

BIOSAFETY AND LEGALITY OF GENETICALLY MODIFIED CROPS

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Abstract

High use of pesticides, infestation by insects and diseases, low yielding crops are some of the primary concerns of the average farmer. Biotechnology offers solutions to this problem by altering the genetic make-up of the plants to make them more disease and pest resilient, high yielding and requiring lesser resources such as water and fertilizers. However, the position related to the legality of use of genetically modified crops is fluctuating in India. The Government needs to balance between the concerns related to environment and health hazards on one hand and food security for the nation on the other. Hundreds of GM crops are pending approval after completion of research. Bt Brinjal's approval was revoked post grant. Bt Cotton is the only GM crop to be grown at a commercialized scale while others like Bt Soya, Bt Mustard etc. are still awaiting approval from the government. However, owing to the lack of regulations many of the GM crops are already finding their way to the market. This paper aims at ascertaining the direction in which this fluctuating legal position relating to GM crops is most likely to go in light of latest judgments, guidelines by government and international position of GM crops.

Keywords: *Pesticides, Infestation, Biotechnology, GM Crops etc.*

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INTRODUCTION

Today technology has pervaded all walks of life. It is influencing the way we communicate, travel, think and even eat. One of the important applications of technology has been in the area of agriculture. From developing better tools and technical implements, better irrigation facilities & potent pesticides and herbicides technology has now leapt into the area of genetically designing crops itself. This marriage of bio-technology and genetic engineering has produced fascinating results and opened a world of limitless possibilities at one hand and given rise to unprecedented challenges and fears on the other. The age-old question “Should man play God” becomes ever more realistic in the light of the capabilities of genetic engineering. New plant varieties developed using recombinant DNA (rDNA) techniques, commonly referred to as genetically engineered (GE), genetically modified (GM) or transgenic plants, have been and are being developed with the aim of: enhancing productivity; decreasing dependence on the use of agricultural chemicals; modifying the inherent properties of crops; and improving the nutritional value of foods and livestock feeds. As more GE plants are released and the resultant food products are commercially available and are traded across various countries, concerns have been expressed about their safety.

MENDELIAN INHERITANCE AND GENETIC ENGINEERING OF CROPS

Since the 20th century, the farmers have followed the practice of accumulating better traits in a crop line by following the principles of Mendelian inheritance. The average farmer knows that a good parent crop gives a good progeny crop. However this method has its own limits i.e only those good traits can be selected which are already present in the population and any new characteristic will develop only by evolution (which is very gradual process) or mutation (which is influenced by some radical changes in the environment). However, both these processes are not of much use to the agricultural practice for two reasons – one, that both of them are chance processes and second that the resulting outcome may not necessarily be favourable for the farmer. Biotechnology by employing the technique of genetic engineering eliminates all these concerns and is able to modify the genetic make-up of crop by utilizing traits existing in other species and produce sustainable and desirable outcomes for the farmers.

BIOTECHNOLOGY, GENETIC ENGINEERING AND BT COTTON

Biotechnology means the application of scientific and engineering principles to the processing of materials by biological agents to produce goods and services¹ whereas "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, 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 of a cell into a host cell, where they occur naturally (self-cloning) as well as modification of an organism or in a cell by deletion and

¹ Rules For The Manufacture, Use, Import, Export And Storage Of Hazardous Micro Organisms Genetically Engineered Organisms Or Cells, 1989

removal of parts of the heritable material.² Bt Cotton is a genetically modified cotton crop in which strains of Bt toxin producing genes of the bacterium *Bacillus Thuringiensis* has been inserted. *Bacillus Thuringiensis* produces Bt toxins which are fatal to most of the insects and pests that prey on the cotton plant. Once genetic modification is done then the cotton plant acquires an inherent insecticidal property. Bt Cotton thus is a fruit of biotechnology and genetic engineering. However, like every new technology it has its own pros and cons.

PROS AND CONS OF GM CROPS

Those who argue in favour of GM crops make the argument that a movement towards GM crops is essential to food security of the world and better nutrition for its citizens. Eminent agronomists advocating for safe use of genetically modified crops have said that GM crops may be the only way to feed the starving millions and if a choice has to be made between no food and GM food then the latter should be accepted wholeheartedly. For farmers too, GM crops may mean lesser crop failure, higher yield and resource optimization. However, those who argue against GM crops have a variety of health, environment and regulatory concerns at heart. The scientific community itself seems divided on the issue of health risks associated with GM food. GM food basically introduces new genes in a species which were not present earlier; sceptics fear that this may expose humans to proteins to which we have never been exposed to earlier. Evolutionarily, we may have no capability of dealing with diseases which may be linked to these proteins. The associated health risks with GM food are thus unidentifiable and limitless. Ecologically too, it makes little sense to introduce GM crops. By growing GM crop we may accidentally tinker with the ecological balance. Those who argue from a legal and regulatory stand point usually make the argument that if GM crops are given a free run then the food sovereignty of our nation will rest in hands of corporate making and marketing GM crops. These regulatory fears however seem to have been answered by restrictions on patenting of GM crops by many jurisdictions.

