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GENETIC ENGINEERING TECHNOLOGY - A BRIEF LEGAL PROBE, NATIONALLY AND INTERNATIONALLY

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Abstract

This paper discusses the legal, environmental, and ethical dilemmas involved with genetic engineering technology. This paper aims to shed light upon the various regulations and guidelines governing genetic engineering and scientific experimentation on plants and animals, which also talks about certain ethical issues arising from genetic engineering and scientific experiments. This paper further talks about the institutes and statutes which help to regulate and govern these practices. This paper looks into the regulations imposed on genetic engineering that vary widely and compares the efficacies of these regulations in different countries. It also tries to compare the international regulations and guidelines(mostly UK and US) with those, which are in existence in India. The paper also deals with the legalities of the human geneline modification scene.It briefly talks about the role of different regulatory statutes present in India and how they collaborate to develop a controlled environment that aids and promotes research and tries to regulate and penalize any unethical and unnatural experiments. The paper also talks about the negative implications of this technology and animal experimentation on the environment and concludes on the author's thoughts about the future of the field.

Key Words:- Animal Experimentation, Genetically Modified Organisms, Genetic Engineering, Genetic Modification, International Guidelines Recombinant DNA (rDNA), Regulations

Introduction

Genetic engineering is the manipulation of an organism's genes using biotechnology.It involves modifying genetic make up of cells , including the transfer of genes within and across species boundaries to produce improved and novel organisms.Since genetic engineering forms an important part of our lives it is essential that we have proper regulationsin place to prevent the misuse of such technology and as genetic engineering achieves new feet it is ever the more required that we have proper regulations and institutions to govern it.

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And also the fact that there is cruel experimentation on animals. These laws prevent suchatrocities and try to punish and prevent such experimentation.

History of Genetic Engineering:

Gene Editing has a rather vast history, which I tried to touch on lines, through this article.While having to comply with strict laws, this industry indeed has grown from doublehelix to the invention of CRISPR.The history of Genetic Engineering, beings only in 1950s,which is rather recent, which happened, thanks to the discovery of the current day term 'double helix' which refers to the very shape/structure of DNA.This was a result from the strenuous work from 3 professors, who laid foundation for even modern day understanding ofgenes.In the late 1950s, Arthur Kornberg, a nobel prize awardee for his work in the field of Genetic Engineering, achieved another milestone in this field, by actually managing to createDNA in a test tube.The 1960s, mostly was an experimentation period, with whatever information, the 1950s provided to these engineers.The 1960s had little to very few discoveries A sudden boom is experienced in 1970s, where successful cloning of DNA is firstdone in 1972.The 1980s was probably the second most crucial phase, as genetic engineering was for the first time, being directly/indirectly put to use for the public.The first 'transgenic' animal was created, when a mouse was induced with the DNA of a rabbit.However, where the genetic engineering technology came to public's aid, was in the form of vaccines and medicines, with synthetic Insulin being one of the first drugs of this kind.It is in 1896, where for the first time, a vaccine for humans, that owes its creation to genetic engineering is approved.As mentioned earlier, with 1980s being the second most crucial phase, the first place is bagged by 1990s, especially with the discovery of CRISPR in 1993.CRISPR stands for Clustered Regularly interspaced palindromic repeats. In simplest words, CRISPR is a technology that is a driving force behind today's genetic engineering field and is capable of gene modification.Post, the invention of CRISPR technology, the genetic field has made huge advancements, being able to make GMO(Genetic Modified Organisms), with the field of agriculture and food, being the most privileged.

I. Indian Scenario

The regulatory framework to biosafety in India contains primarily of biosafety rules and guidelines, the central legislative authority with regard to biosafety guidelines is arguably The Environment Protection Act (1986), the Sections 6,8 and 15 jointly form the preamble through

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which all the biosafety regulations are formed in India.[1] India has always had a structured and systematic regulatory framework for genetic engineering evaluation. India wasone of the first countries to have a proper legal framework for the same purpose back in 1989,i.e., the "Rules for manufacture, use/import/export & storage of hazardous microorganisms/genetically engineered organisms or cells, 1989"[2], implemented by the Ministry of Environment, Forest, and Climate Change. They cover all the activities and by-products involved in genetically modified organisms (GMO's) under sections 8 and 25; this includes the new gene technologies. This Act also laid down several provisions to create few competent authorities implemented by the Ministry of Environment, Forest and Climate Change. The National Biodiversity Authority implemented the Biological Diversity Act,2002, and it aims to regulate the methodology of genetic intervention for improving livestockand crops.

