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INTRODUCTION

Even as India scripts an impressive growth story and is regarded as an emerging economy of some size, poverty and hunger remain widespread. India is home to the largest number of hungry people in the world and malnutrition statistics in states like Jharkhand and Madhya Pradesh are below those for Sub Saharan Africa. On the Global Hunger Index 2008 (Grebmer et al. 2008) India ranks only slightly above Bangladesh, and below several Sub-Saharan African states, such as Cameroon, Kenya, Nigeria and Sudan.
The majority of the hungry and poor people live in rural areas and are largely dependent on agriculture for their livelihoods. Despite this, agriculture remains a neglected sector , farmers are indebted , rural credit has declined over the years and in a survey done by national agencies, almost half the farmers across all states said they would stop farming if they had an alternative.

The Indian government is very much in favour of fully exploiting the potential of genetic modification and has made rather expansive plans to support this sector with commitments to upgrading infrastructure and research capacity. After the adoption of Bt cotton, India's first and so far only transgenic crop, in 2002, the results of which have been hotly debated, Bt brinjal came close to being released. A series of events including widespread protests, led to a moratorium on the release of Bt brinjal, so that India still has only one GM crop in the field.

To provide a more informed basis for consultancy in development cooperation in the sector of agriculture biotechnology , the Indian situation and specific experiences were analyzed in a study by the author, from September to October 2010 . This report contains an overview of the research in Ag biotechnology and the development status of transgenic crops in India. The report describes the Indian policy on transgenic technology and the regulatory system for genetically modified organisms and provides an insight into the relationship of GM food crops with farmers needs and food security. The report also provides an analysis of the political debate over GM crops in India and the manner in which the media has handled this subject.

CONTENTS

ABBREVIATIONS

ASEAN	Association of Southeast Asian Nations
BRAI	Biotechnology Regulatory Authority of India
Bt	*Bacillus thuringiensis*
DBT	Department of Biotechnology, Ministry of Science and Technology, Government of India
EU	European Union
GDP	Gross Domestic Product
GEAC	Genetic Engineering Approval Committee, Ministry of Environment and Forests, Government of India
GM / GMO	Genetically Modified / Genetically Modified Organism
GoI	Government of India
GSDP	Gross State Domestic Product
GSDPA	Gross State Domestic Product from Agriculture
GTZ	Deutsche Gesellschaft für Technische Zusammenarbeit
ha	hectare
ICAR	Indian Council of Agriculture Research
ICRISAT	International Crops Research Institute for the Semi-Arid Tropics
IP	Identity Preservation
IPR	Intellectual Property Rights
Mahyco	Maharashtra Hybrid Seed Company
Mio	million
NGO	Non-governmental organisation
OECD	Organisation for Economic Cooperation and Development
PIL	Public Interest Litigation
PTTC	Platform for Translational Research on Transgenic Crops
PPV-FR	Protection of Plant Varieties and Farmers Rights Act
R&D	Research and Development
UPOV	International Union for the Protection of New Varieties of Plants

Key Terms Used

Apomixis	Apomixis is a biological process which freezes' a hybrid biologically so that the advantages of hybrid vigor are perpetuated through the next generations, without segregating the way normal hybrids do.
Bacillus thuringiensis (Bt)	*Bacillus thuringiensis* (Bt) is a ubiquitous soil bacterium. Some Bt strains (*cry+*) produce a crystal protein highly toxic to larvae of certain insects. By means of genetic modification it is possible to transfer Bt genes into plants, enabling them to produce Bt toxins and thereby to be resistant against certain insects.
Biosafety assessment	Scientific case-by-case assessment of the risks to human health or the environment of a genetically modified organism or products consisting of or containing genetically modified organism before it can be released into the environment or to the market.
Coexistence	Coexistence pursues the aim to achieve segregation between GM crops and crops produced by conventional and organic farming. To ensure conventional or organic farming can sustainably coexist with GM crops technical and administrative measures must be taken to avoid contamination of non-GM crops.
Event	When scientists develop transgenic plants, plant cells are transformed with foreign genes (DNA) individually. Every cell that successfully incorporates the gene of interest represents a unique "event".
Field trials	Refers in this report to experimental trials of a genetically modified crop under field conditions.
Golden Rice	A genetically modified rice containing genes for a precursor for vitamin A.
Herbicide tolerance (HT) or herbicide resistance	A crop is made resistant to a particular herbicide through genetic modification. Herbicide tolerant crops are part of a weed control system consisting of a non-selective herbicide and a corresponding herbicide tolerant crop. Herbicide tolerance is by far the most common genetically modified trait in commercial agriculture.
Identity Preservation	A system of documenting the entire life cycle of a crop from seed to harvest to establish a track record so that the identity of a genetically modified or non-modified product can be established at all stages.
Indo-US Knowledge Initiative on Agricultural Research and Education	An agreement concluded in 2005 between the USA and India for collaboration in the field of agricultural research.
Labelling	Labelling should give consumers the freedom to

	choose between products containing GMOs and conventional products. If labelling is required, it must be indicated on a label if the product contains GMOs.
MAS	Marker Aided Selection (MAS) is a combination of molecular biology and traditional genetics which allows the selection of genes of interest by tracking the marker DNA to which the gene is linked.
Monitoring	Approval of GM varieties for environmental release is in the EU and India tied to the condition of post-release monitoring. The purpose of monitoring is to identify unforeseen effects of large-scale GMO production on the environment. It can also be used for determining if potential negative effects noticed during biosafety assessments actually cause problems.
Public Interest Litigation	This is filed as a writ petition in court, in defence of public interest when action is taken by an agency that could hurt the public interest.

SUMMARY

India has placed a heavy emphasis on agriculture biotechnology and the government sees this technology as the harbinger of a second Green Revolution, one that will bring about the same jump in food production that the original Green Revolution did. Investments in Ag biotechnology are increasing and the government is earmarking considerable funds for both infrastructure and research. In the absence of any dialogue with farmers, the real consumers of this technology, it is not clear to what extent this technology will fulfill the needs of small farmers facing an agrarian crisis.

In India research on transgenic crops is conducted in public sector, private sector and international institutions like ICRISAT. Unlike many developing countries, India has a substantial program on agriculture biotechnology in universities, as well as research institutions, funded by the Government of India. The crops which are in advanced stages of research include cotton, brinjal, chickpea, sugarcane, sorghum, groundnut, potato, tomato, papaya and watermelon. The traits being deployed include insect and disease resistance, as well as drought tolerance. The seed companies and biotechnology corporations are focusing on breeding crops for insect resistance and herbicide tolerance, using Monsanto's two proprietary genes. As a major constituent of the Golden Rice network, Indian labs were active in introgressing the Golden Rice construct into Indian varieties but this has taken a back seat after the stalemate with Syngenta over the changed terms of research.

