GENETIC ENGINEERING AND LAW

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ABSTRACT

Genes are the functional biological units of any living cell. Human genetic engineering deals with the controlled modification of the human genome. The Human Genome Project (HGP) is a project to de-code (i.e. sequence) more than 3 billion nucleotides contained in a haploid reference human genome and to identify all the genes present in it. The reference human genome sequence was considered pragmatically ‘complete’ at 92% in 2005 in publications by an international public HGP and somewhat independently by a private company Celera Genomics3. Recently, several groups have announced efforts to extend this to diploid human genomes including the International HapMap Project, Applied Biosystems, Perlegen, Illumina, JCVI, Personal Genome Project, and Roche-454. The “genome” of any given individual (except for identical twins and cloned animals) is unique. Mapping “the human genome” involves sequencing multiple variations of each gene. The project did not study all of the DNA found in human cells; some heterochromatic areas (about 8% of the total) remain unsequenced.

The UNESCO International Bioethics Committee had their meeting with more than 50 members selected from 35 countries. The committee drafted general guidelines and an international declaration on the human genome and human genetics, was approved by the United Nations General Assembly in 1998, the 50th anniversary of the Declaration of Human Rights.

Key Words : Genetic Engineering, Human Genome, Bioethics, Law, Human Rights

INTRODUCTION

“Genetic Engineering represents a radical break from evolutionary history.”

—Rissler and Mellon (1993)

Genetic engineering refers to direct manipulation of an organism’s genes and changing the genetic make up of a cell using molecular cloning and transformation techniques in order to produce desired characteristics. Genes coding for protein when engineered upon have changed sequences which lead to synthesis of novel versions of the original protein4. This can lead to tremendous changes inside the organism’s body. Genetic engineering may be a boon or a bane depending on their use and execution.

Thus, the regulations regarding genetic engineering becomes a study of prime importance in today’s world. Bio safety regulations have been in key play right from the introduction of The Environmental Protection Act, 19865 in India.
However, since 2004, there has been a widespread discussion regarding bio safety regulations. The objective of the new regulations is two-pronged. Firstly, it intends to cut down red-tapism and bureaucratic corruption and secondly, and more importantly for the purpose of this paper, provide a single-window system thereby unifying the different regulatory bodies and providing an easy and transparent method of bio-safety regulations.

Objective
The objective of the paper is to look into the various regulations governing genetic engineering and re-engineering in India in the present context. Furthermore, the paper is intended to assess the viability and effectiveness of these bio safety regulations.

MATERIAL AND METHODS
The researchers have perused through various Statutes, Articles and Books relating to the bio safety regulations in India. Thus, the researchers have depended on various primary as well as secondary sources and materials for the furtherance of this paper.

RESULTS AND DISCUSSION
GE can open a Pandora’s box if not regulated properly. As observed in 1989, there was an epidemic in the USA of a mysterious disease. It was termed eosinophilia-myalgia syndrome (EMS). This "disease" produced severe, often crippling muscle pain and resulted in over 37 deaths, as well as thousands of permanently disabled people. Eventually EMS was traced to the consumption of certain genetically engineered (GE) batches of the nutritional supplement tryptophan, produced by the Japanese company Showa Denko K.K. The company had used a gene-altered version of the bacteria needed to make tryptophan in order to cut production costs--much like what many food and drug producers are doing today.

Genetic engineering has attracted the wrath of various environmental institutions worldwide. In fact, recently, Greenpeace released a briefing in its technical papers stating the various harmful effects of the genetically engineered trees and the harmful effects they have on the environment. It stated that, Even a small amount of gene flow from one GE tree can have enormous consequences for the genetic make up of wild trees. Consider poplar trees that produce up to 25 million seeds annually. Even if a biocontainment strategy would work in 99.9% of all cases this would result in the case of poplars in the production of 25,000 fertile seeds for every single tree in every single year, enough for a GE trait to escape from the target population into the wild, forever. Furthermore, The ecological consequences of gene escape from GE trees are potentially very severe. They include impacts on species that depend on specific trees for their survival and changes at the forest ecosystem level.

In light of the above, the state of California in USA also passed a Bill in September,2008 AB 541 which is an anti-GE bill. AB 541 indemnifies California farmers who have not been able to prevent the inevitable - the drift of GE pollen or seed onto their land and the subsequent contamination of non-GE crops.

