentious issues and its impaction diverse sectors. Genetic engineering is one such novel technique which grapples with the implications of the ethical and legal vacuum.

Traditionally, humans used to manipulate the genomes indirectly by regulating breeding and selecting offspring with desired traits. But with the enhancement of technology, genetic engineering involved the direct manipulation of one or more genes to give it a desired phenotype.[2]

According to the 'Rules for Manufacture, Use, Import, Export and Storage of Hazardous Micro-Organisms/Genetically Engineered Organisms or Cells Rules, 1989 (Rules of 1989)','Genetic engineering' means *"the technique by which heritable material, which does not usually occur or will not occur naturally in the organism or cell concerned, is generated outside the organism or the cell is inserted into said cell or organism. It shall also mean the formation of new combinations of genetic material by incorporation into a host cell, where they occur naturally (self-cloning) as well as modification of an organism or in a cell by deletion and removal of parts of the heritable material*".[3] Thus, genetic engineering is an umbrella term for such biotechnological solutions involved in mutilating genes of living organisms, extending not only to microorganisms but also to crops and humans.

Genetic engineering is a combination of various biotechnological mediums such as "*recombinant DNA*," "*gene targeting*", or "*genome editing*".[4] Genome editing (also called gene editing) is a group of technologies that gives scientists the ability to modify an organism's DNA. These technologies allow genetic material to be added, removed, or altered at some particular locations in the genome.[5] It means that the pieces of DNA are combined with other pieces of parental DNA. This process is something which is engineered in the laboratory and then propagated in any number of different organisms that range from

[1] Vandana Shiva; https://www.newyorker.com/magazine/2014/08/25/seeds-of-doubt

[2] Government of United States, *Genetic engineering,* NATIONAL HUMAN GENOME RESEARCH INSTITUTE (oct.18, 2020, 10:04AM), https://www.genome.gov/geneticsglossary/GeneticEngineering#:~:text=Genetic%20engineering%20is%20the%20process,selecting%20offspring%20with%20desired%20traits.

[3] Ministry Of Environment & Forests, *The Manufacture, Use, Import, Export And Storage Of Hazardous Micro-Organisms Genetically Engineered Organisms Or Cells Rules, 1989*, NATIONAL BIODIVERSITY AUTHORITY (oct.18, 2020,10:04AM), http://nbaindia.org/uploaded/Biodiversityindia/Legal/28.%20Rules%20for%20the%20manufacture,%20use%20import%20export%20and%20storage%20of%20hazardous%20microorganism%20genetically%20engineered%20organisms%20or%20cells,%201989.pdf

[4] PGed, Personal Genetic Education Project (oct.18, 2020, 10:04 AM), https://pged.org/genetic-modification-genome-editing-and-crispr/#

[5] Genetic Home Reference, *What are genome editing and CRISPR-Cas9?*, MEDLINE PLUS (oct.18, 2020, 10:04 AM), https://ghr.nlm.nih.gov/primer/genomicresearch/genomeediting

bacterial cells to yeast cells, to plants and animals.[6] Whereas, Recombinant DNA (rDNA) refers to the artificial formulation of a singular molecule by incorporating two or more DNA.[7] They are constructed in laboratory through genetic recombination of at least two strands of dissimilar gene material, which would not be found together naturally in a genome[8] such as exotic crossbreeds in pets.

However, the belief that genetic engineering will be the key to unlock a more glorious future suffers from a lack of systematic clinical research and regulation along with the impediment of ethical issues as it still remains a major road block in the process of translation from the bench to bedside.

## SCIENTIFICALLY INDUCED CROPS AND LIFE STOCKS

Basic problems associated with agriculture, especially crop production spreads across India, from a lack of machinery, soil fertility, fertilizers to low yielding seeds.[9]Thus it would be fair to argue that in such a situation, technology seems like a companion for resolving some of the acute issues related to crop production in India.

### 1. **Genetically Modified Crops (GMC)in India.**

#### 1.1 *Modern vs. Traditional*

The journey of creating genetically modified organisms (GMOs) was initiated in 1973.Since then, the novel technology of gene modification (GM) through rDNA has become recognized in agricultural industry of India. According to *Genetic Engineering Appraisal Committee (GEAC)*, GMO or living modified organism refers to any organism whose genetic material has been modified through a laboratory-based transfer of such genetic material from another organism.[10] Thus, GM directly interferes with the DNA of the crops under

[6] David M. Bodine, *Genetic Engineering*, NATIONAL HUMAN GENOME RESEARCH INSTITUTE (oct.18, 2020, 10:04AM),https://www.genome.gov/genetics-glossary/Genetic-Engineering#:~:text=Genetic%20engineering%20is%20the%20process,selecting%20offspring%20with%20desired%20traits.

[7] Ghagne, Shridhar and Nerli, Rajendra and Baligar, Prakash and Hiremath, Murigendra, *Status and Application of Recombinant DNA Therapeutic Products Used in Clinical Practices: An Indian Scenario*, SSRN(oct.18, 2020, 10:04 AM),http://dx.doi.org/10.2139/ssrn.2783940.

[8] Shinde, S & Chavhan, S &Sapkal, Sandip & Shrikhande, V., *Recombinant DNA Technology and its Applications: A Revie*w, 4 IJOMR 79-88. (2018)http://www.medipharmsai.com/home/article_abstract/103

[9] Takashi Sato, *Problems in Field Crop Production*, Asian Survey, 8(10) JAPANESE SCHOLARSHIP ON SOUTHEAST ASIA: SELECTED STUDIES 829-835, (1968).

[10] Ministry of Environment, Forest and Climate Change, Genetically Modified Crops – An Overview ,The Genetic Engineering Appraisal Committee (GEAC), (oct.18, 2020, 10:04 AM), http://www.geacindia.gov.in/resource-documents/17_2-Genetically_Modified_Crops_An_Overview.pdf.

laboratory observation rather than subjecting the cultivation to controlled pollination as a traditional means of modifying crops.[11]

Human controlled pollination practices such as controlled use of animal pollinators have been used for ages in India.[12] Production of cotton, tomato, brinjal, soybean, cumin, okra, chillies are a few examples where human controlled pollination is used.[13] Even though animal pollination is a natural technique for the modification of crops but it has its own set of drawbacks.[14]

The leisurely pace of controlled pollination coupled with challenging habitat, pests, dynamic ecosystem, a lack of adequate funds to ensure natural modification of crops, a lack of necessary-skilled techniques, and high expectation of financial gain proves to be an expensive affair for the front-line cultivators themselves.[15] On the contrary, gene modification in crop production although alike to controlled pollination is manually supervised but allows direct injection of desirable DNA of closely or distantly related organism, further removing the undesirable traits.[16] Moreover, GMO are developed in a much more precise and comparatively shorter time span under observation of strict laboratories[17] such as Network of GMO Testing Laboratory of India (NGLT).[18]

### 1.2 *Procedural Intricacy*

Gene editing in the GMOs is achieved through intricate scientific procedures namely identification/extraction, cloning, transforming and selection.[19]

Firstly, the '***extraction***' process commences with the identification of the desired gene possessed by the host crop.[20] Then the identified gene is located and isolated (snipping off the trait) from the host crop. After running observational test under registered NGTL on