Regulation of GM crops is done under a set of Rules framed under the Environment Protection Act, as is the case in the US. The regulatory system is slated for an overhaul that would introduce a single window clearance system instead of the multi-agency system in place today. The old regulatory framework is to be replaced by a National Biotechnology Regulatory Authority. This is being introduced through the National Biotechnology Regulatory Bill which is awaiting enactment by Parliament. Indian laws do not allow the patenting of genes or seeds and technology is accessed through licensing contracts.

There are no rules or guidelines to enable the coexistence of non-GM and GM and even if there were, it would be impossible to avoid contamination under Indian cultivation conditions. This effectively means that the adoption of GM crops is almost certain to result in contamination of non GM and organic crops. Labeling of GM foods is proposed under the Prevention of Food Adulteration Act but the provisions have not yet been implemented. However, India's position in the Codex Alimenatrius has been in support of mandatory labeling.

GM crops are not quite a political issue the way they are in Europe but the political leadership does debate it from time to time, especially when something is reported in the media. Athough some media houses have a distinct pro GM position, the Indian media has more or less reported in a balanced way about the different aspects of GM crops. Strangely enough, the views of consumers, one of the major stakeholders with respect to GM crops and foods are nearly absent in public debate.

1 THE INDIAN AGRICULTURAL SECTOR

India is the world's largest democracy and covers a vast land area of 3.3 million km^2. It is the world's second most populous country, with a population of over 1.1 billion that is growing at an annual rate of 1.4 percent. With its many languages, cultures and religions, India is highly diverse. This is also reflected in its federal political system, where power is shared between the Central Government and 28 states including 7 union territories (World Bank 2010).

The Indian terrain includes a large variation of geographic and climatic regions (see Figure 1), providing very different agricultural conditions. The main geographic regions are as follows:

- The Himalaya Mountains in the north.
- The Indus-Ganga Plains also known as the Northern Plains, a large and fertile plain encompassing most of northern and eastern India, named after the Indus and the Ganges, the twin river systems that drain it. In the north it is bordered by the abruptly rising Himalayas, which feed its numerous rivers and are the source of the fertile alluvium deposited across the region.
- Central Highlands and Deccan Plateau also called the Great Peninsular Plateau, a large plateau making up the majority of the southern part of the country, receiving only little rainfall especially in the western part.
- The desert region and the west and east coast including the mountain ranges Western and Eastern Ghats.

Figure 1: Agro-ecological zones of India

Source: www.indiawaterportal.org

The climate varies from tropical wet in the south to temperate in the north and arid in some central and southern regions. Dependency on monsoon rain has made Indian agricultural production in most parts of the country closely related to skillful water-management practices.

In the past decade, India has witnessed impressive accelerated economic growth and emerged as a global player with the world's fourth largest economy in purchasing power parity terms (World Bank 2010). However, poverty and hunger continue to be widespread in India and remain major challenges. The country accounts for nearly 50 percent of the world's hungry and about one third of the world's poor. Around 35 percent of India's population -380 million- are considered food-insecure (World Bank 2010, World Food Programme 2010). Strikingly, the majority of these hungry and poor people live in rural areas with a livelihood dedicated to crop production. Although some progress has been made, the World Bank considers that the rate of poverty reduction in India has slowed down during the last 15 years.

Indian agricultural production

India is largely dependent on agriculture with ca 20 percent of the Gross Domestic Product (GDP) coming from agriculture, forestry and fishing in 2009/2010 (GoI 2010) and the agricultural sector employing roughly two thirds of the population (see Table 1). Since independence in 1947, the share of agriculture in the GDP has declined in comparison to the growth of the industrial and services sectors. However, agriculture still provides the bulk of wage goods required by the non-agricultural sector as well as numerous raw materials for industry. Moreover, the direct share of agricultural and allied sectors in total exports is around 18 percent (Directorate of Economics and Statistics 2010). When the indirect share of agricultural products in total exports, such as cotton textiles and jute goods, is taken into account, the percentage is much higher.

The total agricultural land area in India is about 180 million hectares and divided among 105 million land holdings (see Table 1). With an average land holding size of 1.06 hectare and 88 percent of the land holdings less than 2 hectares, Indian farmers are typically small and resource poor, most of them earning hardly enough to cover their basic needs and expenditures.

Table 1: Facts on Indian agriculture and rural employment

Items	**Statistics**
Total land area	298 Mio hectare
Agricultural area	180 Mio hectare
Number of farms	105 Mio
Average farm holding size	1,06 hectare
Employment of total population divided by sectors	60 % agriculture, rural employment
	17 % industry
	23 % services
Gross Domestic Product (GDP)	1,159,170 Mio US $ in 2008
GDP composition by sector	20 % agriculture, forestry, fishing
	27 % industry
	53 % services

Sources: CIA The world fact book 2010, FAOSTAT 2010, GoI 2006, GoI India at a glance 2010, GoI Directorate of Economics and Statistics 2010, World Bank India Country Overview April 2010

Major crops include among food crops rice, wheat and pulses, among oilseed crops groundnut and sesame, among cash and export crops cotton, jute, tea, spices, sugarcane and rubber. Other sources of income for rural people include livestock raising, with buffalo milk being the highest-ranking Indian commodity in terms of value, and fishing. About 2 million people depend on coastal fisheries for their livelihood. Table 2 presents crop production in India by distribution of crop area and gives some details on the top 5 crops ranked by value.

Table 2: Crop production in India by distribution of crop area across different crops (2005-2006) and by value and quantity of top five crops (2008)

Crop	**Percentage of total agricultural area 2005-2006 (in %)**	**Production of 5 top crops in 2008***		
		Commodity	**Billion US $**	**Metric tons**
Rice	23	Paddy rice	30.2	148,260,000
Wheat	14	Wheat	11.7	78,570,200
Other cereals	15			
Pulses	12			
Fruits	2			
Total vegetables incl. onions and potatoes	3	Vegetables, fresh without onions and potatoes	5.9	31,402,000
Oilseeds (groundnut, sesame, rapeseed, mustard, linseed, others)	16			
Condiments and spices	1			
Sugarcane	2	Sugarcane	6.7	348,187,900
Cotton	5	Cotton lint	5.6	3,787,000
Other crops	7			
Total agricultural crops	100			

*Besides paddy rice, buffalo milk (30.4 billion US $) and cow milk (11.7 billion US $) rank among the 3 most important food commodities in terms of value