In India, specific rules regulate Genetically Modified Organisms or GMOs; notified under the Environmental Protection Act, 1986. The specific Rules are "Rules for the manufacture, use, import, export, and storage of hazardous microorganisms, genetically engineered organismsor cells," 1989. Various authorities such as the Ministry of Environment, Forestry andClimate Change, the Department of Biotechnology, and the State Governments are responsible for implementing the said Rules.

India is a member of the Cartagena Protocol on Biosafety (CPB). However, our national legislation has yet to include the CPB's newly revised definition of genetic engineering. When it comes to legislating new rules in India, it looks towards other countries and how they are dealing with new technologies to understand better and implement the same. These observations are backed by constant research by leading institutes.

Per the Rules, 1989, the Ministry of Environment, Forestry, and Climate Change (MoEFCC) exercises its authority under Sections 8 and 25 of the Environment (Protection) Act, 1986, which talked about "Regulation of Genome Technologies in India" notified the issuance ofthe Rules 1989 which tends to cover the whole array of technologies related to genetic engineering, manufacturing and use of GMOs. Six competent authorities govern the implementation of these

[1] Bhuvan Bhaskar Jha & Ashutosh Shankar, EVALUATING THE LAW ON REGULATION OF GENETICALLY MODIFIED CROPS IN INDIA, 2 Jamia Law Journal, 1, 2-3 (2017)

[2] http://geacindia.gov.in/resource-documents/biosafety-regulations/acts-and-rules/Rules-for-the-manufacture-use-import-export-and-storage-1989.pdf

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Rules:

1. rDNA Advisory Committee (RDAC)
2. Institutional Biosafety Committee (IBSC)
3. Review Committee on Genetic Manipulation (RCGM)
4. Genetic Engineering Appraisal Committee (GEAC)
5. State Biotechnology Coordination Committee (SBCC)
6. District Level Committee (DLC)[3]

In India Genetic Engineering Appraisal Committee(GEAC) forms the apex institution to supervise and penalize any noncompliance by the parties. Under the Rules 1989, GEAC supersedes in investigating import, export, transfer or manufacture, produce or sell anyGMOs and implies punitive actions on the acts that have occurred without its approval. Laid down in the Rules 1989 are various prohibitions that allow for the safe conduct of research and the violation of which instigates penalties mentioned under the Environment Protection Act 1986. To mention a few prohibitions: the research related to GMOs must be conducted only in laboratories with the approval of GEAC, and in dealing with any new technology concerning GMOs, the researcher must obtain permission from GEAC and any deliberate andunsupervised release of GMOs into the environment is punishable. GEAC can initiate its supervision through SBCC, DLC, or any authorized person as the apex institute.

Not to mention, Rules, 1989, also provide for numerous prohibitions on acts without the approval of the apex body, which is, the GEAC.GEAC also holds a supervisor-like position and may carry it's supervisory functions via the State-Level or the District Level Committees.Rules, 1989 also authorize the GEAC to carry on it's functions via any other person it may deem fit.The GEAC is vested with the power to penalize offenders in this regard.No mention of handling experiments on humans is given by the rules, althoughmicroorganisms, animals and plants have been adequately addressed.

On the other hand, it is important to note that Foods that are a product of genetically engineered crops, and the safety tests for same are to be in compliance with the guidelines provided by the Indian Council of medical research.The ICMR has devised a smart set of rules and steps for assessing how safe GE Crops are.