Genetically modified food and genetic engineering has been vehemently opposed by various authorities and masses in general in the country. In fact, The South Against Genetic Engineering (SAGE) held a month of opposition in the year of 2007. In solidarity with the Joint GM Opposition Month (JIGMOM) observed worldwide, SAGE observed a day of protest between April 9th and May 10th in the States of Karnataka, Andhra Pradesh, Maharashtra and Tamil Nadu.
Karnataka and APCIDD observed the day on April 9th

Karnataka observed GM Opposition on April 9th in Nanjangud town. A protest march was held in Nanjangud under the auspices of 'Anti GM Campaign, Nanjangud', 'South Against Genetic Engineering (SAGE)' and 'Institute For Cultural Research And Action(ICRA)' against GE crops, specifically BT cotton invading farmers’ field. The protest march was lead by Mr.M.Shivalingegowda of Anti GM Campaign, Nanjangud. Around 700 farmers and farm women from surrounding villages, especially cotton growing areas took part in the protest march. The following were the demands

1. Ban BT Cotton, which has proved disastrous to human, cattle and environment.
2. Declare our district as GM free zone.
3. Lift ban on DCH-32 cotton variety in chamarajanagar and Nanjangud Talukas.
4. Address the technical issues related to spurious seeds, decline in yield immediately.
5. Support farmers directly rather than seed and fertilizer companies.

Protest demonstration in front of ICRISAT, Andhra Pradesh

On April 10th ,2007 DDS- SAGE and The Andhra Pradesh Coalition In Defence of Diversity (APCIDD) observed the Day by staging a protest demonstration in front The International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) of, Andhra Pradesh denouncing ICRISAT for its corporate backed pro- GM research agenda and submitted a memorandum to the Director General12. ICRISAT and demanded him to :

1. Move away from GE and move back to basics. Work with farmers and start building on the foundations of their science once again.
2. Get out of the unholy alliance with the biotech industry which has very little to do with Life and everything to do with Death. Death of the environment, death of the poor and death of food sovereignty and dignity.
3. Stop renting out their facilities which was donated to ICRISAT by the international community to the biotech industry. This is a total breach of trust.
4. Bring back biodiversity and NPM on to their agenda and to redeem the institute as a public research institution.
5. Start repatriating the genetic wealth that have been amassed from the farmers of Asia and Africa. Farmers have the right over it but are unable to access it whereas the biotech industry which is accessing it from ICRISAT do it as biopirates
6. Ban genetic engineering from agriculture from the Medak District. All over the dryland belts of the Deccan genetic engineering as seen in the cultivation of Bt cotton, has proved a disaster for small and marginal farmers resulting in thousands of suicides. Besides it has also started toxifying the soils and killing livestock.
7. Genetic engineering in agriculture is the surest way of depriving farmers their control over agriculture and handing it over to large agrochemical corporations.
8. As the custodian of the farming communities in Medak, where small and marginal farmers constitute nearly 70% of the population, it becomes the institute’s duty to do everything to save their life, honour and dignity. One of the ways of achieving this is to stop institutions such as ICRISAT and the state agricultural research institutions from engaging in genetic engineering.

9. Promote ecological farming which is the surest answer to the horrifying water wars and the climate change that looms threateningly on the farmer’s horizon.

10. Expand the state support to food farmers, particularly in the rainfed farming systems thereby reducing the stress on natural resources. This can be done by promoting dryland crops such as sorghum, millets and pulses which still form the finest mosaic of biodiversity on the farms of Medak District.

Media Meet

- **Maharashtra observed the day on April 30th**

  To observe the day, Maharastra organized a press meet in Nagpur, Maharastra where SAGE partners Mr. Tarak Kate, Mr. Vijay Jhawandiya and Mr. Vasant Futane addressed the Media Meet and highlighted the plight of Bt cotton farmers and the havoc it has spelt on the lives and livelihoods of the farmers.

- **Tamil Nadu observed the day on May 10th**

  On the occasion of International GM opposition Month, South Against Genetic Engineering [SAGE]-Tamil Nadu, composed of farmers, farmers organizations, civil society groups, consumers, human rights and media organizations, scientists and academicians held a Day Long Protest in the South Indian city of Chennai, and drafted a charter of demands. The charter was presented to the Government of Tamil Nadu and Government of India.

**Charter of demands**

1. Tamil Nadu should be declared a GM Free State. GM trials and cultivation of genetically engineered crops should be declared illegal in the state of Tamil Nadu.

2. In the light of the recent Supreme Court decision on GM Trials, Panchayats [local assemblies at the village level] should be given the power to disallow any GM Trial in their territory. In order to ensure that the real people keep vigil over such decisions Gram Sabhas must be made the centres of such decisions. No trial should be undertaken without obtaining the approval of the Gram Sabha in a given Panchayat to avoid the possibility of Panchayats being appropriated by big money and corporate power. Tamil Nadu Agricultural University which has a hoary past as the repository of people's knowledge and indigenous science, must stop getting into the trap of doing research in genetic engineering. The Government of Tamil Nadu must order the Tamilnadu Agricultural University (TNAU) to stop all such activities. If it does not stop it, Tamil Nadu farmers will boycott TNAU and hold a series of rallies against it in all parts of the state.