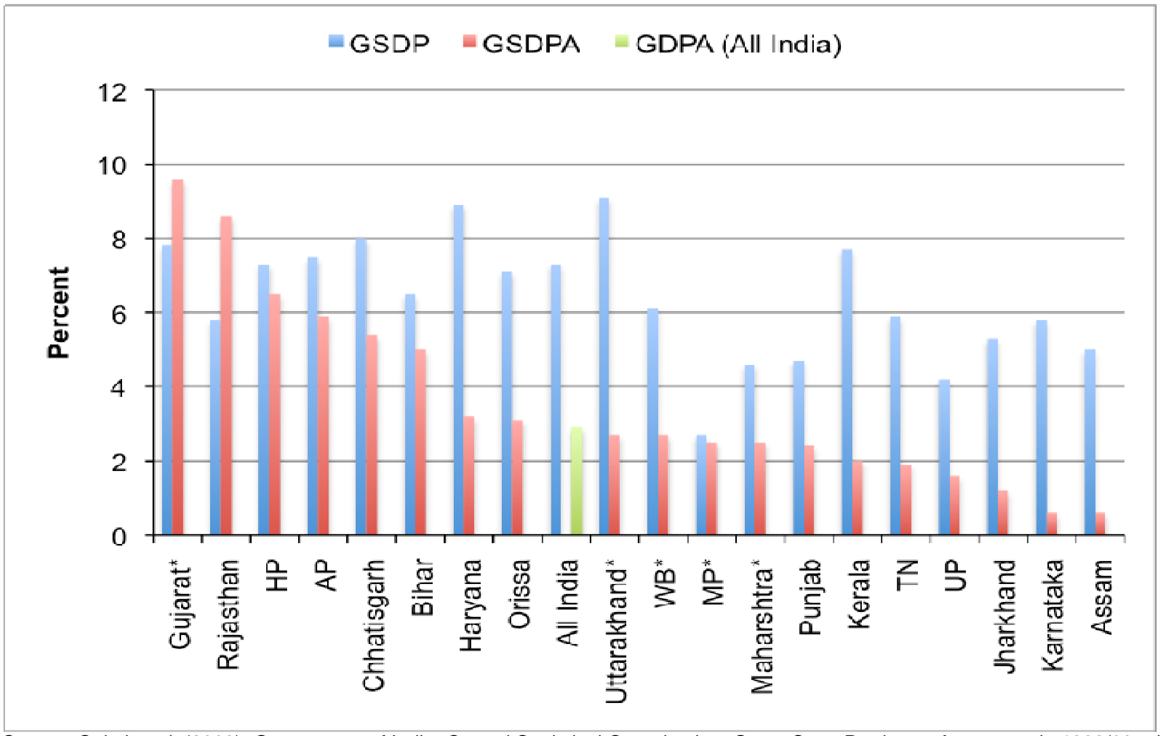
Sources: Department of Agriculture and Cooperation 2008, Land use statistics 2008 (dacnet.nic.in/eands/At_Glance_2008). FAOSTAT 2010, Food and Agricultural commodities production 2008 (http://faostat.fao.org/DesktopDefault.aspx?PageID=339&lang=en&country=100)

There are large disparities among India's states and territories in agricultural performance, only some of which can be attributed to differences in climate or initial endowments of infrastructure such as irrigation. Realising the importance of agricultural production for economic development, the Central Government has played an active role in all aspects of agricultural development. Planning is centralized, and plan priorities, policies, and resource allocations are decided at the central level. Planning by the Planning Commission, Government of India, is usually done in five-year terms, the latest plan being the Eleventh Five Year Plan (2007-2012).

Figure 2, presenting the annual growth rates of Gross State Domestic Product (GSDP) and Gross State Domestic Product from Agriculture (GSDPA) in the last decade, shows how differently growth rates in different states are developing. While Gujarat, the state with the highest agricultural growth rate of 9.6

percent, was growing three times as fast as the Indian average of 2.9 percent, three of the largest agricultural states, Uttar Pradesh, West Bengal and Maharashtra, grew below the Indian average. It also shows, that the contribution of agricultural growth to growth rates of Gross State Domestic Products varies tremendously from state to state.

Figure 2: Average annual growth rates of Gross State Domestic Product (GSDP) and Gross State Domestic Product from Agriculture (GSDPA) for major states and all India 2001/02-2007/08



Source: Gulati et al. (2009), Government of India, Central Statistical Organisation, Gross State Product at factor cost in 1999/00 prices (as of February 2009) * Average annual growth rate is from 2000/01-2006/07, the latest year for which data is available.

Food and price policy also are decided by the Central Government. Thus, although agriculture is constitutionally the responsibility of the states rather than the Central Government, the latter plays a key role in formulating policy and providing financial resources for agriculture. Because of the omnipresent risk of food shortages, the government tightly controls the grain trade, fixing minimum support and procurement prices and maintaining buffer stocks. The Food Corporation of India, a government enterprise, distributes several million tons of food grains annually under the governments public distribution system and is increasing its storage capacity.

Agricultural reform period and Green Revolution

Dependence on agricultural imports in the early 1960s convinced planners that India's growing population, as well as concerns about national independence, security, and political stability, required self-sufficiency in food production. This perception led to a program of agricultural improvement called the Intensive Agriculture District Programme (IADP) and eventually the Green Revolution, to a public distribution system, and to price supports for farmers. In the same period the National Bank for Agriculture and Rural Development (NABARD) was set up.

Under the Green Revolution the introduction of high-yielding varieties of rice and wheat after 1965, the increased use of fertilisers and pesticides, and the improvement of irrigation and education of farmers provided the increase in production needed to make India self-sufficient in food grains. Food-grain production increased from 51 million tons in 1950 to 176 Mio tons in 1990 and by the early 1990s India was self-sufficient in food-grain production. The dramatic changes of the 1960s and 1970s could not be sustained at the same rate in later years, but the total food grain production in 2009 reached 230 Mio tons (Heitzman & Worden 1995, Centre for Monitoring Indian Economy 2009).

Despite the increase in food grain production the Global Hunger Index (GHI) 2008 reveals India's continued unglamorous performance at eradicating hunger. India still ranks number 66 out of 88 developing countries and countries in transition for which the index has been calculated (Grebmer et al. 2008). All 17 major Indian states, for which the India State Hunger Index (ISHI) 2008 was constructed, scored worse than the 'low' and 'moderate' hunger categories, 12 states even fall into the severe hunger category 'alarming', and one state in the category 'extremely alarming' (Menon et al. 2009).

Agricultural trade

India is one of the fastest growing economies today. From 2003, its high growth rates of around 8 percent were surpassed only by China. It is among the world's leading agricultural producers and yet its agricultural trade flows are relatively modest compared with those of other main players on the world agricultural markets. However given the size of Indian agriculture, even small changes in its trade have a potentially large impact on world markets. India is also a major consumer, with an expanding population to feed. It is still ranked as a low-income country, with an estimated GDP/capita around US $ 1,124 in 2010 (International Monetary Fund 2010).

India has an overall trade deficit since the 1990s but has been a small net exporter of agricultural products since 1990. In 2005, its agricultural trade generated a surplus of just under 4 billions US $. Agriculture accounts for 9 percent of total exports and 5 percent of imports.

