

GENETICALLY MODIFIED CROPS ISSUES AND CHALLENGES IN THE CONTEXT OF INDIA

RESEARCH UNIT (LARRDIS) RAJYA SABHA SECRETARIAT NEW DELHI

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PREFACE

This publication is next in the series of 'Occasional Papers' being brought out on topical issues from time to time for the benefit of the Members of Parliament.

The issues relating to Genetically Modified Crops have generated intense public debate, engaging the attention of the Government, the farming community and the civil society. Though it has been widely claimed that genetically engineered foods will go a long way in tackling food security issues of the 21st century, doubts and apprehensions have been expressed about its safety and environmental viability. This paper attempts to present the varied dimensions of GM crops and briefly discusses the use of genetic engineering in Indian agriculture outlining the related issues and challenges.

I am grateful to Prof. M.S. Swaminathan, M.P. and Shri Sharad Anantrao Joshi, M.P., whose valuable suggestions have enriched the contents of this paper.

It is hoped that Members would find this paper interesting and useful.

New Delhi 17th December, 2009 V.K. AGNIHOTRI Secretary-General Rajya Sabha

Introduction

The issues relating to the Genetically Modified Foods have generated intense public debate in many parts of the world. Even though the issues under debate include the costs and benefits of the GM crops and the inherent safety concerns, the outcome of the debate differs from country to country, depending on its geographical location, strength and resilience of the farm sector, attitudes of people towards food, and so on.

In India also, this debate has engaged the attention not only of the Government but also of the farming community and the civil society. Though, it is widely claimed that biotechnology, particularly genetically engineered food offers dramatic promise for meeting some of the 21st century's greatest challenges; like all new technologies, it also poses certain apprehensions and risks, both known and unknown. It is, therefore, paramount in this context, to know the basic processes involved in genetic modification for proper appreciation of the related issues and challenges.

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Genetically Modified Organisms

(i) Genetically Modified Organisms (GMOs)-the definition

Genetically Modified Organisms, are the ones in which the genetic material (DNA) has been altered in such a way as to get the required quality. This technology is often called 'gene technology', or 'recombinant DNA technology' or 'genetic engineering' and the resulting organism is said to be 'genetically modified', 'genetically engineered' or 'transgenic'. GM products (current or those in development) include medicines and vaccines, foods and food ingredients, feeds and fibre.

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I

(ii) Genetic Engineering— the process

All living organisms, from viruses to human beings, are made up of cells, with a nucleus at the centre, which contains a unique set of instructions regarding their size, strength and other qualities. These instructions are found on a long molecule called DNA (Deoxyribonucleic Acid), which is divided into small sections called genes. It is the sequencing of genes on DNA that determines an organism's characteristics. Very simple organisms such as bacteria may have fewer genes than the more complicated ones. In simple terms, the complete set of genetic material of an organism, *i.e.*, all the DNA contained in an organism, is called a genome. The process of isolating gene(s) from the genome of one organism and inserting the same into the genome of another organism is known as Genetic Engineering. In nature, exchange of genes happens only between compatible or closely related species. However, the modern technique of genetic engineering facilitates the removal of group of genes from one species and insertion into another, there being no need for compatibility.

The transfer process involves shifting the desired gene from the chromosome of a particular plant or animal or any other organism into a cell. This genetically modified cell is then regenerated to produce a 'genetically modified organism' (GMOs). The modified organism passes the new gene onto its progeny. Such methods are now being used to create GM plants, of desired quality, growth and strength. Basic idea is to have plant varieties with high yield, pest/ disease resistant, or other such qualities mainly for better marketability and durability. This is different from the processes of modifying crops/plants from their wild ancestors through selective breeding or mutation breeding, which have been practised by farmers as part of their regular farming activity.¹

¹Kavitha Kuruganti and G.V. Ramanjaneyulu, 'Genetic Engineering in Indian Agriculture–An Introductory Handbook', Centre for Sustainable Agriculture, Secunderabad, April 2007