[11] Ministry of Environment, Forest and Climate Change, Genetically Modified Crops – An Overview, THE GENETIC ENGINEERING APPRAISAL COMMITTEE (GEAC), (oct.18, 2020, 10:04 AM), http://www.geacindia.gov.in/resource-documents/17_2-Genetically_Modified_Crops_An_Overview.pdf.
[12] Chaudhary, O.P. & Chand, R., *Economic benefits of animal pollination to Indian agriculture*, 87 IJAS, 1117-1138, (2017).
[13] Chaudhary, O.P. & Chand, R., *Economic benefits of animal pollination to Indian agriculture*, 87 IJAS, 1117-1138, (2017).
[14] Chaudhary, O.P. & Chand, R., *Economic benefits of animal pollination to Indian agriculture*, 87 IJAS, (2017).
[15] Food And Agriculture Organization of the United Nations, *The Pollination of Cultivated Plants a Compendium for Practitioners: A compendium for practitioners Volume 1*, GREEN INDUSTRY PLATFORM (oct.18, 2020, 10:04 AM),http://www.fao.org/3/i9201en/I9201EN.pdf.
[16] Meenakshi Raina, Pankaj Pandotra, R.K. Salgotra, Sajad Ali, Zahoor A. Mir, Javaid Akhter Bhat, Ajaz Ali, Anshika Tyagi, and Deepali Upadhahy, *Genetic Engineering and Environmental Risk*, SPRINGER INTERNATIONAL PUBLISHING AG, Springer International Publishing, (oct.18, 2020, 10:04 AM), DOI 10.1007/978-3-319-64501-8_4
[17] TAKASHI SATO, *supra* note 9.
[18] The Ministry of Environment, *Forest & Climate Change, about NGLT*, Network of GMO testing laboratories (NGLT) India (oct.18, 2020, 10:04 AM), http://gmolabs.nbpgr.ernet.in:9090/.
[19] The Energy and Resources Institute, Status of Genetically modified (GM) crops in India , TERI (oct.18, 2020, 10:04 AM), https://www.teriin.org/library/files/GM-crops-in-India.pdf.
[20] The Energy and Resources Institute , Status of Genetically modified (GM) crops in India, TERI (oct.18, 2020, 10:04 AM), https://www.teriin.org/library/files/GM-crops-in-India.pdf.

the snipped gene, next step is '***cloning'***.[21] For gene cloning, the snipped gene is to be attached to a carrier to transfer the desired DNA into the cell of guest/modifying crop. For DNA to be transferred, one of the method is **Agrobacterium** approaches.[22] Agrobacterium, a naturally occurring microorganism, itis the only organism known for inter-kingdom transfer of genes.[23] Hence, the selected gene is engineered into the transferred DNA (T-DNA) of the bacterial plasmid, which further integrates itself to the chromosomes in the cell of the guest plant to complete the T-DNA transfer.[24] Before the T-DNA is latched to the guest, a carrier package is mixed, which includes a 'selectable marker gene' to recognize the 'transformants' i.e. to differentiate the plant cells that has adopted the modified gene from the 'non-transformants'.[25] Further transformation occurs when the picked transformants are inserted into bacterium to generate multiple copies of the desired trait. Once the plant cells have completely adopted the modification, the healthy cells are selected to be grown under observation until they produce seeds to ensure the modified crops can be sowed naturally.[26]

As far as India is concerned, in 1965-66, Dr. M.S. Swaminathan also known as 'the father of green revolution'[27] introduced and further worked towards the development of the high yielding varieties of crops[28] under the High Yielding Varieties Programme (HYVP) which was an attempt to metamorphose the Indian agricultural system.[29] Subsequently, the first-commercialized genetically modified, non-food plant product that is *Bt* cotton hit the market.[30] The rationale behind developing *Bt* cotton genetically was over-infestation of bollworms which destroyed heathy cotton balls and the lack of resistant trait available in closely related crops to cotton.[31] Thus, the cultivator's plight turned the researchers away from conventional breeding to gene modification. GMO marked whole set of advantages

[21] TAKASHI SATO, *supra* note 9.
[22] TAKASHI SATO, *supra* note 9.
[23] 5 Komari, T., & Kubo, T., MOLECULAR IMPROVEMENT OF CEREAL CROPS : ADVANCES IN CELLULAR AND MOLECULAR BIOLOGY OF PLANTS *43–82*. (Vasil I.K. ed. Kluwer Academic Publishers 1999).
[24] United States Department of Agriculture, *Biology and Control of Crown Gall* (Agrobacterium tumefaciens) , UNITED STATES DEPARTMENT OF AGRICULTURE (oct.18, 2020, 10:04 AM), http://archive.bio.ed.ac.uk/jdeacon/microbes/crown.htm.
[25] MEENAKSHI RAINA et. Al., *supra* note 16.
[26] MEENAKSHI RAINA et. Al., *supra* note 16.
[27] Sandhya Ramesh, How MS Swaminathan, father of India's Green Revolution, got GM crops 'all wrong', The Print, (oct.18, 2020, 10:04 AM), https://theprint.in/science/how-ms-swaminathan-father-of-indias-green-revolution-got-gm-crops-all-wrong/166011/
[28] M. Lakshmikumaran, *Innovation, Economic Development, and Intellectual Property in India and China*, ARCIALA Series on Intellectual Assets and Law in Asia 367-386(Liu KC. Racherla U. Ed. Springer, Singapore 2019).
[29] Planning commission of India, The high yielding varieties programme in India (1970-75) , NITI Aayog, (oct.18, 2020, 10:04 AM),https://niti.gov.in/planningcommission.gov.in/docs/reports/peoreport/cmpdmpeo/volume2/thy.pdf.
[30] UNITED STATES DEPARTMENT OF AGRICULTURE, *supra* note 24.
[31] TAKASHI SATO, *supra* note 9.

like disease and insect resistance, high yielding and nutritional value, potential extension in the shelf life of fruit, and the slow aging process.[32]

## 2. **Asymmetry between Technology and Ecology: Effects of Intervention**

### 2.1 *Environmental Assessment by Parliamentary standing committee*

Since Bt cotton was made commercially available in 2002, various genetically engineered crops have been approved for confined field trials since then. Such GE crops include brinjal, cabbage, chickpea, mustard and okra tested for insect resistance, abiotic stress tolerance, and hybrid seed production.[33] Thus, ahead-to-head competition among the developed and developing countries marked negligent attitude towards proper ecological balance that should have been prioritized. Acknowledging the wide span of environmental risk, India ratified the Cartagena Protocol on Biosafety to the Convention on Biological Diversity,[34]which is an international agreement acting as a framework for safe handling, transport and use of living modified organisms that may have adverse ecological impact due to a raise in modern biotechnology.[35]

Even after adoption of the Cartagena protocol since 2000, the flaws of environmental regulation have forced India to revaluate the well-established procedure set forth to ensure ecological safety. The exponents of the prevalent use of GM crops consider rDNA technologies as an alternative to provide food safety but many experts and reports have suggested that expectation over GM crops to achieve food safety and security is not the sustainable way.[36]

Firstly, the trumpet over the success of Bt cotton can be called superficial as its cultivation has been observed to have adverse effect on soil fertility as it can secrete toxins from its roots into the soil.[37] Moreover, parliamentary standing committee on science & technology, environment & forests in its 301th report[38]discovered that the government agencies are portraying a rosy picture claiming that the increase in the volume of production of cotton

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[32] CHAUDHARY, O.P. & CHAND, R., *supra* note 13.