Table 3: Most important import and export commodities in 2007 ranked by value in US $

Top imports in 2007			**Top exports in 2007**		
Commodity	*Value (billion US $)*	*Quantity (tonnes)*	*Commodity*	*Value (billion US $)*	*Quantity (tonnes)*
Palm oil	1.63	3,514,900	Rice, milled	2.78	6,143,344
Peas, dry	0.67	1,738,283	Cotton lint	2.12	1,531,980
Soybean oil	0.67	1,138,892	Soybean cake	1.65	4,906,897
Wheat	0.64	1,793,209	Buffalo meat	0.86	480,429
Cashew nuts, with shell	0.41	591,329	Sugar, raw, centrifugal	0.66	2,422,203
Beans, dry	0.30	486,159	Sugar, refined	0.65	2,261,228
Fatty acids	0.23	372,834	Maize	0.59	2,727,715
Cotton lint	0.22	112,398	Cashew nuts, shelled	0.53	110,815
Rubber, dry	0.19	86,179	Tea	0.47	193,459
Pulses	0.19	351,230	Sesame seed	0.40	317,015

Source: FAOSTAT 2010, commodities by country

The European Union (EU) is India's top export market, followed by Association of Southeast Asian Nations (ASEAN), United States of America, Bangladesh and China. Commodities represent around one third of agricultural exports (EU 2007). The single biggest export commodity is milled rice, accounting for ca 20 percent of the value of exports in 2007 (Table 3). Cotton lint is the second and soybean cake the third most important export commodity, accounting for ca 15 and 12 percent of sales respectively.

ASEAN is by far the biggest supplier of agricultural products to India, accounting for a massive 40 percent of India's imports in 2003-2005. Argentine and Brazil rank second and third respectively (EU 2007). Vegetable oils account for a major part of India's agricultural imports (Table 3). Palm oil imports, mainly from Indonesia and Malaysia, represent ca 25 percent of the total imports value.

India is expected to play a bigger role in world markets in the future. It is likely to remain a small net exporter of agricultural products, consolidating its position among the world's leading exporters of rice. For sugar, India has in recent years switched from being a net importer to a net exporter (FAOSTAT 2010).

Emerging trends in Indian agriculture

In order to meet the present and future demand Indian policy makers at the central and state level are constantly making efforts to promote agricultural growth. In this connection several trends and issues are emerging on changes in agricultural production and their importance and impact is being discussed in politics (Gulati 2009):

- **Increasing role of corporate sector**

While the Green Revolution in the late 1960s was mainly driven by the government in cooperation with international research institutes like International Rice Research Institute (IRRI) and International Maize and Wheat Improvement Center (CIMMYT), the corporate sector plays an increasing role today by infusing new technologies and accessing new markets. The introduction of genetically modified cotton through the US Monsanto company and the Indian Mahyco company (Maharashtra Hybrid Seed Company) in 2002 for example, played a major role in tremendous changes in the cotton sector.

- **Structural transformation in the agri-system**

Another noticeable trend in recent years is that of a structural transformation in the agri-system. The traditional agri-system that stretches from input dealers to farmers to wholesalers, processors and retailers, has witnessed a new trend during the past 6-7 years. Major corporate firms are entering at the retail end of the system in organised food and raw material processing, as well as at input service providers at the production end.

Another new phenomenon is the exceptional rise of the organised food and grocery retail sector, which was almost non-existent a few years ago. The top 10 Indian food and grocery retailers, for example, have grown at an average rate of more than 70 percent per annum during 2002-2007.

As a consequence of these changes especially the retailers and processors feel an upcoming need to streamline supply channels and to link farms to firms. Whether these developments in the agricultural sector will benefit the Indian small holding farmers is still to be seen.

- **Spatial variation of agricultural growth**

There is a wide variation in agricultural growth across different states in India at least during the last 5-7 years (see Figure 2) and it is being discussed how the states with low growth can be stimulated. With an increasing role of the corporate firms in technology generation and diffusion it is discussed which role the government needs to play as a coordinator, facilitator and also a regulator.

2 RESEARCH ON TRANSGENIC FOOD CROPS

The Government of India (GoI) strongly feels that for India, Agbiotechnology is a powerful enabling technology that can revolutionise agriculture (DBT 2007).

India is recognized as a mega bio-diversity country and official policy aims to use agbiotechnology to convert its biological resources into economic wealth and employment opportunities.

According to the GoI, Indian agriculture faces the formidable challenge of having to produce more farm commodities for the growing human and livestock population from diminishing per capita arable land and water resources. It firmly believes that agbiotechnology has the potential to overcome this challenge to ensure the food and livelihood security of 105 million farming families in the country.

The Government of India admits that there are several social concerns that need to be addressed in order to propel the emergence of agbiotechnology innovation, such as conserving bioresources and ensuring safety of products and processes. However, despite the admission, little is done to address these concerns and civil society continues on a collision course on issues of biosafety with the biotechnology regulatory bodies as well as the Department of Biotechnology.

2.1 Current research on transgenic food crops

The program on transgenic research in India remains heavily dependent on the *Bacillus thuringiensis* (Bt) and herbicide tolerance (HT) genes available from Monsanto. Notable exceptions include the potato being transformed by Asis Datta's group in Delhi at the National Centre for Plant Genome Research using the protein synthesising '*ama*' gene from amaranth species2 and the effort by the MS Swaminathan Research Foundation in Chennai, to transform rice using salt tolerant genes from the mangrove plant *Avicennia marina* as also from plants like *Prosopis juliflora* and *Porteresia coarctata* (George & Parida 2010, Prashanth et al. 2008, Senthilkumar et al. 2005). There is also some research on virus resistance and drought tolerance (see Appendix 1 for details).

Apart from Bt cotton, which was commercially approved in 2002 as an insect resistant cotton, no other genetically modified (GM) crop has been approved for commercial use as yet. Bt eggplant (Bt brinjal) was approved in 2009 by the final regulatory body, the Genetic Engineering Approval Committee (GEAC) for commercial use but given the sensitive nature of this decision, the fact that it would be India's first GM food crop, the GEAC chose to refer the final decision to the Indian Minister of Environment and Forests, Mr. Jairam Ramesh. As it happened, the Minister decided to impose a moratorium on Bt brinjal after a series of public hearings.

GM food crops under trial (2006-2010)

GM Food crops under trial (2006 to 2010): Eggplant (brinjal), cabbage, castor, cauliflower, corn, groundnut, okra, potato, rice, tomato, chickpea, sorghum, watermelon, papaya, sugarcane, maize.

Most crops being transformed are using some form of the Bt gene to confer insect resistance. These crops include the vegetables eggplant, cabbage, cauliflower, okra, potato, as well as rice and sorghum, the latter being eaten as staple but also used as fodder, the legume chickpea, the oilseed crop castor and corn which is used as a staple food as well as for fodder and sometimes for oil.