GM CROPS AND IPR

Whether companies like manufacturing Bt Cotton enjoy patent rights on the seed is a burning issue in the Indian IPR regime. For now, this has been settled in the negative by a division bench of the Delhi High Court.³ This decision which is seen as a victory of farmers and food sovereignty of the nation has largely upset the Indian agrimarket. Presently, Monsanto's appeal against this decision is pending in the Supreme Court. However, as a major victory for Indian seed manufacturers the apex court has refused to put a stay on the high court's decision. India while the TRIPS negotiations were going advocated on behalf of the farmers of the country to exclude out seeds and plant varieties from patentability. Article 27 of the TRIPS is important in this regard. Article 27(2) of TRIPS provides that

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public*

² *ibid*

³ *Monsanto v Nuziveedu Seeds FAO* (OS) (COMM) 86/2017, C.M. APPL.14331, 14335, 15669, 17064/2017 Delhi High Court pronounced on 11.04.2018

or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law

More Specifically Article 27(3)(b) provides that members may also exclude from patentability,

Plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

On the basis of this India enacted the Protection of Plant Varieties and Farmers' Rights Act 2001 (PPVFR Act) which is an effective *sui generis* system for protection of plant varieties. Also section 3(j) of the Patents Act 1970 (Patents Act) states that “plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals” are not inventions.

The Delhi High Court ruled that Bt-cotton seeds are not inventions as per section 3(j) of the Patents Act and that Monsanto can seek protection under PPVFR Act. This gave double relief to the Indian farmer. First, Bt Cotton could be made available to it at cheaper rates by Indian seed manufacturer and second and more importantly, freedom from terminator gene technology. Terminator gene is a type of gene which is inserted in GM crops to make the seed unviable in the second growing season so that the farmer has to purchase a new seed every growing season. The PPVFR Act has a specific protection for farmers that they can sow, resow, exchange or even sell seeds and that all seeds shall be free from this terminator gene technology.

LEGALITY OF GM CROPS

The GM crops struggle to trace their legality in primarily in various rules framed by Ministry of Environment and Forests (MoEF) under the Environment Protection Act, 1986, the Food Safety and Standards Act, 2006 (FSS Act), The Biosafety guidelines framed by Department of Biotechnology under the Ministry of Science and Technology and Plant Quarantine (Regulation of import into India) Order, 2003. The MoEF in exercise of its powers conferred by sections 6, 8 and 25 of the Environment (Protection) Act, 1986 has framed certain rules namely “Rules For The Manufacture, Use, Import, Export And Storage Of Hazardous Micro Organisms, Genetically Engineered Organisms Or Cells, 1989” these rules have effectively set up 6 authorities responsible for implementation of these Rules,

- Recombinant DNA Advisory Committee (RDAC);
- Review Committee on Genetic Manipulation (RCGM);

- Genetic Engineering Appraisal Committee (GEAC); (earlier, Genetic Engineering Approval Committee)
- Institutional Bio-safety Committees (IBSC);
- State Biotechnology Coordination Committees (SBCC);
- District Level Committees (DLC).

These committees basically screen the GM crops at four stages pre-research, research, release and post release. The most important committee, the GEAC is responsible for giving research and release related approvals to GM crops. Till date the GEAC has given research related approvals to hundreds of GM crops however Bt Cotton continues to remain the only commercialized GM crop in the country. GEAC has given commercial approval to 809 varieties of Bt Cotton to date.⁴ In October 2009 GEAC had cleared another crop, the Bt-Brinjal for commercial release however it was later revoked by government. In 2017 also the government with a view to give impetus to its mission of doubling farmers' income by 2022 seemed inclined to allow GM crops. However a detailed note put up by the Environment Ministry somewhat in favour of Bt-mustard was withdrawn as quickly as it was put up.⁵ It is pertinent to mention here that at least 5 out of the 7 parameters identified by the government to double farmers' income may directly be impacted by GM crops.⁶

WHY BT COTTON AND NOT BT BRINJAL/MUSTARD?