[33] Vibha Ahuja, *Regulation of emerging gene technologies in India*, BMC Proceedings (Oct.18, 2020, 10:04 AM),https://doi.org/10.1186/s12919-018-0106-0.

[34] Convention on Biological Diversity , *The Cartagena Protocol on Biosafety*, Convention on Biological Diversity (Oct.18, 2020, 10:04 AM), https://bch.cbd.int/protocol/#:~:text=The%20Cartagena%20Protocol%20on%20Biosafety%20to%20the%20Convention%20on%20Biological,diversity%2C%20taking%20also%20into%20account.

[35] Convention on Biological Diversity , *The Cartagena Protocol on Biosafety*, Convention on Biological Diversity (Oct.18, 2020, 10:04 AM), https://bch.cbd.int/protocol/#:~:text=The%20Cartagena%20Protocol%20on%20Biosafety%20to%20the%20Convention%20on%20Biological,diversity%2C%20taking%20also%20into%20account.

[36] Manish Shukla, Khair Tuwair Al-Busaidi, Mala Trivedi & Rajesh K. Tiwari, Status of research, regulations and challenges for genetically modified crops in India, 9(4) GM Crops & Food 173-188(2018),https://doi.org/10.1080/21645698.2018.1529518

[37] CHAUDHARY, O.P. & CHAND, R., *supra* note 13.

[38] Rajya Sabha Secretariat, *Three Hundred First Report "Genetically Modified Crops and Its Impact on Environment"*, Parliament of India Rajya Sabha (oct.18, 2020, 10:04 AM) http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%20on%20S%20and%20T,%20Env.%20and%20Forests/301.pdf.

was due to the introduction of Bt cotton. However, on the contrary, the substantial increase in the production of cotton is a result of more areas being harvested for cotton cultivation, fertile areas, and a significant increase in irrigation[39]. Further, the committee also found that even though in the initial stage of cultivating Bt cotton, when it was covering only 12% of the total cotton produce, there was a reported decrease in the pesticide use and infestation of boll worms in 2012. But as the produce share of bt cotton grew to 95% by 2015, a new sucking pest called pink boll worm was discovered that was resistant to Bt cotton and again the use of pesticides increased rapidly.[40]

Second, the 'killing trait' introduced in GM crops is concerning as it has the ability to destroy biodiversity.[41] Like the illegal cultivation of HT (Bt) cotton in India, the district authorities are unable to control the production of Ht cotton also known as Herbicide-tolerant Bt (HT (Bt)) Cotton.[42] As herbicide is a poison which is sprayed as pesticide to kill unwanted vegetation but when subjected to over use can kill cotton plant too. Ht(Bt) cotton is not approved by GEAC, still farmers are preferring Ht(Bt) cotton as it would be herbicide resistant and would act like an 'ingrown pesticide'. However, on the contrary it would also act as a killing machine for significant insect, pollinators, birds, and unsuspecting animals (non-target organisms) who might get poisoned on consumption of Ht(Bt) cotton.[43]

Third, the strict scrutiny assessment laid down in various rules and authorities falls short in the very basic system of data collection. According to the standing committee, the existing systems like Assessment of Food/Feed and Environmental Safety (AFES)[44] of GM crop along with other environmental assessment procedure do not directly collect the data from independent agencies rather the assessment is predominantly based on the information provided by the applicant himself.[45] Furthermore, the claims over the safe consumption of GM crops for humans and their ecological sustainability are based on secondary data

[39] Rajya Sabha Secretariat ,*Three Hundred First Report "Genetically Modified Crops And Its Impact On Environment"*, Parliament Of India Rajya Sabha (oct.18, 2020, 10:04 AM) http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%20on%20S%20and%20T,%20Env.%20and%20Forests/301.pdf.
[40] Supra 31.
[41] Timothy Leslie and Randa Jabbour, Genetically Modified Crops and Biological Conservation on Farmlands, American Museum of Natural History, (oct.18, 2020, 10:04 AM)https://www.amnh.org/research/center-for-biodiversity-conservation/resources-and-publications/lessons-in-conservation/volume-9
[42] CHAUDHARY, O.P. & CHAND, R., *supra* note 13.
[43] Sukhbir Siwach, *Explained: The GM cotton conundrum*, Indian Express Limited (oct.18, 2020, 10:04 AM), https://indianexpress.com/article/explained/explained-the-gm-ht-bt-cotton-conundrum-5823356/.
[44] The Centre for Genetic Manipulation of Crop Plants (CGMCP), Assessment of Food/Feed and Environmental Safety of GE Mustard, India Environment Portal,(oct.18, 2020, 10:04 AM),http://www.indiaenvironmentportal.org.in/files/file/genetically%20engineered%20mustard.pdf
[45] Rajya Sabha Secretariat, *Three Hundred First Report "Genetically Modified Crops And Its Impact On Environment"*, Parliament Of India Rajya Sabha (oct.18, 2020, 10:04 AM) http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%20on%20S%20and%20T,%20Env.%20and%20Forests/301.pdf.

provided by the Agri-biotech companies.[46] These secondary data can be subject to bias and manipulations by Agri-biotech companies.[47] Hence, the absence of independent long-term scientific studies projects the baseless claim of the government regarding the safety of GM crops. Independent scientific studies have shown possible health effects on animals. These studies showed that when rats were exposed to such transgenic potatoes or soya suffered abnormal young sperm. Whereas in cows, buffalo, goats, pigs, grazing on Bt-maize or modified cottonseed and corn showed complications including early deliveries, infertility, abortions.[48]

Moreover, when it comes to the notion of growing resistance, if boll worms can grow resistance to evolve into pink boll warms, so can humans. GM crops induced with antibiotic resistance can trigger allergies as well as resistance to antibiotic medications. Transgenic crops such as GM potato being one of the many modified crops, tested under confined field trials, is supposed to be packed with 60% more protein and fungal resistance, hence can adversely affect human health.[49] GM potato tested in India is alleged to cause antibiotic resistance when consumed by animals and humans.[50] Antibiotics are the most common medications prescribed for treating and preventing bacterial infections and the antibiotic resistance causes the bacteria to change the response towards the antibiotic medications (develop resistance).[51] According to WHO, antibiotic resistance is one of the leading threats for global health and food security.[52] Thus the whole notion of GMO being safe and promoting food security falls into a pit of confusion and contradictions as noted by the parliamentary standing committee on science & technology, environment & forests in its 301th report,[53] according to the committee:

"*In view of the above, the Committee is at a loss to understand as to why the Government is pushing for GM crops without even having thoroughly assessed its environmental impacts, even when the desired result of increased productivity could be achieved through our own traditional methods of farming and the long term benefits of GM crops were under a doubt*".[54]

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[46] Rajya Sabha Secretariat, *Three Hundred First Report "Genetically Modified Crops and Its Impact on Environment"*, Parliament of India Rajya Sabha (oct.18, 2020, 10:04 AM) http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%20on%20S%20and%20T,%20Env.%20and%20Forests/301.pdf.

[47] *Id.*

[48] Behrokh Mohajer Maghari, Ali M. Ardekani, *Genetically Modified Foods and Social Concerns*, 3(3) Avicenna J Med Biotechnol 109–117 (2011).