Groundnut (for oil), water melon, papaya and tomato are being transformed for virus resistance and the herbicide tolerance trait is being introduced in corn. Groundnut and chickpea, both legumes and both crops of dryland areas, are naturally drought resistant but are nevertheless being bred for GM-induced drought tolerance. The potato is the only crop which is being engineered for enhanced nutritional content in that it is being transformed with the protein gene from amaranth species.

Details of GM crops under various stages of trial currently, both by the public and private sectors, are given in Appendix 1.These trials range from the first trial stage, biosafety research level-I to biosafety research level-II, leading to large scale trials and finally, when these are cleared, then to multi-location research trials.

Rationale of producing particular transgenic crops

The rationale of producing particular transgenic crops presented by the developers of the various GM crops is summarized below (Bhattacharya et al. 2002, Butcher 2009, GMO Compass 2010, ICRISAT 2003, Indiagminfo 2010, Monsanto 2010).

Eggplant- Insect resistant variety with cry1Ac/ cry1Aa and cry1Aabc
India is the second largest producer of eggplant in the world and eggplant is the second highest consumed vegetable. Apparently the Fruit and Shoot Borer causes up to 60-70% of loss in the range of 50-70 % in India to eggplant production. The Bt eggplant is being developed as insect resistant variety and would make plant tolerant to the fruit and shoot borers.

Cabbage- Insect resistant with cry1Ba and cry1Ca
Cabbage is an important vegetable crop grown extensively throughout the world, including India. One of the major limitations in cabbage production is considered to be damage due to insect pests. Synthetic insecticides used to control the pest have raised concerns about food safety and environmental pollution.

Castor- Insect resistant with cry1Aa and cry1Ec
India is a major producer of castor in the world with an annual production of about 0.85 million tonnes annually. The crop is grown mostly in Andhra Pradesh and Gujarat. The major problem is the attack of insect pests like the Castor Semilooper, Red Hairy Caterpillar, Capsule Borer and diseases like Wilt and Botrytis Grey Rot. On an average, the loss is over 70 percent due to these pests and diseases.

Cauliflower- Insect resistant with cry1Ac, cry1Ba and cry1Ca
An important cash crop for low income farmers throughout Asia and Africa. Lepidoptera are the most problematic pests on cauliflower. Without insecticide, damage could reach up to 90 percent.

Corn- herbicide and insect resistant cry 1 Ab, cry2Ab2, cryA.105
Traits that have been engineered into corn include resistance to herbicides and resistance to insect pests, the latter being achieved by incorporation of Bt gene.

Groundnut- virus resistant GN TSV 3, GN TSV 9, GN TSV 30, GN TSV 31, GN TSV 33, GN TSV 40, GN TSV 41, GN TSV 48, GN TSV 50, GN TSV 94, GN TSV 101; drought tolerant 166-4 (A1), 187-3-1-1 (A2) and 296-12-4-4 (A4), 475-1-6-1 (B9), 505-7-5-6 (B11), 525-10-2-3 (B14), 537-6-6-1 (B15), 526-6-1-4 (B16), ; fungal resistant RC-GN-12, RC-GN-23, RC-GN-24, RC-GN-27, RC-GN-29, RC-GN-30, RC-GN-31, RC-GN-36 and RC-GN-44 insect resistant cry1Ac, cry1F
According to the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), groundnut in India is grown on 5.7 million hectares of land with an average productivity of 0.8 tonnes per hectare, irrigation facilities being a major constraint besides fungal attack. Enhanced productivity would translate into greater foreign exchange for India, which exports groundnuts to over 60 countries.

Okra- insect resistant with cry1Ac, cry2Ab
As a major producer, India delivers more than half of the total global production of okra. Okra is susceptible to many insect pests and diseases, which reduce the yield across the okra growing regions. Okra Yellow Vein Mosaic Virus is a devastating disease in India. This crop is extensively damaged by lepidopterous insects like shoot and fruit borer.

Potato- transgenic GA 20 oxidase1 dwarf potato; disease resistance R B gene (Late Blight); reduction in cold-induced sweetening and chip colour improvement K.ChipInvRNAi-2214, K.ChipInvRNAi-2013, K.ChipInvRNAi-2311, K.ChipInvRNAi-2123,K.ChipInvRNAi-2262, K.ChipInvRNAi-2213, K.ChipInvRNAi-2015; increased protein content.
Being promoted to overcome protein deficiency in Indian population. Fungal resistance against the pathogen causing potato late blight (*Phytophtora infestans*), which affects leaves, stems and tubers.

Rice- Insect resistant with cry1B-cry1Aa , fusion gene/ cry1Ac

India is the second largest consumer of rice on the globe after China, and more than twice that of the next country, Indonesia. In India the research is focusing to develop insect resistant Bt varieties and to fight Bacterial Blight disease.

Tomato- increased lycopene *NAD9* content; virus resistant PR 38-7, PR42-1, PR55-5
Being developed for a longer shelf life.

Chickpea- drought resistance DREB1A; insect resistance *cry2Aa*
India is a major chickpea producing country. Several pests and diseases of chickpea including *Helicoverpa* pod borer, Botrytis Grey Mold, *Ascochyta* blight and Dry Root Rot need to be tackled.

Sorghum- insect resistance *cry1B*
Nearly 150 insect species have been reported to damage this crop worldwide, causing an estimated loss of more than 1,000 million US Dollars annually. Of these, Sorghum Shoot Fly, stem borers, Sorghum Midge and head bugs are the major pests worldwide. Host-plant resistance is one of the most effective means of controlling insect pests in sorghum.

Watermelon- virus resistance AMa112a-1, AMa412-20

Papaya- virus resistance TSolo4R, TSolo4Y
Being developed to provide resistance to the Papaya Ringspot Virus in India.

Sugarcane- insect resistance Co 86032-Bt-7 (B), Co 86032-Bt-8 (B)
More than half of the world's sugar is derived from sugar cane. The largest sugar cane cultivating country is Brazil, followed by India, China and Thailand. Losses due to pests and weeds are estimated at more than half of the actual yield.

Maize – insect resistance cry1F and herbicide tolerance CP4EPS
Traditionally grown for grain and fodder in India. Decreasing the harvest losses caused by insect pests is a major factor in yield improvement and stability. The most important insect pests of maize are the corn borers.