Bt Cotton is a non-food crop and crops like Bt Brinjal, Bt Mustard, Bt Soya etc. are food crops and are likely to be consumed by humans. The suspecting scientists and public have deep rooted concerns about consumption of genetically modified food and health related complications which may arise from the same. Stating that there was no urgency to introduce Bt-Brinjal and given overwhelming negative sentiments against introduction of Bt Brinjal the government was more inclined towards taking a more cautious, precautionary and principles based approach and hence, in a move which deeply injured the credibility of GEAC the government revoked the approval granted to Bt Brinjal in February 2010.

ANTI GM CAMPAIGN IN INDIA

There have been several Public Interest Litigations filed by various groups against GM crops citing various healths, environmental and regulatory concerns. Gene Campaign India has filed four PILs which are at various stages. Their core concerns are setting up a national bio-ethics committee, making GEAC more transparent and competent, setting up a national biotechnology regulator authority and ingraining the precautionary and the polluter pays

⁴ *Yearwise list of commercially released varieties of Bt cotton hybrids by GEAC*; Available at: www.geacindia.gov.in (Accessed on: November 05, 2018)

⁵ *PM Narendra Modi Government rethinking plan to get GM food in India for the first time ever?*, Financial Express, May 15 2017

⁶ *Doubling Farmers' Income*; NITI Policy Paper No.1/2017 Available at: www.agricoop.nic.in (Accessed on: November 05, 2018)

principle in the biotechnology regime more explicitly and effectively. The PILs are at various stages of litigation and appropriate directions have been passed by the Supreme Court on various dates.⁷

MARKETING OF GM FOOD IN INDIA

The regulatory authority in this regard is the Food Safety and Standard authority of India set up under the Food Safety and Standards Act, 2001. Importantly, the act includes genetically modified foods within the definition of food under it. Section 22 of the Food Safety and Standards Act, 2006 provides that “no person shall manufacture, distribute, sell or import any genetically modified article of food except as otherwise provided under the Act and regulations made thereunder”. Hence, in a reply given to the Supreme Court the FSSAI has maintained that it has not framed any regulations allowing GM Crops in India and so they continue to remain illegal. The work on framing regulations on GM Food has however commenced and draft regulations are underway. These regulations will lay down procedures for the safety of GM food for human consumption however GEAC will continue to regulate the environmental aspect of such food. Both these bodies hence, need to work in close conjunction and cooperation. In the meanwhile, FSSAI has come up with draft Food Safety and Standards (Labelling and Display) Regulations that also specify threshold levels for labelling requirements of GM foods. The labeling requirements will give information to consumers about the maximum GM content contained in the given food item. This will help the consumers in making informed choices. The proposed maximum permissible level for GM content for which no labeling will be required is 5% by weight. This follows international practice being followed in countries like Japan, Canada, Thailand and Indonesia however it is more liberal than the practice in EU which prescribes threshold of 0.9 %. However, draft is open for public as well as industry inputs.

INTERNATIONAL FRAMEWORK

Agenda 21 was adopted at the Rio Summit in 1992. It is a non-binding agenda which calls upon the international community to address a wide spectrum of environmental and developmental issues. Chapter 16 of Agenda 21 recognizes the importance and growing significance of biotechnology and the need to ensure that it is developed and applied in an ecologically sustainable manner. Apart from Agenda 21 there are two major international protocols that address genetically modified organisms, the Cartagena Protocol of 2000 of which India became a signatory on January 23, 2001 and the Nagoya-Kuala Lumpur Supplementary Protocol of 2010 of which India became a signatory on October 11, 2011. Both these protocols are attached to the Convention on Biological Diversity of 1993 and are in force. The Cartagena Protocol aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health. Whereas The Nagoya - Kuala Lumpur Supplementary Protocol on Liability and redress aims

⁷ *Gene Campaigns Legal Actions on GMOs*; Available at: www.genecampaign.org (Accessed on: November 05, 2018)

to contribute to the conservation and sustainable use of biodiversity by providing international rules and procedures in the field of liability and redress relating to living modified organisms and damage resulting from living modified organism which find their origin in a transboundary movement. Another international treaty on this subject which is in harmony with Convention on Bio diversity is the International Treaty on Plant Genetic Resources for Food and Agriculture also known as the “Seed Treaty”. Article 9.2 (c) of the treaty determines that farmers’ rights include “the right to participate in making decisions, at the national level, on matters related to the conservation and the sustainable use of plant genetic resources for food and agriculture”.

CONCLUSION

Genetically modified food crops are the future of food security in this world. The solution can never be in the form of a blanket ban on these crops but in robust regulation and risk assessment. India has so far adopted a very cautious approach in giving approval to these crops. Till the time the concerns of the two most important stakeholders of this system i.e the farmer and the consumer are taken care of it will not be prudent to introduce GM crops in the ecosystem given that once introduced their impact is going to be irreversible. However, gradually we have to move in an era of GM food to meet the needs of the burgeoning population.