[49] Vibha Ahuja, *Regulation of emerging gene technologies in India*, 12 a BMC Proceedings (2018).

[50] Ritu Mathur, *Genetic Engineering and Biosafety in the use of Genetically Modified Foods*, 1 IJASRM (2018).http://ijasrm.com/wp-content/uploads/2018/02/IJASRM_V3S1_438_76_82.pdf.

[51]WHO, *Antibiotic resistance*, World Health Organization (oct.18, 2020, 10:04 AM) https://www.who.int/news-room/fact-sheets/detail/antibiotic-resistance.

[52] *Supra* note 42.

[53] Rajya Sabha Secretariat ,*Three Hundred First Report "Genetically Modified Crops And Its Impact On Environment "* , Parliament Of India Rajya Sabha (oct.18, 2020, 10:04 AM) http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%20on%20S%20and%20T,%20Env.%20and%20Forests/301.pdf.

[54] Rajya Sabha Secretariat ,*Three Hundred First Report "Genetically Modified Crops And Its Impact On Environment"*, Parliament Of India Rajya Sabha (oct.18, 2020, 10:04 AM)http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%20on%20S%20and%20T,%20Env.%20and%20Forests/301.pdf.

### 2.2 *Legal Conundrum*

There is no specific legislation that deals with the regulation of GMOs as a whole. But there are statutes such as the Biological diversity Act, 2002, which deals with the issues related to sustainability, conservation of biological resources like genes, and benefit-sharing to produce improvised crops.[55] Whereas, Food Safety and Standards Act, 2006, regulates the distribution, storage, sale, and import of genetically modified food.[56] But there are no operational provisions in these acts which specifically counters issues related to GMOs and their illegal use.[57]

The Rules for Manufacture, Use, Import, Export and Storage of Hazardous Micro-Organisms/Genetically Engineered Organisms or Cells Rules, 1989 (Rules of 1989),[58] do not resolve the underlying problem of possible environmental degradation and human health.[59] The 1989 rules provides biosafety standards and punitive actions for non-compliance but still fails to include vital legal notions such as the polluter's pay and the precautionary principle.[60]

The precautionary principle is well-recognized under Principle 15 of the Rio Declaration on Environment and Development.[61] It is also one of the objectives under Article 2(2) of the Cartagena protocol.[62]

The principle states that Government agencies must analyse and assess the risks related to handling, transportation, and modern biotechnology[63] in the environment. It also puts the onus of liability on the developer, mandating the Government to undergo critical risk

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[55] Ministry of Environment and Forests, *The Biological Diversity Act, 2002*, INDIA CODE,(oct.18, 2020, 10:04 AM) https://www.indiacode.nic.in/bitstream/123456789/2046/1/200318.pdf

[56] Ministry Of Law And Justice, *Food Safety and Standards Act, 2006*, FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA, (oct.18, 2020, 10:04 AM) https://fssai.gov.in/cms/food-safety-and-standards-act-2006.php

[57] The Ministry of Environment, Forest and Climate Change, *regulatory framework for genetically engineered (GE) in India*, GEAC, (oct.18, 2020, 10:04 AM) plantshttp://www.geacindia.gov.in/resource-documents/13_2-Regulatory_Framework_for_GE_Plants_in_India.pdf

[58] Ministry Of Environment & Forests, *The Manufacture, Use, Import, Export And Storage Of Hazardous Micro-Organisms Genetically Engineered Organisms Or Cells Rules, 1989*, National Biodiversity Authority (oct.18, 2020,10:04AM), http://nbaindia.org/uploaded/Biodiversityindia/Legal/28.%20Rules%20for%20the%20manufacture,%20use%20import%20export%20and%20storage%20of%20hazardous%20microorganism%20genetically%20engineered%20organisms%20or%20cells,%201989.pdf

[59] Bhuvan Bhaskar Jha & Ashutosh Shankar, *Evaluating The Law On Regulation Of Genetically Modified Crops In India*, MANUPATRA(oct.18, 2020, 10:04 AM) http://docs.manupatra.in/newsline/articles/Upload/F622B184-AACE-4235-9188-00A4C07AD9DD.%20Bhuvan%20Bhaskar%20Jha%20&%20Ashutosh%20Shankar__Civil.pdf

[60] *supra* note 36.

[61] Secretariat of the Convention on Biological Diversity , Rio Declaration on Environment and Development , the Convention on Biological Diversity(oct.18, 2020, 10:04 AM),https://www.cbd.int/doc/ref/rio-declaration.shtml

[62] *Id.*

[63] V. Venkatesan, Legal Struggle, The Frontline, (oct.18, 2020, 10:04 AM),https://frontline.thehindu.com/cover-story/article30179446.ece

assessments to warn the potential victims.[64] This principle has been recognized in various cases like the Taj Trapezium case[65] and Calcutta canneries case.[66]

Moreover, under article 10(6), the protocol mandates the responsible governmental agencies to endure scientific certainty, information, and knowledge to minimize risk.[67] Furthermore, under article 21, the protocol suggests that the summary risk assessments should not be confidential and readily available to the general public.[68]

Another vital concept called the 'polluters pays' principle has also been incorporated under the Cartagena protocol.[69] It recommends rectifying the environmental damage that occurred at the source while holding the polluter responsible for the damage.[70] The principle puts the burden of liability on the producer of the harmful substance.[71]

These principles can be associated with section 15 of the Environment Protection Act,[72] 1986. Under section 15, the central government, authorized officer, or a person after 60 days' notice to central government or authorized officer can register a complaint against any developer acting in contravention to the provisions of the act.[73]

Apart from EPA, under the 1989 rules, genetically modified organisms or products are only classified into appropriate schedules based on their risk intensity.[74] However, there are competent authorities available to deal with risk assessment[75] but the existing legislations or rules, such as EPA or 1989 rules do not adequately fulfil the requirements of the protocol.

In January 2004, a PIL by Gene campaign,[76] an advocacy and research organization dedicated towards food and livelihood safety,[77] asked for the reconstruction of the GM

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[64] MINISTRY OF LAW AND JUSTICE, *supra* note 56.
[65] Mc Mehta v. Union of India, AIR 1997 SC 734.
[66] Mc Mehta v. Union of India AIR 1997 2 SC 411430.
[67] Secretariat of the Convention on Biological Diversity, Cartagena Protocol On Biosafety To The Convention On Biological Diversity, the Convention on Biological Diversity (oct.18, 2020, 10:04 AM) https://www.cbd.int/doc/legal/cartagena-protocol-en.pdf
[68] *Id*.
[69] Executive Secretary of Cartagena Protocol On Biosafety To The Convention On Biological Diversity, *Cartagena Protocol On Biosafety Summary Of Submissions By Parties Received By The Executive Secretary On Liability And Redress, Convention On Biological Diversity* (oct.18, 2020, 10:04 AM),https://www.cbd.int/doc/meetings/lr/eglr-01/information/eglr-01-inf-03-en.pdf
[70] *Id*.
[71] The Organisation for Economic Co-operation and Development (OECD), ENVIRONMENTAL PRINCIPES AND CONCEPTS, OECD (oct.18, 2020, 10:04 AM) https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=OCDE/GD%2895%29124&docLanguage=En
[72] The Environment (protection) Act 1986 s.15.
[73] The Environment (protection) Act 1986 S. 15.
[74] Ministry Of Environment And Forestry, Rules For The Manufacture, Use, Import, Export And Storage Of Hazardous Micro Organisms, Genetically Engineered Organisms Or Cells, Indian Council of Agricultural Research Biosafety Portal (oct.18, 2020, 10:04 AM), https://biosafety.icar.gov.in/wp-content/uploads/2015/11/Rules-1989.pdf
[75] *Id*.
[76] Gene Campaign (a Society registered under
The Societies Registration Act, 1860), Writ Petition (CIVIL) NO. 606/2007 ,The Gene Campaign (oct.18, 2020, 10:04 AM),https://genecampaign.org/wp-content/uploads/2014/07/pil-Against-Deregulation-of-GM-Foods.pdf
[77] Gene Campaign (a Society registered under

regime (regulations and related authorities).[78] The PIL incorporate the absence of precautionary principle and polluter's pays principle along with other lacunas in the system.[79] The organization also sent some recommendations to the Department of Biotechnology (DBT) to reconstruct the GM risk assessment system later completely denied by the authority.[80]