Table 4. TRANSGENIC CROPS UNDER DEVELOPMENT 2006 -2010

Public Sector Institutions		
Crop	Properties	Company
Brinjal	Insect Resistance	University of Agricultural Sciences, Bangalore
”	”	Tamil Nadu Agricultural University, Coimbatore
Cotton	”	Central Institute for Cotton Research, Nagpur
Chickpea	”	NRC for Plant Biotechnology, Indian Agricultural Research Institute (IARI), New Delhi
Sugarcane	”	Sugarcane Breeding Institute (ICAR), Coimbatore
Sorghum	”	National Research Centre for Sorghum, Hyderabad
Sorghum	Abiotic tolerance / drought resistance	Central Research Institute for Dryland Agriculture, Hyderabad
Groundnut	”	University of Agricultural Sciences, GKVK Campus, Bangalore

Potato	Transgenic dwarf potato	Central Potato Research Institute, Shimla
”	Disease Resistance (late blight	Central Potato Research Institute, Shimla
”	Reduction in cold-induced sweetening & chip colour improvement	Central Potato Research Institute, Shimla
Tomato	Virus Resistance	Indian Institute of Horticultural Research, Bangalore
Cotton	”	Central Institute for Cotton Research, Nagpur
Watermelon	”	Indian Institute of Horticultural Research, Bangalore
Papaya	”	Indian Institute of Horticultural Research, Bangalore
International Institutions		
Crop	Properties	Company
Groundnut	Fungal Resistance	ICRISAT, Hyderabad
Groundnut	Virus Resistance	ICRISAT, Hyderabad
Chickpea	Abiotic tolerance/drought resistance	ICRISAT, Hyderabad
Private Sector Institutions		
Crop	Properties	Company
Brinjal	Insect Resistance	MAHYCO, Mumbai
”	”	Sungro Seeds Research Ltd. New Delhi
”	”	Bejo Sheetal Seeds Pvt. Ltd. Jalna
Cabbage	”	Nunhems India Pvt. Ltd., Gurgaon, Haryana
Cauliflower	”	Sungro Seeds Research Ltd, New Delhi.
”	”	Nunhems India Pvt. Ltd. Haryana
Groundnut	”	Dow Agro Sciences India Pvt. Ltd. Mumbai
Okra	”	MAHYCO, Mumbai
Rice	”	MAHYCO, Mumbai
”		Bayer Bioscience Pvt. Ltd. Hyderabad
Cotton	”	Dow Agro Sciences India Pvt. Ltd., Mumbai
”	”	JK Agrigenetics Ltd
”	”	Metahelix Life Sciences, Bangalore
Corn	”	Dow Agrosciences India Pvt. Ltd.
”	”	Syngenta Biosciences Pvt. Ltd. Mumbai
Corn	Insect resistance and Herbicide tolerance	Monsanto India Ltd. Mumbai
”	”	Pioneer Overseas Corporation, New Delhi
Cotton	”	MAHYCO, Mumbai
RRF cotton	”	Maharashtra Hybrid Seeds Co. Ltd., Mumbai
Maize	”	Pioneer Overseas Corporation, Hyderabad
Hybrid rice SPT maintainer	Male sterile female inbred rice lines.	M/s. E.I. DuPont India Pvt. Ltd, Haryana

Tomato	Increased lycopene content	Avesthagen Ltd. Bangalore

See Apendix 1 for further details

The Bt Brinjal Case

Bt brinjal was developed by India's Maharashtra Hybrid Seeds Company (Mahyco) using the modified gene *Cry1Ac,* under license from Monsanto. The modified *Cry1Ac* gene, found in the soil bacterium *Bacillus thuringiensis,* along with two other supporting genes, *nptII* and *aad,* are assembled in such a way that they work to produce an artificial insecticidal protein that is toxic to the targeted insect, in this case the fruit and shoot borer. Thus the intended effect is that the fruit and shoot borer is killed after ingesting any part of the Bt brinjal plant but that other organisms such as secondary insects, animals, and humans are unaffected. Field trials which must be performed before the release of GM crops are done to evaluate (a) the effectiveness of the insecticidal properties against the targeted insect; and (b) the safety of human, animal, and environmental health upon exposure to or consumption of the modified plant containing the transgenic construct.

Confined trials of Bt brinjal were first carried out between 2002 and 2004 and the data from these trials was submitted to the Review Committee of Genetic Modification (RCGM) in April 2006. On the basis of this data, generated and reported by Mahyco, RCGM recommended that GEAC should consider granting approval for large scale field trials of Bt brinjal.

In June 2006 Mahyco submitted bio-safety data to the Genetic Engineering Approval Committee (GEAC), the statutory and regulatory body for all genetically modified technology in India, and sought permission for large scale trials. GEAC decided to create a sub committee, called the Bt Brinjal Expert Committee I (EC-I), to look into the concerns raised by civil society on the accuracy of the submitted bio-safety data along with other overriding concerns such as cross contamination of normal brinjal by genes from Bt brinjal. These civil society concerns found expression in a May 2005 Public Interest Litigation (PIL) petition filed by four activists, Aruna Rodrigues, Devinder Sharma, PV Satheesh, Rajeev Baruah (Writ Petition (Civil) No. 260 of 2005). According to their lawyer, Prashant Bhushan, the petition requested that field trials should only be allowed once “comprehensive, scientific, reliable and transparent bio-safety tests have been carried out” (Sreelata. 2006). This PIL eventually resulted in the Supreme Court issuing a ban on all GM field trials on September 22, 2006, pending scientific consensus on the risks involved with such field trials.

In July 2007 the EC-I submitted its report to GEAC, which recommended that 7 more studies on bio-safety be repeated to verify data which had been generated during the confined trials. Despite this, the EC-I gave the recommendation to go forward with large scale field trials. In August 2007 GEAC accepted this report and gave approval to begin large scale field trials. The Supreme Court subsequently lifted the ban on GM crop field trials so long as they abided by certain regulations such as isolation distance to prevent the risk of cross-breeding. As per GEAC direction, the Indian Institute of Vegetable Research (IIVR) implemented large scale trials of Bt brinjal at 10 research institutions across the country in 2007 and 11 in 2008. (Decisions taken in the 79th Meeting of the Genetic Engineering Approval Committee held on 8.8.2007. <http://moef.gov.in/divisions/csurv/geac/geac-aug-79.pdf>).

On a separate front, Gene Campaign, followed by Greenpeace, had asked under the Right to Information (RTI) Act for data to be released on toxicity and allergenicity tests conducted on Bt brinjal. The Department of Biotechnology (DBT) refused to release this data saying it was Confidential Business Information. Gene Campaign approached the Supreme Court submitting that data having a bearing on public health could not be considered Confidential Business Information. In March 2008 the Supreme Court directed the Government to release allergenicity and toxicity data obtained from Bt brinjal.

Once the field studies carried out by Mahyco were obtained by civil society organizations data from them were sent to several expert scientists for independent reviews. These reviews yielded several reports by eminent scientists which questioned Mahyco’s experiment protocols as well as their interpretation of the data collected from trials (Carman 2009, Seralini 2009, Gurian-Sherman 2009, Heinemann 2009).