GM Crops/Food-relevant issues

(i) Commercial venture

The first commercially grown GM food crop was Tomato (called Flavr Savr), modified to ripen without softening by a Californian company Calgene, which took the initiative to obtain approval for its release in 1994. Currently, a number of food crops such as soyabean, corn, cotton, tomatoes, Hawaiian papaya, potatoes, rapeseed (canola), sugarcane, sugar beet, field corn as well as sweet corn and rice have been genetically modified to enhance either their yield, or size,or durability, etc. Scientists are also working on crops which they hope will be useful for industry, such as plants that produce oil for the cosmetics industry, crops with altered nutritional value, and even crops that produce pharmaceutical drugs. Major producers of transgenic crops include USA, Argentina, Brazil, India, Canada, China, Paraguay, South Africa, among others.

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(ii) Issues of crop protection

The initial objective for developing GM plants was to improve crop protection. The GM crops currently in the market are mainly aimed at an increased level of crop protection through the use of one of the three basic traits: resistance to insect damage; resistance to viral infections; and tolerance towards herbicides. All the genes used to modify crops so far are derived from micro-organisms².

Insect resistance is achieved by incorporating into the food plant the gene for toxin production from the bacterium Bacillus thuringiensis (Bt). This toxin is used as a conventional insecticide in agriculture and is safe for human consumption. GM crops that permanently produce this toxin have been shown to require lower quantities of insecticides;

²'WHO: 20 questions on genetically modified foods' (http://www.who.int/)



- Virus resistance is achieved through the introduction of a gene from certain viruses which cause disease in plants. Virus resistance makes plants less susceptible to diseases caused by such viruses, resulting in higher crop yields;
- Herbicide tolerance is achieved through the introduction of a gene from a bacterium conveying resistance to some herbicides. In situations where weed pressure is high, the use of such crops has resulted in a reduction in the quantity of the herbicides used.

(iii) Understanding risks and benefits

The risk-benefit analysis of the GM crops can be summarized as below:

Benefits		Improved resistance to diseases, pests and herbicides
	٥	Improved tolerance to cold/heat
	٥	Improved tolerance to drought/ salinity
	٥	Reduced maturation time
	٥	Increased nutrients, yields, quality and stress tolerance
		Food with greater shelf life or food with medicinal benefits, such as edible vaccines—for example, bananas with bacterial or rotavirus antigens
	٥	Increased food security for growing population
Issues of concern (Human health risks and environmental safety concerns)		Potential impact on human health including allergens, transfer of antibiotic resistance markers and 'outcrossing'. The movement of genes from GM plants into conventional crops or related

	species in the wild (referred to as 'outcrossing'), as well as the mixing of crops derived from conventional seeds with those grown using GM seeds, may have an indirect effect on food safety and food security. It has been found that genes inserted into GM food survive digestive processes and are transferred into the human gut.
	Potential impact on environment, including transfer of transgenes through cross-pollination, unknown effects on other organisms (e.g., soil microbes), and loss of flora
	anu launa biourversity.

(iv) Some other concerns

Critics of genetically modified food have also pointed out certain other aspects apart from human health risks and environmental safety concerns.

These are:		
Access and Intellectual Property Rights	Critics claim that patent laws g developers of the GM crops dangerous degree of control o the food supply	
	Domination of production by a feature	world food w companies
	Increasing de developing c industrialized nat	pendence of ountries on ions
	Biopiracy, or foreignatural resources	gn exploitation of
Ethical concerns	Violation of nate intrinsic values b species	ural organisms' y mixing among
	Objections to co genes in plants	nsuming animal

(v) Safety assessment

The starting point for the safety assessment of genetically engineered food products is to assess if the food is 'substantially equivalent' to its natural counterpart. In deciding whether a modified product is substantially equivalent, the product is tested by the manufacturer for unexpected changes in a limited set of components such as toxins, nutrients or allergens that are present in the unmodified food. The data is then assessed by an independent regulatory body. If these tests show no significant difference between the modified and the unmodified products, then no further food safety testing is required. However, if the product has no natural equivalent, or shows significant differences from the unmodified food, then further safety testing is carried out. This method has, however, been severely criticized by some scientists since it is not clear what level of similarity makes something 'substantially equivalent'.