A few of the issues which were both addressed in the PIL and the report of the parliamentary standing committee are:-

A. Transparency and possible biases - the Gene campaign suggested that GEAC should be more transparent, competent, and accountable.[81] The campaign stated GEAC's failure to comprehend the effects of using Bt cotton over a long period.[82] Likewise, the GEAC failed to stop the illegal modification and trials of various genetically modified crops such as Ht(bt) cotton.[83] Several states such as Maharashtra and Telangana have reported illegal production GM seeds.[84] The GEAC also lacks transparency while arriving at a decision based on scientific materials.[85] Example, when GEAC decided to allow commercial field trials for (Bt)brinjal which was later sent into the moratorium period by The Ministry of Environment, Forest and Climate(MoEF).[86] Although lack of transparency and competence may lead to harmful effects on human health and the environment, the committee would not be held liable as the 1989 rules are silent about the same.[87] Thus lacks accountability. Moreover, the 1989 rules do not provide for an established procedure to deal with illegal farming, lack of transparency, accountability, and competence of GEAC.[88]
B. Lack of long-term scientific researches - the efficacy of GM crops can be determined by undergoing scientific testing. Such can be duly noticed as scientists are involved panels and boards formed under government agencies. However, a lack of transparency

The Societies Registration Act, 1860), About Us, The Gene Campaign (oct.18, 2020, 10:04 AM),https://genecampaign.org/about-us/

[78]Gene Campaign (a Society registered under The Societies Registration Act, 1860),Gene Campaign for legal action on GMOs , The Gene Campaign (oct.18, 2020, 10:04 AM)https://genecampaign.org/gene-campaigns-legal-actions-on-gmos/

[79] MINISTRY OF LAW AND JUSTICE, *supra* note 56.

[80] *Supra* note 69.

[81] *Supra* note 69.

[82] Journal of Pesticide Reform, Bacillus Thuringiensis (B.T.), ECOLOGICAL AGRICULTURE PROJECTS, (oct.18, 2020, 10:04 AM)https://eap.mcgill.ca/MagRack/JPR/JPR_22.htm

[83] Sukhbir Siwach, *Explained: The GM cotton conundrum*, INDIAN EXPRESS LIMITED (oct.18, 2020, 10:04 AM), https://indianexpress.com/article/explained/explained-the-gm-ht-bt-cotton-conundrum-5823356/.

[84] Anubhuti Vishnoi, Govt advisory on illegal 'Genetically Modified' crops soon, THE ECONOMIC TIMES,(oct.18, 2020, 10:04 AM), https://economictimes.indiatimes.com/news/economy/agriculture/govt-advisory-on-illegal-genetically-modified-crops-soon/articleshow/73346749.cms?from=mdr

[85] Nupur Chowdhury And Nidhi Srivastava, Decision on Bt-Brinjal: Legal Issues, ECONOMIC AND POLITICAL WEEKLY (oct.18, 2020, 10:04 AM), https://www.jstor.org/stable/25664325?seq=1

[86] *Id.*

[87] Supra 66.

[88] *Id.*

poses problems to meet the required international requirements. According to a report published by WHO in 2017, microbial pest control agent Bacillus thuringiensis (Bt) has nominal adverse effect on non-target organisms and humans.[89] However, vegetative Bt or other forms of Bt with Bc-like toxins that may have adverse effects on humans are yet to be known.[90] Another loophole is the use of studies and reports submitted by the developer to the GEAC rather than independent researchers.[91] In the case of Bt brinjal, the committee established by MoEF saw divided opinion of well-known scientists over the nutritional value and effect on biodiversity on the release of Bt brinjal.[92] Later, an expert committee appointed by the Supreme Court of India banned the release of Bt brinjal on account of lack of scientific consensus.[93]

C. Right to be informed- non-confidentiality is a vital principle under Cartagena protocol.[94] Despite that, the governmental agencies are allowing field trials without publishing scientific studies in the public domain.[95] The gene campaign PIL also raises this issue of lack of information and public participation over GM crops.[96] However, steps towards transparency were seen in the case of Bt brinjal, but the same cannot be said about trials of Bt rice and the release of Bt cotton.[97]

D. Lack of liability- The polluters pay principle is adopted since the 1970s by the Organisation for Economic Co-operation and Development (OECD) or OECD countries.[98] However, to relate this principle with agriculture or genetically engineered crops is challenging as it involves farmers as producers.[99] Farmers cannot be held liable for their gullible nature. They may lack intention, can be influenced by companies and, lack finance. Even if farmers are responsible for the possible environmental damage, they cannot pay for the cost of compensation. The scientist or companies involved in GMOs should be held liable if any subsequent danger occurs to the consumption of such certified GMOs. The authority involved in certifying these GMOs should also be held responsible for not taking adequate precautions.

Along with the above-mentioned issues, lack of information about test protocols, independent test laboratories, annual reviews are some of the risks which remain

[89] Environmental Health Criteria 217, Environmental Health Criteria For Bacillus Thuringiensis , World Health Organization (oct.18, 2020, 10:04 AM),,https://www.who.int/ipcs/publications/ehc/en/EHC217.PDF
[90] *Id.*
[91] Supra 56.
[92] Aniket Aga , Serious concerns over Btbrinjal, The Hindu,(oct.18, 2020, 10:04 AM),https://www.thehindu.com/opinion/op-ed/serious-concerns-over-bt-brinjal/article28022577.ece
[93] *Id.*
[94] Supra 62.
[95] Supra 70.
[96] Supra 56.
[97] Supra 77.
[98] Supra 71.
[99] The European Commission, Applicability of the polluter pays and producer responsibility principles in EU environmental law, The European Commission(oct.18, 2020, 10:04 AM)https://ec.europa.eu/environment/legal/law/pdf/principles/4%20Polluter%20pays%20in%20other%20area_revised.pdf

unnoticed.[100] These issues are in violation of not only the Cartegena protocol but also the precautionary principle and 'polluters pays' principle.

### 2.3 *Innovators Concern: IPR and Genetic Engineering*

Revolutionary innovations and the creators contribute immensely towards the model use of technology. Thus, such highly influential discoveries like genetically modified crops entail protection under various intellectual property rights. But the question arises as to what extent the rights of innovators of transgenic crops are protected? Can patents protect the illegal use commercial genetically modified crops?