One notable report was authored by Gilles Eric Seralini in January 2009 just prior to the GEAC session slated to decide on the commercialization of Bt brinjal. Seralini, a biochemist with the Institute of Basic and Applied Biology (IFBA) at the University of Caen, found numerous discrepancies in Mahyco’s reporting of statistically significant data. For example, in goats which were fed Bt brinjal, blood took longer to coagulate and the bilirubin count had increased which indicates liver damage. Other adverse reactions were found in tests conducted on rabbits, cows, chickens, and rats which were fed Bt brinjal. These ranged from decrease in liver weight to changes in red blood cell profiles. Moreover the longest toxicity test which was conducted was for a 90 day duration which is far too short to gauge the risk of long-term effects such as cancer or tumour development. The overall validity of the trials has also brought into question as Seralini reports that Bt brinjal was modified to produce an insecticide toxin containing Cry1Ab and Cry1Ac modified sequences. However, in the toxicity tests (against target and non-target insects) a different Cry1Ac toxin was used instead.

Mahyco claims they disregarded the findings mentioned by Seralini for a variety of reasons. For example, deviations which did not show a linear dose response or a time response were disregarded, as were differences which showed up in either males or females, but not both. This omission of statistically significant results is contrary to standard scientific procedures. Seralini concluded his analysis of the mammalian biosafety trials by stating, "Clear significant differences [between Bt and non-Bt brinjal] were seen that raise food safety concerns and warrant further investigation. The GM Bt brinjal cannot be considered as safe as its non GM counterpart…it should be considered as unsuitable for human and animal consumption."(Seralini. 2009).

Seralini also analyzed the environmental risks associated with the release of Bt brinjal. He characterized experiments done on the effect of Bt brinjal on non-target organisms, beneficial insects, and soil health as "woefully inadequate and give no assurances for the environmental safety of growing Bt brinjal."(Seralini.2009). This is because indirect effects are not taken into account, such as the effects of Bt brinjal as it moves up the food chain. Seralini found that the gene flow studies performed were also inadequate as they failed to assess the risks of other methods of contamination, such as through the mixing of seeds. Based on these insufficient experiments Seralini recommended that Bt brinjal not be released into the environment for field trials or commercialization.

In January 2009 the IIVR submitted the results of the large scale trials. Due to concerns raised by several stakeholders, including experts such as Seralini, GEAC decided to constitute a second sub-committee (EC-II) to look into the adequacy of biosafety data which had been submitted as well as the broader concerns raised by stakeholders. The EC-II was to be overseen by Dr. P.M. Bhargava, a retired scientist with expertise in cell biology, who had been recommended by the Supreme Court as an observer in GEAC.

On October 14th, 2009 the Bt brinjal EC-II submitted its report, dated October 8, 2009, at the 97th meeting of GEAC. GEAC accepted the report and approved the environmental release of Bt Brinjal containing the event EE1 for commercialization. However, this approval was qualified by stating, "..as this decision of the GEAC has very important policy implication at the national level, the GEAC decided its recommendation for environmental release may be put up to the Government for taking final view on the matter"(GEAC 97th Meeting. October 14, 2009).

Within 48 hours of GEAC's approval Minister of Environment and Forests, Jairam Ramesh, intervened and halted the approval for commercialization. Responding to strong views expressed both for and against the release of Bt Brinjal, he extended an invitation to the public for comments. He further said that a decision regarding Bt brinjal's release would only be made pending a nationwide consultation in January and February 2010.

From January 13th, 2010 to February 6th, 2010 seven public hearings on Bt-brinjal were organised by the Center for Environment Education (CEE) supported by the Ministry of Environment and Forests (MoE&F). These were held in Kolkata, Bhubaneshwar, Ahmedabad, Nagpur, Chandigarh, Hyderabad and Bangalore. Almost 8000 people from different sections of society participated in these seven public hearings. Participants included farmer organizations, scientists, seed suppliers, state agriculture department officials, NGOs, allopathic and ayurvedic doctors, students and housewives.

On February 9, 2010, after concluding the public hearings, Minister Ramesh announced a moratorium on the release of Bt brinjal. This, he said, was done in response not only to public concern but also significant input from national experts and the international scientific community, pressure from an active and civil society, and opposition from ten State governments, including all the major brinjal producing ones (Decision on Commercialisation of Bt-Brinjal. 2010). He said this moratorium would remain until there was further safety testing and a regulatory system specifically for genetically modified crops set in place. The Minister further said that the moratorium period would be used to commission fresh scientific studies and improve the testing process. Ramesh stated "If you need long term toxicity tests, then you must do it, no matter how long it takes… There is no hurry. There is no overriding urgency or food security argument for [release of] Bt brinjal."(Decision on Commercialisation of Bt-Brinjal. 2010). Ramesh also made clear that the moratorium period should also be used to implement a functioning independent regulatory authority and hold a parliamentary debate on private investment in agricultural biotechnology.

This decision by Ramesh was followed by a request from civil society for a report to be drawn up to further assess the EC-II report. David A Andow, an eminent scientist at the University of Minnesota, was requested to assess the EC-II report and the environmental risk assessment (ERA) of Bt brinjal. In his report Andow said that the ERA which was submitted to GEAC had a too narrow scope to adequately gauge the risks posed by the commercial release of Bt brinjal. Andow states, "the EC-II is criticized not for whether it has accomplished what it set out to do, but whether it set out to do the right thing in the first place"(Andow. 2010). Andow's main conclusion from his analysis of the EC-II report along with the original Mahyco bio-safety dossier is that the EC-II has not effectively characterized the risks associated with the release of Bt brinjal. These risks include not only environmental contamination and bio-safety hazards but also socio-economic risks to smallholder farmers which comprise a large part of Indian agriculture. Andow recommended that the risks posed by Bt brinjal need to first be adequately characterized, after which a proper risk management analysis can be performed.

At the same time that Andow was requested for an independent expert analysis, Ramesh commissioned six of India's top scientific academies (The Indian Academy of Sciences, the Indian National Academy of Engineering, The National Academy of Sciences (India), The Indian National Academy of Agricultural Sciences, and The National Academy of Medical Sciences) to more broadly assess the feasibility and safety of genetically modified (GM) crops and their regulation. The report was supposed to specifically focus on the case of Bt brinjal.

On September 24th 2010 the Inter-Academy report was released which stated that Bt brinjal's safety for human consumption had been established "adequately and beyond reasonable doubt"(Inter-academy Report on GM Crops. 2010). They supported the quick release of Bt brinjal at limited sites across the country provided that distance and isolation requirements were maintained. Countering the findings of Seralini and Andow, the Inter-academy Report said that environmental risks associated with Bt brinjal were "negligible" and that there would be "no appreciable effect of GM crops on biodiversity." However, the Inter-academy Report quickly became embroiled in scandal as proven allegations of plagiarism and blatant pro-GM biases surfaced within days of the report's release. (India Today. September 26, 2010. Indian Express. September 26, 2010)

By September 27, 2010, this report had been dismissed as unscientific and overtly influenced by pro-GM thinkers by not only civil society and activist groups but by Minister Ramesh, himself. It was found that significant sections of the text were plagiarised from an article published in 'Biotech News' magazine and authored by Dr. Ananda Kumar, a scientist who heads the National Research Centre on Plant Biotechnology. The report did not contain proper references and was criticized for using an unscientific tone rife with generalizations and clichés. Minister Ramesh dismissed the report and stated that it did not "appear to be the product of rigorous scientific evaluation." (Indian Express. September 28, 2010)

The poor quality of the Inter-Academy report and the Minister's response to it has further confused the matter of Bt brinjal in India. As it stands today, the moratorium on Bt brinjal continues.