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Genetic Engineering and Indian Agriculture

(i) Institutional Framework and the Governing Rules

In India, application of biotechnology in agriculture is being dealt with by three different Ministries/Departments: (1) Ministry of Agriculture; (2) Ministry of Environment and Forests; and (3) Department of Biotechnology, Ministry of Science and Technology. The legislative framework on agrobiotechnology rests mainly with the Ministry of Environment and Forests, Government of India. Under the Environment (Protection) Act, 1986, the Ministry of Environment and Forests has notified the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms/ Genetically Engineered Organisms or Cells, 1989, or in short, the Rules, 1989. These rules and regulations cover the areas of research as well as large scale applications of the

GMOs and such products throughout India. These rules also define the competent authorities and composition of such authorities for handling of various aspects of the rules. Presently, there are six competent authorities³:

Competent Authorities dealing with the GMOs

Recombinant DNA Advisory Committee (RDAC) under the Department of Biotechnology, Ministry of Science and Technology, to recommend appropriate safety regulations in recombinant research, use and applications.

Institutional Biosafety Committees (IBSC)⁴ under the Department of Biotechnology, Ministry of Science and Technology, to prepare site-specific plans for use of genetically engineered micro organisms.

Review Committee on Genetic Manipulation (RCGM) under the Department of Biotechnology, to monitor safety related aspects in respect of ongoing research projects and activities involving genetically engineered organisms. It lays down procedures/regulations regarding research, production, sale, import and use of genetically engineered organisms with a view to ensure environment safety.

Genetic Engineering Approval Committee (GEAC) under the Ministry of Environment and Forests, to look into approval for large scale releases and commercialization of the GMOs.

State Biotechnology Coordination Committee (SBCC) in the States wherever necessary to inspect, investigate and take punitive action in case of violations of safety and control measures in the handling of genetically engineered organisms.

District Level Committee (DLC) in the districts wherever necessary under the District Collectors to monitor safety regulations in installations engaged in the use of genetically modified organisms and their applications in the environment.

³www.envfor.nic.in/legis/hsm/hsm3.html ⁴For more information, see www.dbtbiosafety.nic.in/committee/ibsc.htm



Further, the Department of Agriculture and Cooperation, (Ministry of Agriculture) had set up a Task Force under the Chairmanship of Prof. M.S. Swaminathan to formulate a long term policy on Application of Biotechnology in Agriculture in May 2003. The Swaminathan Task Force recommended the establishment by an Act of Parliament an autonomous, statutory and professionally led National Biotechnology Regulatory Authority. This is essential for inspiring public, political, professional and media confidence in the procedures adopted for measuring risks and benefits. The Swaminathan Task Force also recommended that:

'The bottom line of our national agricultural biotechnology policy should be economic well being of farm families, food security of the nation, health security of the consumer, biosecurity of agriculture and health, protection of the environment and the security of national and international trade in farm commodities.'

As per the recommendation contained in the Report of the Task Force, the Government formulated the National Biotechnology Development Strategy in November 2007. The Strategy, while enabling the full utilization of currently available opportunities in manufacturing and services, *inter alia* would lay a strong foundation for discovery and innovation, effectively utilizing novel technology platforms with potential to contribute to long term benefits in agriculture, animal productivity, human health, environmental security and sustainable industrial growth. The stated vision of the Strategy is responsible use of life sciences and biotechnology to promote balanced growth of all sections of the society⁵.

Regarding the setting up of the National Biotechnology Regulatory Authority (NBRA), the Department of Biotechnology has been entrusted with this task. The NBRA

⁵For more information, refer to the National Biotechnology Development Strategy: Key Elements, Department of Biotechnology, Ministry of Science and Technology, Government of India (Website: www.dbtindia.nic.in)



would be set up as an independent, autonomous and professionally led body to provide a single window mechanism for biosafety clearance of genetically modified products and processes. This would be done through the promulgation of a new legislation, the 'National Biotechnology Regulatory Act' or the NBR Act. Draft establishment plan of the NBRA and a draft National Biotechnology Regulatory Bill, 2008 have been prepared by a Consultative Committee of experts, on which the Department has invited feedback from all the concerned stakeholders through placing these documents on the website⁶ as well as organizing regional consultations.