Intellectual property rights related to genetically engineered crops/ seeds are still unrecognized in the legal system. In 1995, the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), a comprehensive multilateral agreement on intellectual property, was signed by 164 member countries.[101] The TRIPS Agreement sets out minimum standards of protection for its member countries concerning intellectual property including patents.[102] India being a signatory of the TRIPS agreement under Article 27.3b[103] harmonizes with the provisions related to plant variety protection (PVP) through the protection of plant varieties and farmers' rights act, 2001(PVR Act).[104]

PVP is an alternative protection regime to patents specifically designed for agro-biotechnology (crop research and development).[105] India does not provide for patents concerning plant variety.[106] Hence PVR Act plays a significant role in recognizing farmers and plant breeder contributions in the research and modification of commercially available crops.[107]

The PVR Act and subsequent establishment of the PVP regime work towards food security, biotechnological conservation, benefit-sharing, and importance to farmers and plant breeders than commercial breeders involved in industrial use.[108] However, there have been speculations that allowing patents for the transgenic crop has more benefits than following the PVP regime.

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[100] Supra 56.
[101] WTO , Trade-Related Aspects of Intellectual Property Rights , The World Trade Organization (oct.18, 2020, 10:04 AM), https://www.wto.org/english/tratop_e/trips_e/trips_e.htm
[102] WTO , Trade-Related Aspects of Intellectual Property Rights , The World Trade Organization (oct.18, 2020, 10:04 AM), https://www.wto.org/english/tratop_e/trips_e/trips_e.htm
[103] Dr Philippe cullet, radhikakolluru, Plant variety protection and farmers rights, 24 Delhi law review 41 (2002-2003).
[104] https://niti.gov.in/planningcommission.gov.in/docs/reports/sereport/ser/ser_alla.pdfPlanning commission of india, THE HIGH YIELDING VARIETIES PROGRAMME IN INDIA (1970-75) , NITI Aayog, (oct.18, 2020, 10:04 AM), https://niti.gov.in/planningcommission.gov.in/docs/reports/peoreport/cmpdmpeo/volume2/thy.pdf
[105] Dr Philippe cullet, radhikakolluru, Plant variety protection and farmers rights, 24 Delhi law review 41 (2002-2003).
[106] Jan Holthuis and Marc van der Velden, Nusrat Hassan, Plant variety rights versus plant patents: legal developments and frictions in a regional perspective, 20(2) BUSINESS LAW INTERNATIONAL 91-190 (2019)
[107] *Id.*
[108] Supra 103

The PVR act has its shortcomings, like the benefit-sharing regime. The benefit-sharing[109] under the act provides that individuals, organizations even, villages, and the local community can send claims over a protected variety.[110] Such a program can more likely spread the initial research in the public domain which may be illegally appropriated. Moreover, the claimed right should be in respect of a registered '*variety*'.[111] If a *'variety'* is not registered then any person can use the initial research to develop a newer *'variety'*.[112] Second, the criteria for registering the *'variety'* adopted from the UPOV Convention under the act does not provide any alternative criteria.[113] Hence this makes it extremely difficult for the farmers to register the *'variety'*.[114] As a result, even with the highest number of farmer's variety applications the number of certifications so granted is less.[115]

Patent systems are the most preferred form of protection used by genetic engineering companies for commercial use.[116] The patent provides exclusive rights over the engineered material and prevents knowledge exposure in the public domain.[117] Thus these exclusive rights over the knowledge of the 'engineered material' and subsequent confidentiality may prevent illegal use and duplicity by the general public.[118] Hence this may curb illegal production of genetically modified crops as the information would not be available for possible reverse engineering.[119] However, the plant patent system will create a monopoly having moral and ethical consequences.[120]

Even though the patenting system can provide more commercial success, confidentiality, and better protection to the innovator's rights. Whether or not it is better than the PVP regime and protects from the illegal use of GMOs is not apparent.

## GENOME EDITING: THE MANIPULATION OF GENES BY SCIENCE IN HUMANS

Louise Brown, the first woman to be born with IVF technique in the year 1978 stumped the world as it was the most remarkable breakthrough of the 20th century. Now, the world is

[109] The Protection of Plant Varieties and Farmers' Rights Act, 2001 S 26.
[110] Supra 102.
[111] M. Lakshmikumaran, Innovation, Economic Development, and Intellectual Property in India and China. ARCIALA Series on Intellectual Assets and Law in Asia 367-386 (Liu KC. Racherla U. Ed. Springer, Singapore 2019).
[112] *Id.*
[113] Supra 102.
[114] *Id.*
[115] Supra103.
[116] National Research Council (US) Board on Agriculture., Genetic Engineering of Plants: Agricultural Research Opportunities and Policy Concerns, NCBI, (oct.18, 2020, 10:04 AM)https://www.ncbi.nlm.nih.gov/books/NBK216400/
[117] *Id.*
[118] Supra102.
[119] Supra113.
[120] Archana K, Do We Need Patent Protection to Biotechnology Inventions?, 3(2) International Journal of Scientific and Research Publications (2013).

again grappling to accept the scientific innovation of 'genome editing" which alters the genes to get the desired traits of the human baby.

The discovery of DNA, enabled the scientist to deliberately intervene in the selected genome for extracting desired human traits in order to arrange them in future children.[121]

The fundamental reason of discovering such a novel technique was to harness the potential of science to remove human illness. As the genes are responsible for transferring genetic disorders, genetic engineering is expected to be a panacea for all patients. Scientists all over the world are improving the existing technologies and developing safer products for curing genetic disorders in humans.

It is further characterized, based on two gene therapies, one germanile therapy and the other, somatic therapy. The germanile therapy has the power to alter the DNA which passes to the future generation while the somatic therapy targets the non- reproductive cells which affects only the recipient of the therapy. Like in 2015, the scientists cured a one year old name Layla to fight her leukaemia by using the somatic therapy known as the "TALENs".[122] However, these techniques are still surrounded by ethical concerns.

1. **Deeper Look Into the Technique: CRISPR**

Since the late 2000s, the scientists have kept themselves busy with the "genome editing". Now, the focus of research has shifted from correcting the genetic disorders to treating the multiple disorders efficiently in the clinics. The scientist's aim was to formulate a method using this technique to grant "powers" to an individual by altering its DNA to improve his quality of life, and provide the requisite platform to the genetically modified human beings.[123]

Thus development of "CRISPR", short for "Clustered Regularly Interspaced Short Palindromic Repeats", acted like molecular scissors, has taken the field of science by surprise as it is was inspired by the method used by bacteria to protect itself against viruses.[124]

The dawn of the most remarkable technique, CRISPR has widened the horizon when it comes to the scope of genetic engineering field. CRISPR has revolutionized genetic manipulation as it is simpler, faster, cheaper, accessible and efficient than the other genome editing techniques.[125] The experiments done on mice, have soon been developed into diverse

[121] Karen Yeung, *Genome Editing and Human Reproduction*, NUFFIELD COUNCIL ON BIOETHICS (oct.18, 2020, 10:04 AM), Genome-editing-and-human-reproduction-FINAL-website%20(2).pdf.
[122] TALEN And CRISPR/Cas Genome Editing Systems: Tools of Discovery, natural bacterial tale and crispr/cas systems as the basis for the development of new tools for eukaryotic genome editing, (Oct 182020)Https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4207558/
[123] Supra 52
[124] Personal genetic education project, *genetic modification, genome editing and crisper*, Personal genetic education project (oct.18, 2020, 10:04 AM), https://pged.org/genetic-modification-genome-editing-and-crispr/#.
[125] *Id*.

fields of biology and humans. With its rapid development the scientists are keen to apply this technique without defining its bounds.