[3] Ahuja. V, "Regulation of emerging gene technologies in India". BMC Proc 12, 14 (2018). https://doi.org/10.1186/s12919-018-0106-0

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It should come of as no surprise, when I say India's regulations on GMOs are rather quite solid, taking into consideration the fact that India is an agricultural country, that widely uses genetically modified crops, with over 500 IBSCs that further strengthen the R&B scene in thecountry.

II. International guidelines

When using agricultural technology, the safety of our food, animal feed, and environmental protection remain essential factors for risk assessment. All agricultural products destined for consumption and use, including varieties created using traditional plant breeding methods, must meet these standards. The classification of a new crop or plant product as a "geneticallymodified organism," or GMO, is one way that has evolved to trigger national rules that include risk evaluations and management plans.

European Union[4]

In 2003, the European Union implemented regulatory legislation that may be the world's most restrictive GMO regulations. All GMOs and irradiation food are classified as "novel foods" and must be evaluated by the European Food Safety Authority on a case-by-case basis(EFSA). The four basic types of authorisation criteria are "safety," "freedom of choice,"
"labelling," and "traceability." The European Parliament's Committee on the Environment, Public Health, and Consumer Protection advocated for and endorsed a "safety first" conceptin the case of GMOs, requiring that anybody responsible for any harmful health effects caused by GMOs is held accountable. The Genetically Modified Food and Feed Regulation (EC) No 1829/2003 binds all 27 Member States immediately and specifically concerns GM food and feed generated "from" a GMO4. The Regulation intends to ensure that GM food andfeed authorisation procedures provide a high level of protection for human, animal, and environmental health[5]. In conjunction with Regulation 1830/2003 on GM product tracing andlabelling, this Regulation applies primarily to food and feed goods and their imports. On the other hand, the cultivation of GM crops is a decision made by the Member States under Directive 2001/18/EC on the deliberate release of genetically modified organisms into the environment (also known as the "Cultivation Directive"). This latter tool allows for growing genetically modified foods and plants after a thorough

[4] Crystal Turnbull, Morten Lillemo and Trine A. K. Hvoslef-Eide, *Global Regulation of Genetically Modified Crops Amid the Gene Edited Crop Boom – A Review*,FRONTIERS IN PLANT SCIENCE, February 24, 2021 https://www.frontiersin.org/articles/10.3389/fpls.2021.630396/full
[5] Department for Environment, Food and Rural Affairs, ' New Legislation reduces time and cost of gene editing trails for researchers', 21 January, 2022

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examination of potential negative impacts on human health and the environment. It also states that an organism must include foreign DNA in order to be classified as genetically modified. Even if gene-editing was employed to create the creature, organisms that have had the foreign DNA removed (for example, via selective breeding) do not qualify as GMOs. While the European Union used tohave rather severe controls on genetically modified foods, it now allows newer varieties of modified maise and other agricultural products. EU member states can utilize a safeguard clause' to prohibit individual kinds if there are "justifiable reasons" to believe the variety willharm persons or the environment. After then, the member state must provide adequate proof to show that this is the case. [63] The Commission must look into these issues and either overturn the initial registrations or suggest that the country remove the temporary limitation.

In the case of the UK, the draft of Genetically Modified Organisms(amendment)(England) Regulations, 2022, is all set to ease restrictions on Genetically modified crops for the food industries, that is only if the bill is approved[5].Nonetheless, this affirmative move, has been quite a sigh to scientists and pioneers in the Genetic Engineering fields, as their countless requests for the ease of extra-strict restrictions have been heard for once.This proposed regulation, aims at removing a few additional procedure, capable of halting or being a deadend to the researchers and also allows for various kinds of plant breeding methods, thataren't quite accepted in the other parts of the world, if not for the US.The new set of regulations does so, without compromising the lowering of safety and standards in the field.Ifpassed, this regulation could actually inspire a lot of other countries to ease their own regulations and promote ethical and safe advancements.