(ii) Bio-safety regulations followed in India

Regulation of genetically engineered crops is extremely important to address the biosafety concerns associated with these products. As more genetically engineered plants are being developed for commercial release, concerns have been expressed about their safety. The concept of food safety assurance has assumed importance as with any method of genetic manipulation, there is a possibility of introducing unintended changes along with intended changes, which in turn have an impact on the health and nutritional status of the consumer. Unintended effects can result from the random insertion of DNA sequences into the plant genome which may cause disruption or silencing of existing genes, activation of silent genes, or modifications in the expression of existing genes. The international food code or the Codex Alimentarius⁷ has been used as a point of reference. In India, the Rules 1989, cover the areas of research as well as large scale applications of GMOs. However, with continuous advancements in the area of

⁶For more information refer <u>www.dbtindia.nic.in</u>

⁷The Codex Alimentarius Commission (Codex) is the joint FAO/WHO body responsible for compiling the standards, codes of practice, guidelines and recommendations that constitute the Codex Alimentarius. The premise of these principles dictates a premarket assessment, performed on a case-by-case basis including an evaluation of both effects (from the inserted gene) and unintended effects (that may arise as a consequence of insertion of the new gene)

research and development of GM crops, fresh guidelines have been framed from time to time. Some of these are:

- Recombinant DNA Safety Guidelines, 1990 by Department of Biotechnology covering research in biotechnology, field trials and commercial applications;
- Revised Guidelines for Research in Transgenic Plants, 1998 by Department of Biotechnology;
- Protocols for Food and Feed Safety Assessment of GE Crops, 2008 by Department of Biotechnology;
- Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants, 2008 by Indian Council of Medical Research (ICMR);
- Guidelines and Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated, Genetically Engineered (GE) Plants, 2008 by Department of Biotechnology and Ministry of Environment and Forests.

The Government of India follows a policy of case-by-case approval of transgenic crops. As per the guidelines framed by the ICMR, safety assessment is designed to identify whether a hazard, nutritional or other safety concern is present, and if present, to collect and analyse information on its nature and severity following a structured and integrated approach performed on a case-by-case basis. Factors taken into account in the safety assessment include:

- Identity
- □ Source
- □ Composition
- Effects of processing/cooking
- I Transformation process
- The recombinant DNA (e.g., stability of insertion, potential for gene transfer)
- Expression product of the novel DNA

*Effects on function *Potential toxicity *Potential allergenicity



- Possible secondary effects from gene expression or the disruption of the host DNA or metabolic pathways, including composition of critical macro, micro-nutrients, anti-nutrients, endogenous toxicants, allergens and physiologically active substances; and
- Potential intake and dietary impact of the introduction of the GM food.

With a view to streamline the regulatory mechanisms for biosafety evaluation and release system/protocol, the Task Force on Application of Biotechnology in Agriculture suggested as below:

"Once an extant/transgene has been declared biosafe, its derivatives need not always be evaluated for bio-safety to the same extent again. Such derivative crop varieties may be considered for biosafety clearance after case verification and need-based trial by RCGM. Studies on gene stability and expression levels will however have to be repeated for new varieties....For example, cotton Cry 1Ac gene has been found to be safe. Therefore, the use of this gene for improvement of other varieties in the same crop need not be subjected to the same degree of biosafety assessment...⁸"

Doubts have been expressed in some quarters that the case-by-case policy of approval followed by the Government is time consuming and arduous and provides ample scope for spreading misinformation about GM crops. But the opposing view argues that genes cannot be assessed in isolation, but only as part of the genome into which they are introduced and so testing should be done on a caseby-case basis.