### 1.1 *Putting CRISPR to Work: The Process*

The two components to the CRISPR system are: a molecule known as a "guide RNA" (gRNA), which has the exact same sequence as the target site in the genome; and a "nuclease" (i.e., a DNA-cutting molecule) called Cas9.[126]

The crispr-cas9 technique which has the power to target the entire genetic code or alter the DNA, which behaves like a molecular scissors to cut paste on DNA strands containing the genetic information. After identifying the specific location on the DNA strand which has to be edited the cas9 protein cuts off the location from the strand. Once the DNA is cut, researchers use the cell's own DNA repair machinery to add or remove pieces of genetic material or modify the DNA by substituting an existing segment with a customized DNA sequence.[127]

In other words, the cas9 protein forms a complex with gRNA in the cell; the complex then attaches to the similar genomic DNA sequence; the Cas9 cuts the double strands of the DNA and then the programmed or the edited DNA is inserted into the cells.

### 1.2 *Benefits of CRISPR*

#### 1.2.1 Enhancing the Immune System

The mandate of this novel method concerns to formulate a formidable immune system for the patients who have undergone transplants as the transplanting cells are perceived as foreign to the body and in response, the immune cells reject the transplant cells leaving the body affected.

When the results of IPSC (induced pluripotent stem cell)[128] did not impede the stem cells to reject the cells during transplantation, scientists resorted to CRISPR technology. They created a universal iPSC, using CRISPR/Cas9 genome editing to alter three genes and make the cells 'invisible' to the immune system.[129] By transplanting human iPSCs into humanized mice, the researchers found that the cells did not evoke any form of immune response and were able to evade the radar of the immune system.[130] It was concluded that this was the world's first universal cell which was engineered using CRISPR technique to eradicate the problem of stem cell rejection, marking it as an achievement in the field of stem cell therapy.

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[126] Supra 53
[127] Supra 52.
[128] University of California, *Induced Pluripotent Stem Cells (iPS)*, UCLA Broad Centre of Regenerative Medicine & Stem Cell Research(oct.18, 2020, 10:04 AM), https://stemcell.ucla.edu/induced-pluripotent-stem-cells.
[129] Jenny Straiton, *Genetically modified humans: the X-Men of scientific research*, 66(6) BIOTECHNIQUES (2019).
[130] Tobias Deuse, Xiaomeng Hu, *Hypoimmunogenic derivatives of induced pluripotent stem cells evade immune rejection in fully immunocompetent allogeneic recipients*,37 Nature Biotechnology 252–258(2019).

The scientist now aimed at producing a technique coupled with advances in 3D printing of organs to apply CRISPR technique which may result in an 'invisible' kidney, lung or heart.[131]

### 1.2.2 HIV Resistant

Dr. He Jiankui, the brain behind this technology revealed to the world that the premature twin daughters, the world's first known gene-edited human babies have been born by altering their embryos to make them resistant to their father's HIV infection. The reason for the doctor to develop a HIV resistant gene by mutation instead of developing a technique of editing a gene which could offer protection from familial hypercholesterolemia, was the injustice done to the HIV positive parents who were barred from getting fertility treatment in China.[132]

He stated, "Gene surgery is another IVF advancement" and granted a ray of hope for the parents who cannot conceive, and therefore "need this technology". He collected the non-viable embryos from the IVF clinics, then injected the cas9 on the HBB gene which causes thalassemia, and cut out the disease causing region. The twins born showed satisfactory results, one of them showed that her DNA was successfully edited while the other was partially edited, making it unclear whether it would resist HIV.[133] He highlighted that this technique is used for healing, enhances the memory and the learning power of the genetically edited baby.

However, after this, the doctor did not receive the intended reaction, but was called as selfish and fame driven, with the Centre for Genetics and Society (CA, USA) labelling it as the work of "a grave abuse of human rights".[134] This further a attracted profound question on the ethics of this technique. It was not welcomed and condemned for altering the embryos, as these genes would be transferred to the future generation posing risk to their life and side-lining the humans who are already suffering from the disabilities.

## 2. **Guidelines for Ethical Concerns of Genome Editing**

Genetic engineering has exalted the status of a novel technology, it has to face the slings and arrows of ethics. Different countries have different approaches towards its legality and have

[131] Jenny Straiton, *Genetically modified humans: the X-Men of scientific research*, 66(6) BIOTECHNIQUES (2019).
[132] Preetika Rana, *How a Chinese Scientist Broke the Rules to Create the First Gene-Edited Babies*, Wall Street Journal (oct.18, 2020, 10:04 AM), https://www.wsj.com/articles/how-a-chinese-scientist-broke-the-rules-to-create-the-first-gene-edited-babies-11557506697.
[133] Preetika Rana, *How a Chinese Scientist Broke the Rules to Create the First Gene-Edited Babies*, Wall Street Journal (oct.18, 2020, 10:04 AM), https://www.wsj.com/articles/how-a-chinese-scientist-broke-the-rules-to-create-the-first-gene-edited-babies-11557506697.
[134] Supra 60.

issued various ethical guidelines for the same. Based on concerns about ethics and safety, germline cell and embryo genome editing are illegal in many countries.[135]

### 2.1 *International Initiatives and Guidelines*

Though the new biomedical tools have brought in excitement in the scientific community by making it achievable to change the DNA sequence of living organisms, the question of ethics worry the scientists of the technology which was developed with ease and precision.

The prime concern is the "off target editing" of any gene as it can impair the cognitive functions and may not prove to be effective if used for the enhancement purposes. The researchers further worry about obtaining the consent from the prospective parents when the risks of this technology are unknown. With the onset of such a vehement technique, the class distinction is sure to exist, as, the wealthy people will be able to access it formerly and the disparities between the non-treated patients will prevail.[136] As a result to counter the prevailing issues many initiates have been taken.

The International Hap Map (short for "haplotype map) Project is a scientific effort to identify common genetic variations among people. The collected data helps the scientists and the researchers to find the genetic differences and their response to medicines and the environmental factors. The genetic variants which are known as SNPS, represents the variations in person's DNA. As it would be time consuming and expensive for the researchers to indulge in initial research to determine such variants.[137] Thus it can provide more accessibility among desired parents due to cost cut in the initial research.

The U.S. National Academy of Sciences, the U.S. National Academy of Medicine, the Royal Society, and the Chinese Academy of Sciences hosted an international summit in December 2015 to answer the governance issues associated with human gene editing. The report titled "Human Genome Editing: Science, Ethics, and Governance" was published in 2017 which stated the minutes of the summit. It highlighted that the present legislations to regulate the usage of genome editing suffers from safety, technical, and ethical barriers. The report concluded that the gene therapy trials should be limited to the practice of treating disease or disability, and also the public participation be given paramount stature in the enhancement of this technology.