United States[6]

In contrast to Europe and the international community, which have developed stringent premarket approval processes, mandatory labelling, and moratoriums, the United States has not developed a regulatory scheme with special GMO safeguards because the US governmentdoes not recognise biotechnology as posing special risks. As a result, the Regulation of biotechnology food items in the United States is similar to conventional food products. The United States reviews genetically altered items using health and safety laws enacted before introducing contemporary biotechnology. So far, no new legislation covering these items hasbeen introduced in the United States. The Coordinated Framework for Regulation of Biotechnology governs US regulatory

[6] Debra M. Strauss, *The International Regulation of Genetically Modified Organisms: Importing Caution intothe U.S. Food Supply,* BUSINESS FACULTY PUBLICATIONS FAIRFIELD UNIVERSITY, 2006 https://core.ac.uk/download/pdf/268549743.pdf

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policies. There are three tenets to the policy: "(1) US policy would focus on the product of genetic modification (GM) techniques rather than the process itself; (2) only regulation based on verifiable scientific risks would be tolerated; and (3) GM products are on a continuum with existing products, so existing statutes are sufficientto review the products." To be approved for release in the United States, a genetically modified organism must be evaluated under the Plant Protection Act by the USDA's Animal and Plant Health Inspection Service (APHIS), as well as the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) depending on the organism's intended application. The United States Department of Agriculture assesses plants' propensityto become weeds. The FDA examines plants that could infiltrate or affect the food chain. TheEPA oversees pesticide-resistant genetically engineered plants and agrochemical residues. The Animal and Plant Health Inspection Service withdrew a proposed rule in 2017 after receiving public feedback. Agricultural stakeholders, in particular, believed it would have severely limited genetic engineering and even new conventional plant breeding approaches.

National & International Stand on: Human Geneline Editing

Legally, there is a ban altogether on any kind of genetic engineering process that has something to do with humans. In some regions, there is a moratorium, with no specified end date. India, China, Ireland and Japan can be said to be on the same page as they clearly place aban in this field[7] .In 2018, a Chinese scientist, has surprised the scientific world with his successful project of creating two so called ‘CRISPR babies’. He managed to actually make human embryo and then infuse them into a pregnant woman. As outstanding the feat might be,this news has attracted widespread contempt, with most legal scholars claiming that the Chinese Scientist has broken several regulations, and failed to comply with the minimumrequired ethical standards. China, too, has always had complete ban on Human Gene editing. This lead to the scientist being penalized with imprisonment for 3 years[8]. This has lead to the Chinese authorities being more stern with regulations and also alerted other countries and thereby tightening regulatory framework. However, for a scientist point of view, this kindof a reaction is quite a demotivation and such strict regulations actually do put a bar on advancements/improvements/innovations in the field. It is sad to note that, an experiment touse CRISPR technology to treat blindness in humans, which

[7] Motoko A, Tetsuya I. International regulatory landscape and integration of corrective genomeediting into in vitro fertilization.
[8] Ian Sample, ‘Chinese scientist who edited babies’ genes jailed for three years’, Guardian, Dec. 31,2019,

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was showing positive results was also called to halt, post this incident.

The USA, which is widely regarded as the country that grants the most comparative freedom for innovations and experiments, in the field of genetic engineering, also places quite a few deadends to Human Geneline Modifications. It is interesting to note that Human Geneline Engineering isn't directly or expressed banned, however, the kind of precautions that the regulations needs the engineers and scientists to take, makes it impossible to conduct researchin this field of genetic engineering. Not to mention, US's FDA has made it's stand against human genetic modification and has made clear that, it's stand will remain the same for the foreseeable future.

On the other hand, it is safe to say that the UK, is rather leading this race, with the granting of expressed permission for a few processes under the broad umbrella of Human Genetic Modification.Of course, this was a result of long term political deliberations[9]. The Oviedo Convention plays an important role in allowing Human Gene Work, only for diagnosis and non-modification purposes in the rest of the EU.

However, for the most part, Human GeneLine Editing is prohibited worldwide, be it Indian, US, China or the UK. The reason behind this, being the dread and taboo attached to the very concept of editing or playing around with human genes or humans, in general. Nonetheless, it is clear that the CRISPR technology has promised so much good, than bad, and it probably is time to prudently ease restrictions in this arena, and get done with the dread associated. This arena also suffers from the blur between the terms 'treatment' and 'enhancement'.