(iii) The case of Bt Cotton

The Maharashtra Hybrids Seed Company (Mahyco) jointly with the US seed company Monsanto developed the

⁸Report of the Task Force on Application of Agricultural Biotechnology, Ministry of Agriculture, Government of India, 2004, page 40, para 12.5



genetically modified Bt Cotton to tackle the bollworm problem that had devastated cotton crops in the past, by introducing into the cotton seed a gene of the common soil microbe called Bacillus Thuringiensis that encoded an insecticidal protein lethal to the bollworm (hence the name Bt. Cotton). In 2002, Bt Cotton became the first and only transgenic crop approved by the GEAC for commercial cultivation in six States namely, Andhra Pradesh, Gujarat, Karnataka, Madhya Pradesh, Maharashtra and Tamil Nadu. It has been further extended to Punjab and Haryana. The Bt Cotton seeds were marketed by the Monsanto-Mahyco joint venture. Though the public opinion has been divided on this issue, the Government has indicated satisfactory performance of the Bt Cotton. As per the Government figures, the area under Bt Cotton has increased from 0.70 lakh acres in Kharif-2002 to 2.30 lakh acres in Kharif-2003 and further increased to 12.00 lakh acres in Kharif–2004⁹. As per the latest unofficial report¹⁰, India has become the fourth largest adopter of biotech crops in 2008 with cotton alone occupying 7.6 million hectares.

On the one hand, it has been claimed as the 'Bt Cotton Revolution' with transgenic cotton being grown in 90 percent of the cotton growing areas, increasing yields by as much as 50 percent in certain regions. However, the critics, especially various civil society groups have contested this claim. It has been argued that Bt Cotton cultivation has resulted in adverse economics for farmers, highly priced seeds, changed pest ecology in cotton fields, increased incidence of diseases (requiring more pesticides to control these), unpredictable crop performance and more resources being used by farmers as part of their risk insurance mechanisms (use of more irrigation, fertilizers, etc.). Stress tolerance of the Bt Cotton, such as surviving adverse weather conditions, has been said to be very low.

⁹Rajya Sabha Unstarred Question No. 1286 answered on 05.08.2005 regarding 'Coverage area of Bt Cotton' Rajya Sabha Debate dated 05.08.2005 (pages 79-80) ¹⁰Amarnath K. Menon, 'GM Food: How Safe is it?, *India Today*, 2 November 2009



There have been reports of adverse impact on soils, human health (allergic symptoms) as well as toxicity in animals grazing on the Bt Cotton fields. There have also been reports of large scale contamination and rapid proliferation of various illegal varieties.

(iv) The case of Bt Brinjal

In India, Brinjal is grown all over the country and is one of the most popular vegetables. It is mainly grown in small plots as a cash crop by the farmers. The main growing areas are in the States of Andhra Pradesh, Bihar, Karnataka, Maharashtra, Orissa, Tamil Nadu, Uttar Pradesh and West Bengal. There are many local varieties in India, in addition to improved varieties and hybrids. It is estimated that the damage caused by the Fruit and Shoot Borer, which has been the major pest for the past two decades or so, ranges from 50 to 70 percent. It is to lend tolerance to this pest primarily that the Bt Brinjal has been developed. Bt Brinjal is a transgenic Brinjal created out of inserting a gene [Cry 1Ac] from the soil bacterium Bacillus thuringiensis into Brinjal. The insertion of the gene into the Brinjal cell is being done alongwith other genes like promoters, markers, etc. This is said to give the Brinjal plant resistance against lepidopteran insects like the Brinjal Fruit and Shoot Borer. It is reported that upon the ingestion of the Bt toxin by the insect, there would be disruption of digestive processess, ultimately resulting in the death of the insect. Bt Brinjal is being developed in India by the Maharashtra Hybrid Seeds Company (Mahyco). Recently, the GEAC has cleared Bt Brinjal-country's first genetically modified food-for commerical use. However, amidst protests and campaigns by the anti GM groups, the Government of India would take a final call on this matter.