China hasn't devised a law pertaining to this technique but in 2003, it stated that genetic manipulation of human gametes, zygotes and embryos for reproductive purposes is prohibited. While the 2017 report from the USA National Academies of Sciences, Engineering and Medicine didn't ban this technique but restricted its usage to medical reasons in the absence of reasonable alternatives, and with maximum transparency and strict over sight.[138]

[135] Supra 53
[136] Supra 53.
[137] Supra 52.
[138] Supra 60.

### 2.2 *India and Ethics*

The Indian Council of Medical Research (ICMR), a government organization, in the National Ethical Guidelines for Biomedical and Health Research involving human participants has stated that Technology should not be exploited for pre-implantation genetic screening, creation of designer babies, sex selection, etc.[139]

The changes in genome editing are limited to somatic cells which don't get passed to the next generation but affects certain tissues. However, the changes made to genes in eggs or sperms known as the germline cells have the possibility of being passed to the future generations which is considered to be unethical as it will promote class distinction amongst the babies with deformities.[140] Enhancing the normal traits and perfecting the baby with desired result attracts the question of safety, justice and equity etc.

Though, the field of stem cells has taken a big leap globally in the study of biomedical researches. The unscientific and unethical stem cell therapy has posed a threat to the well-being of vulnerable individuals. In lieu of the above statement, the National Guidelines for Stem Cell research were issued.

As per the guidelines, stem cell used in patients could only be done under the purview of a monitored clinical trial with the intent to advance science and medicine, and not for any therapy. With this stringent rule, use of stem cells in patients outside an approved clinical trial would be considered as unethical and a malpractice.[141]

Moreover, the guidelines have also highlighted the prohibitive areas of stem cell research.[142] The restricted areas are research related to human germ line gene therapy and reproductive cloning,[143] in vitro culture of intact human embryos,[144] use of genome modified human embryos, germ-line stem cells or gametes for developmental propagation[145] and breeding of animals in which any type of human stem cells have been introduced at any stage of

[139] Dr. Roli Mathur, handbook on national ethical guidelines for biomedical and health research involving human participants, Indian council of medical research(Oct.25, 2020),https://naitik.gov.in/DHR/resources/app_srv/DHR/global/pdf/downloads/Handbook_on_ICMR_Ethical_Guidelines.pdf
[140] Supra 52.
[141] Dr. Geeta Jotwani, National Guidelines For Stem Cell Research , Indian Council of Medical Research & Department of Biotechnology, (oct.18, 2020, 10:04 AM), http://dbtindia.gov.in/sites/default/files/National_Guidelines_StemCellResearch-2017.pdf
[142] Prohibited Areas of Research of Guidelines, National Guidelines For Stem Cell Research , Indian Council of Medical Research & Department of Biotechnology, (oct.18, 2020, 10:04 AM), http://dbtindia.gov.in/sites/default/files/National_Guidelines_StemCellResearch-2017.pdf
[143] Prohibited Areas of Research of Guidelines, National Guidelines For Stem Cell Research , Indian Council of Medical Research & Department of Biotechnology, (October 25, 2020), http://dbtindia.gov.in/sites/default/files/National_Guidelines_StemCellResearch-2017.pdf
[144] Supra 70.
[145] Supra 70.

development.[146] Therefore, the genome editing technology must go through a rigorous scrutiny to let the future generation reap the benefits.[147]

## CONCLUSION

Does the efficacious nature of genetic engineering override its cynical effects?

With countries like USA spending about 518 million dollars towards research related to genetic engineering,[148] there is absolutely no denial that we are experiencing the outbreak of biotechnology where different countries have made their attempt to answer the above question. Though India has succeeded in developing few regulations and legislations such as Environment Protection Act, 1986, the GEAC and 1989 rules, it still falls short on transparency, efficient implementation and conducting long -term scientific researches.

The USA and Japan focus more on the initial research and analysis as compared to India. Japan has a risk-level based system developed, wherein it first determines the level of risk i.e. high, medium or low to regulate them accordingly. Whereas USA involves ab initio based approach where it runs the test or trials on equal risk basis.[149]

The USA Japan and EU involved themselves into the public consultation scheme, making them aware about the pros and cons of the GMOs. In USA, the National Environmental Policy Act 1970, provides for accurate scientific analysis, expert agency comments, and public scrutiny over the major decisions of the federal government over projects involving question of environment.[150] Other countries like Canada formed a royal commission on latest reproductive technological initiative, which travelled the country holding public hearings.[151] European Union (EU) provides for a detailed procedure for public consultation. It is more inclined towards genetically modified crops by encouraging public domains to provide information on subsequent products that can effects biodiversity.[152] They alter government's decisions through public scrutiny and exert pressure on the government to ensure adequate environmental assessment. In the end alternatives such as public consultation would ensure proper scrutiny and scientific based risk recognition systems would benefit in terms of GMOs. Though genetic engineering has widened the scope of the scientific field, it still raises profound questions on the unintended consequences of this technology. Tampering with the genetic code in human beings has been regarded as the

[146] Supra 70.
[147] Roli Mathur, *Ethical Considerations in Human Genome Editing–An Indian Perspective*, 20(2) ASIAN BIOTECHNOLGY AND DEVELOPMENT REVIEW 47 (2016).
[148] Jennifer Reineke Pohlhaus, "*Robert M Cook-Deegan, Genomics Research: World Survey of Public Funding*", 9 BMC Genomics 472 (2009).
[149] National Academies of Sciences, Engineering, and Medicine, COMMITTEE ON HUMAN GENE EDITING: SCIENTIFIC, MEDICAL, AND ETHICAL CONSIDERATIONS, PubMed (oct.18, 2020) https://pubmed.ncbi.nlm.nih.gov/28796468/
[150] Council on Environmental Quality Executive Office of the President, Protection of Environment, NATIONAL ENVIRONMENTAL POLICY ACT (NEPA) (October 18, 2020), https://www.usbr.gov/gp/nepa/cip/nepa.pdf
[151] Stu Marvel, "*Laws of Conception: A Queer Genealogy of Canada's Assisted Human Reproduction* Act", 12 FIU LAW. REV. 81 (2016).
[152] Supra 76.

most contentious issue. The editing done by this technique is irreversible, unsafe and unethical. Hence, the Indian legislators shall formulate such rules and regulations which supervises its usage and consists of a clause to penalise the defaulter. India can also learn from countries like USA, Japan, and EU about high public scrutiny schemes and risk based scientific approach towards GMOs. Moreover, the off target editing or the mutation elsewhere shows that the edited cells might trigger cancer, or disrupt the genes and impair their functions. Hence, the application so formulated should outweigh the risks.

From gene editing of babies to gene modification of crops, promotion and acceptance of technology without conclusive scientific results would only cease the natural process of evolution. As said according to Darryl R.J. Macer in his book Shaping Genes: Ethics, Law and Science of Using Genetic Technology in Medicine and Agriculture, "*it has been claimed that genetic engineering is like a nuclear science, as both confer a power on humans for which they are not psychologically and morally ready*".[153] Thus, a risk benefit analysis of Genetic Engineering should be done.

## CONFLICT OF INTEREST

The author declare that the research work does not have any conflict of interest and the was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

[153] Macer, D. R. J., SHAPING GENES; ETHICS, LAW AND SCIENCE OF USING GENETIC TECHNOLOGY IN MEDICINE AND AGRICULTURE (1ed. Eubios Ethics Institute 1990).