3. More than 10,000 farmers in Tamil Nadu have lost heavily by cultivating Bt cotton. The government must immediately take steps to force Mahyco Monsanto to adequately compensate these farmers. Currently not even 15% of these farmers have received compensation. The compensation given is a pittance. It is time that all farmers are provided proper
compensation commensurate with the losses they have incurred.

This Charter of Demands has been put forward by more than 300 members of South Against Genetic Engineering [SAGE] – Tamil Nadu who held a day long protest against Genetic Engineering in front of the Legislators hostel in Chennai.

### Regulations and rules regarding bio-safety

- **Recombinant DNA advisory council**

  The Recombinant DNA Advisory Committee (RDAC) is constituted by and based in Department of Biotechnology. Its main function is to review developments in biotechnology at national and international levels and recommend suitable and appropriate safety regulations in India in recombinant research, their use and applications.

- **Review committee on genetic manipulation**

  The Review Committee on Genetic Manipulation too, is based in the Department of biotechnology. The Committee is entrusted with the responsibility of bringing out guidelines, specifying procedures and processes for activities involving genetically engineered organisms in research, use and applications, all with the objective of ensuring environmental safety. All high risk category products, controlled field experiments and containment conditions are reviewed by this committee which also lays down procedures for respecting or prohibiting production, sale, importation and use of genetically engineered organisms or cells as listed in the schedule. Industries carrying out genetic research and projects come under the purview of the Committee.

- **Institutional biosafety committee**

  The Institutional Biosafety Committee (IBSC) is constituted by the institution conducting research that handles micro-organisms/genetically-engineered organisms. The committee comprises the Head of the institution involved in research, scientists engaged in DNA work, a medical expert and a nominee of the DBT. The institutions involved in the process are required to prepare, with the assistance of the Institutional Biosafety Committee (IBSC), an up-to-date on-site emergency plan according to the manuals/guidelines of the RCGM and make available copies to the District Level Committee/State Biotechnology Co-ordination Committee and the Genetic Engineering Approval Committee.

- **Genetic engineering approval committee**

  The Genetic Engineering Approval Committee (GEAC) is constituted and based in the Ministry for Environment and Forests (MoEF). It gives approvals for activities involving large-scale commercial use and release of hazardous microorganisms including imports of GMOs and recombinants in research and industrial production from the environmental angle. Where necessary, the Committee also restricts or prohibits production, sale, import or use of GMOs.

- **Monitoring and evaluation committee**

  This committee is required to undertake field visits at experiment sites, suggest remedial measures to adjust original trial design, assist the RCGM in collecting and analyzing field data and collect or cause to collect information on comparative agronomic advantages of transgenic plants.

  A product runs through the four domains, which are characterized by the presence of the six structures described above. The RDAC is in the pre-research domain as it triggers research through its initial approval mechanisms. The RCGM
functions in the research domain, closely monitoring the process of research and experimental releases. Commercial releases of organisms or biotech products containing GMOs come under the purview of the GEAC, a body that dominates the release domain. The Monitoring and Evaluation Committee and the SBCC and The District Level Biotechnology Committee (DLC) basically occupy the post-release domain, although they contribute to the research domain activities through data-provisioning to the RCGM. The Institutional Bio-Safety Committee (IBSC) undertakes monitoring and implementation of safeguards at the RandD sites, under the close supervision of the RCGM, the SBCC and the DLC.

- **District level biotechnology committee**

  The District Level Biotechnology Committee (DLC) is constituted below the State Government level in the district where biotechnology projects function. It is headed by the District Collector (who is the chief executive of the Government at this level of administration) and monitors safety regulations in installations engaged in the use of GMOs and hazardous substances. The Committee investigates compliance with rDNA guidelines and reports violations to the SBCC or the GEAC. The Committee also coordinates activities with a view to meeting emergency situations arising from accidental releases.