III. Advantages and Disadvantages of Genetic Engineering

The concept of genetic engineering has many advantages in the field of medicine, research, industry and agriculture.They are :

-Bacteria can be modified into plasmid DNA's which codes for various medicines. The samecan also be used to code various enzymes which have a role in food processing and similar industries.

-Various plants have also been modified using genetic engineering into herbicidal agents, to

[9] Rowena Mason & Hannah Devlin, *MPs Vote in Favour of 'Three-Person Embryo' Law* ,Guardian, Feb. 3, 2015.

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produce virus resistance, to improve nutrition etc. This is very much used in modern day agriculture.

-Genetically modified animals have been used for research, model animals and production of agricultural and pharmaceutical products.

-As mentioned earlier, genetic engineering has a huge application in medicine, especially in manufacturing drugs and gene therapy. Most important among those is production of human insulin in bacteria, growth hormones, follicle stimulating hormone (used in infertility), antihemophilic factors, and most importantly vaccines. They have also been used in making monoclonal antibiotics which is very important in modern day medicine.

-Gene therapy, which basically means genetic engineering of humans, is used to treat many diseases like SCID, chronic lymphocytic leukemia and Parkinson's disease.[10]

-Coming to its advantages in research, it is a very important tool for natural scientists, in the creation of transgenic organisms, one of the most important tools for analyzing gene function.

-Genetic engineering has a very significant role in industries. Some of the important productsof genetic engineering include biofuels, complex proteins, various biomaterials, synthetic consortia, etc. Genetically modified virus is also used in making environment friendlylithium ion battery.

-Modern day agriculture depends on genetic engineering. Genetically modified crop andlivestock are used to produce genetically modified food. These crops have higher productivity. Genetically modified fish has also been developed.

DISADVANTAGES-

-Practically there are very minimal disadvantages of genetic engineering. However there are afew ethical, ecological and economical concerns. These controversies have led to litigations, international trade disputes, etc

-Few critics have raised the issue of patenting of life, use of intellectual property rights, accusations that scientists are “playing god” have been raised.

-Few drawbacks of genetically modified food include allergies and minor ailments.

-One of the major drawbacks of genetic engineering is the cost. It is a very expensive field .

-Lack of trained professionals in this field is one the main hindrance in India Overall, leaving a

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few drawbacks, genetic engineering has a lot of benefits. There havebeen a few articles which say the future of medicine and research is genetic engineering.

Conclusion

Bioengineering technologies, a key for cloning animal and creating whole new species of plants and animals alike, promises a lot of victory, however, it faces the problems in the formof uncertainty and other backlashes. The only major arguments of the advocates of the technology is that it would one day help with the potential grievous problems of extinction, starvation, diseases and other environmental issues. A larger group of critics believe that it brings with itself, a greater number of problems, than the problems it currently is solving. Thiswould mean that the genetic engineering space requires extremely capable regulations and an efficient legal framework. Nonetheless, amongst all this Criticisms, it is clear that genetic engineering technology will still triumph it's way, evident from the incorporation of the technology in various fields, by the hour. However, the current regulations are a little too sternand outdated, tending to unknowingly curb advancements in the field.

As for the Indian Scenario, unlike what a layman or anyone who's not had his/her touch withthis topic would think, Indian Law's on GE are very much on par with the laws around the world, if not better. The practical framework in our country is actually better off , when compared to the regulatory mechanisms in the developed nations. Not to mention, India beinga huge user of GMCs, it should be no surprise. Just because Indian legislations in this space aren't slacking behind it's counterparts, it doesn't mean the legislations are sufficient. GeneticEngineering laws, in general, need some looking into, be it national or internationally. The last notable international conference/ convention on this was in 2003, followed by ignored proposals, mostly. Bio Engineers, lawyers and legal scholars have constantly expressed their dissatisfaction with the current outdated laws, not because the laws don't deal with new technologies but because these laws do not promote new advancements. Hence, there's a worldwide need for genetic engineering regulations to undergo a reform, to enhance progress in a field that shows-off unlimited possibilities, whilst still ensuring that the regulations are capable enough, to prevent legal and ethical breaches.