(v) Other GM Crops

As per the Indian GMO Research Information System (IGMORIS), the GM crops, apart from Brinjal that are being currently tested are:

SI.	No. GM Crop	Trait
1.	Cabbage and Cauliflower	Insect resistance
2.	Potato	Transgenic dwarf potato Disease resistance Reduction in cold- induced sweetening and chip colour improvement
4.	Cotton	Insect resistance
5.	RRF Cotton	Insect resistance and Herbicide tolerance
6.	Corn	Insect resistance and Herbicide tolerance
7.	Rice	Insect resistance
8.	Groundnut	Virus resistance
9.	Sorghum	Insect resistance

V

GM crops: opposing views

There have been claims and counter claims regarding growing of the GM crops and as of now with limited facts and figures, it is very difficult to analyse the risks and benefits associated with this technological breakthrough in agriculture. A glance at some of the arguments put forth by the opposing viewpoints would shed some light on this aspect:

	For	Against
	No significant difference was noted between Bt Brinjal and Non-Bt Brinjal as per bio- safety tests like acute oral toxicity, sub-chronic oral toxicity in rats, allergenecity of protein to rats, gesmination, weediness and aggressiveness tests, soil studies, etc.	The current safety assessments are inadequate to catch most of the harmful effects from the GM crops. GM technology is unpredictable and imprecise, that too when released in an open environment situation. Moreover, the regulatory regime in India with regard to the GM crops has never been

According to Prof. M.S. Swaminathan ¹¹ , "Bt, or <i>Bacillus thuringiensis</i> , is a naturally occurring bacterium that produces crystal proteins that are lethal only to insect larvae. Bt genes are lethal only in the acidic, insect gut environment and do not get activated in an alkaline environment, prevalent in humans and other animals that feed on these plants.	assessed thoroughly with regard to the GM risk assessment in Indian conditions.
Human health concerns due to pesticide use can be addressed with this transgenic Brinjal with its in-built tolerance to pests resulting in lesser use of pesticides.	Several studies in Bt crops show that there are many potential health hazards. With Bt crops, allergies have been reported. Itching skin, eruptions on the body, swollen faces, etc., have been reported, correlated with levels of exposure to Bt Cotton. Many groups ¹² are also studying the decline in fertility and milk yield of cattle due to GM Cottonseed cattle feed. Bt toxin has caused powerful immune responses and abnormal cell growth in mice. Cry proteins in Bt crops have amino acid sequence similar to known allergens and are hence potential allergens.
With this in-built tolerance against pests in Bt Brinjal, there would be substantial increase in marketable yields resulting in higher incomes for farmers. With reduced waste ¹³ , farmers could	Apprehension has been expressed that the target pest would grow resistance to the Bt toxin with time. Not enough studies on soil ecology have been done to understand the impact of Bt toxin. Farmers from various parts of the country have

¹¹ M.S. Swaminathan, 'GM: Food for thought', *The Asian Age*, 26 August 2009.
¹² Lola Nayar, 'Ubergene Cometh', *Outlook*, 10 August 2009.
¹³ Prakash Chandra, 'The vegetable war: GM crops will benefit farmers', *The Asian Age*, 22 October 2009.



Genetic engineering and its application in agriculture especially in the context of India, where majority of population depends on agriculture as a mainstay for livelihood, involves too many questions. As the Food and

¹⁴ Latha Jishnu, 'Farmers' resounding no to Bt bringal', *The Business Standard*, 22 October 2009.



Agriculture Organisation (FAO) has rightly pointed out in 2004, "Science cannot declare any technology completely risk free. Genetically engineered crops can reduce some environmental risks associated with conventional agriculture, but will also introduce new challenges that must be addressed. Society will have to decide when and where genetic engineering is safe enough". Arguments both for and against the cultivation and use of the GM crops are varied and there is a wide consensus that assessment should take place on a case-by-case basis before genetically modified food is brought to the market. These assessments should be done by Government or an independent credible regulatory authority or private agencies and these should not be driven by any commercial interests. Moreover, educating public opinion is also very important as food is always a sensitive cultural issue. Merely indicating whether a product is genetically modified or not, without providing any additional vital information, would not serve any purpose; rather information on its content and possible risks or benefits should be provided. To sum up in the words of M.S. Swaminathan¹⁵,

"GM foods have the potential to solve many of the world's hunger and malnutrition problems, and to help protect and preserve the environment by increasing yield and reducing reliance upon chemical pesticides. Yet there are many challenges ahead for governments, especially in the areas of safety testing, regulation, industrial policy and food labeling."

¹⁵ M.S. Swaminathan, 'GM: Food for thought', *The Asian Age,* 26 August 2009.



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