**Ministries and departments of regulation of gm food**

- **Ministry of environment and forest**

  This ministry holds the Secretariat of the Genetic Engineering Approval Committee, the apex body that gives approval for manufacture, sale, import and export of all GMOs and products thereof including foodstuff, ingredients in foodstuff and additives using genetically modified (GM) organisms or cells

- **Department of biotechnology**

  This department holds the Secretariat of the Review Committee on Genetically Modification that gives approval for research and small scale field trials involving GMOs and products thereof. It also interacts with the Institutional Biosafety Committees (IBSCs) set up in all organizations undertaking activities involves GMOs

- **Department of health and family welfare**

  Department of Health is responsible for implementation of the PFA Act under which the quality and safety of food is regulated. The Directorate General of Health Services has also been designed as the nodal Ministry with the Codex Alimentarius Commission.

- **Centre for DNA fingerprinting and diagnostics.**

  It is an autonomous institution supported by the DBT and is engaged in providing services for DNA fingerprinting and diagnostics in addition to basic research in related areas. DNA fingerprinting services are also being provided to various government and law enforcement agencies

**Committee reports**

**The Swaminathan task force recommendations**

The Ministry of Agriculture had set up a task force under the chairmanship of Dr. M. S. Swaminathan in May 2003 to examine the potential and problems of biotechnology applications, particularly GM crops. The task force recommended the setting up of an independent and professional watchdog, namely the National Biotechnology Regulatory Authority (NBRA), to generate public confidence in the use of GMOs. The task force has suggested that the role of the GEAC may be confined to biosafety and environmental safety till the formation of the
authority. It has suggested that the monitoring and evaluation committee (MEC) should report to the GEAC on biosafety and environment safety issues. Further, the committee calls upon the Indian Council of Agricultural Research under the Union Agriculture Ministry, to organise testing of GM crops through an All-India Coordinated Research Project.

CONCLUSION

The risk-benefit ratio of genetic engineering is still being debated upon by the international community. The most controversial type of GE is definitely related to its applications in humans. GE in humans has opened up a Pandora’s box of possibilities as it can be beneficial or disastrous. Many countries (U.K., etc.) have developed stringent laws to regulate genetic engineering research while some others (Brazil, China) have fewer legal restrictions. In India there are various committees such as the Recombinant DNA Advisory committee (RDAC), Review Committee on Genetic Manipulation (RCGM), Institutional Biosafety Committee (IBSC), Genetic engineering approval committee (GEAC), etc., which monitor the ongoing genetics research in the country. Reproductive cloning is prohibited in India but therapeutic cloning for research purposes is allowed. According to a Greenpeace report, GE food research in India has increased by almost 250% since 2005. After brinjal, which is in the last stage of approvals without its safety independently verified, there are 25 kinds of rice varieties and 23 kinds of tomato and many kinds of groundnut, pigeon pea, potato, mustard, sugarcane, cowpea and soy in the line of approvals. Genetic engineering is still in its nascent form and one can never be sure of the potential effects genetically modified organisms’ can cause. The key regulatory issue is the balance between biotechnology industry growth objectives and biosafety concerns. In practical terms, this means balancing the interests of the industry with that of civil society and consumers of biotech products. India is still in the process of achieving this balance with legal and ethical issues of genetic engineering being widely debated upon.

The answer to the problems of biosafety regulations in India is neither simple nor straightforward. India’s environmental regulatory mechanisms in the field of biotechnology were instigated right from the onset.

Uncertainties and gaps in the knowledge base in relation to high-tech disciplines formed the original rationale for a government-led biosafety regime. However, as industry and civic communities gain in knowledge and overcome their ignorance of the impacts of hi-tech products, the top-down approach needs to be re-adjusted to alter the boundaries itself and seek to alter the boundaries of regulatory exclusiveness. There are strong, distinctive proposals mooted by the Government of India, civil society groups and industry for restructuring India’s biosafety regulations. However, all proposals are based on certain implicit presumptions. The first presumption is that there can be no meeting ground between those who believe in the norm of case-to-case approaches to biosafety project clearance and those who are against it. The second assumption is that biosafety regulations in India are stand-alone in nature and do not face prospects of interference from the cognate legislations. The third assumption is that the single window approach to decision-making could lead to transparency and quick and effective results. The foregoing discussions point to the need of addressing these assumptions in the larger interests of greater stakeholder-convergence on biosafety issues. An approach that standardizes processes and products can be rewarding to government, civil society and
industry, if transparently designed and impartially administered. Likewise, incorporation of biodiversity conservation and PPVFR players in the biosafety processes could broad base its effective functioning. Finally, a process of inclusive regulation can render decision-making transparent and acceptable to all stakeholders.

Adjust regulatory order is not fenceless: it lives with properly modified fences that represent change from the past. In practical terms this means that single window initiatives in the field of biosafety regulations should not only be vertically stacked but also horizontally broad-based with both civil society and industry associations accorded their due role in decision-making processes.

REFERENCES

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