Research on Golden Rice

Golden Rice is a genetically modified rice primarily developed for use in South- and South-East Asia to address the lack of Vitamin A in overwhelming rice diets. The name "GoldenRice" is due to the rice grains showing a pale yellow color owing to the presence of beta-carotene, a precursor of Vitamin A. Golden Rice was developed by a joint research effort of the Swiss Federal Institute of Technology (ETH-Zurich) and the University of Freiburg,Germany. The research was supported by the Rockefeller Foundation and the European Community Biotechnology Program. The research team first engineered a "japonica" variety of rice because the transformation systems were established for this variety, later indica varieties were transformed as well.

Syngenta Corporation which owns the technology of Golden Rice decided to set up a Humanitarian Board to give the Golden Rice genetic material to developing countries for free, to cross with their own varieties to produce varieties suited to local conditions. The Humanitarian Board had originally declared that countries would do their own research using the genetic material of Golden Rice and that the locally developed varieties would be made available to small farmers free of charge. These varieties would become their property and they could use and reuse seed for further plantings according to prevailing custom. Big farmers on the other hand, would be able to cultivate Golden Rice only after paying a license fee.

A few years ago, Syngenta changed the terms according to which the genetic material of Golden Rice could be used by researchers, ignoring the earlier conditions set up by the Humanitarian Board. Syngenta now has much greater control over the technology after new contracts were signed with all research institutions that were involved in Golden Rice research.

Syngenta has now laid down stringent conditions, which do not allow researcher partners the freedom to operate, as was negotiated earlier. Research partners for example, have now lost the flexibility to design their research according to the methods established in their laboratories. They are allowed to do genetic transformation only by using the Agrobacterium method. The new contract demands that only those Golden Rice lines that have been transformed by Syngenta can be used further by breeders/researchers. The Humanitarian Board has demanded in addition, that all existing transgenic lines developed individually by the different research laboratories so far have to be destroyed. Regrettably, partner institutions have complied with this. (Sahai 2004)

After the first phase of research on Golden Rice, the levels of beta carotene were fairly low, causing justifiable skepticism about the utility of the product. It was clear that for Golden Rice to contribute to alleviating vitamin A deficiency, the beta carotene content would have to be increased. The second phase of research by Paine et al (2005) achieved the objective of increasing the beta carotene content. The scientists identified a psy gene from maize that substantially increased carotenoid accumulation in a model plant system. The research group went on to develop 'Golden Rice 2' introducing this psy gene in combination with the Erwinia uredovora carotene desaturase (crtl) gene used to generate the original Golden Rice. This led to an increase in total carotenoids of up to a maximum of 37 µg/g, with a preferential accumulation of beta-carotene.

In wild type-rice endosperm, carotenoid biosynthesis is blocked by both phytoene synthase and carotene desaturase, which are provided by the daffodil psy and crtI transgenes in Golden Rice. All tissues that accumulate high levels of carotenoid have a mechanism for carotenoid sequestration including crystallization, oil deposition, membrane proliferation or protein-lipid sequestration. The non carotene starchy rice endosperm is very low in lipid and apparently lacks any means to facilitate carotenoid deposition. (Paine et al 2005)

Golden Rice Network

The Golden Rice Network that was set up originally is coordinated by Dr. Gerard Barry of the International Rice Research Institute (IRRI), Philippines. Other partners are the Philippines Rice Research Institute (PhilRice); Cuu Long Delta Rice Research Institute, Vietnam; Department of Biotechnology, Directorate of Rice Research, Indian Agricultural Research Institute, University of Delhi South Campus, Tamil Nadu Agricultural University, Agricultural University, Pantnagar and University of Agricultural Sciences, Bangalore, all in India; Chinsurah Rice Research Station and Bangladesh Rice Research Institute in Bangladesh; Huazhong Agricultural University, Chinese Academy of Science, Yunnan Academy of Agricultural Sciences, in China, and the Indonesia Agency for Agricultural Research and Development in Jakarta.

Indian Network on Golden Rice

The Indian Network on Golden Rice is funded by the DBT and coordinated by Dr. S.R. Rao, Adviser, Department of Biotechnology (DBT) . The network now consists of just three centers namely, Indian Agriculture Research Institute (IARI), New Delhi, Directorate of Rice Research (DRR), Hyderabad and Tamil Nadu Agriculture University , Coimbatore. The first phase of the project started in 2002 and the second phase in 2006.

The objective of scientists working in the network is to introgress the Beta carotene synthesis pathway genes (*Psy and CrtI*) from transgenic Golden Rice lines into Indian rice varieties Swarna (IARI), MTU 1010 (Cottondora Sannalu), Improved Sambha Mahsuri (DRR), ADT43 and ASAD 16 (TNAU).

The transgenic donor:
Six transgenic events in the background of an American long grain *javanica* rice variety Kaybonnet were developed through *Agrobacterium* mediated transformation by Syngenta and made available to the Indian Network through Humanitarian Board on Golden Rice (HumBo). These events, initially known as SGR-2 and now as GR-2, carry *Psy* gene from maize and *CrtI* gene from *Erwinia erodovora,* a soil bacterium and have a total carotenoid level ranging from 11-25µg/g of endosperm. After detailed analysis on event selection, one of the six events namely, GR2-R was chosen as a donor for backcross breeding. Marker assisted backcross breeding using foreground selection for the transgene and background selection for recovery of recurrent parent genome, was done.

Selecting recurrent parents:
In a meeting on Biofortification, held at the MS Swaminathan Research Foundation (MSSRF), Chennai , the issue regarding the choice of recurrent parents for backcross breeding was discussed and based on considerations like breeder seed indent, prevalence of Vitamin A Deficiency (VAD) and varieties grown in the areas having VAD, rice varieties were selected and assigned to different partners

Initially, among the Indian partners, IARI received the GR-2 events first and the other partners got the material only recently. At IARI, 10 BC_2F_3 lines homozygous for the transgene and 41 BC_2F_3 lines hemizygous for the transgene, having up to 94% recovery of recurrent parent (Swarna) genome have been developed and these lines were evaluated during *Kharif* 2010 under containment. Some of these lines are very similar to Swarna in their agronomic performance; these lines are now being evaluated for carotenoid content. Crosses of these lines have been made with Swarna sub-1, to incorporate submergence tolerance in these lines. In addition, BC_3F_1 seeds in Swarna background have also been produced. Both at DRR and TNAU, BC_1F_1 generation in the genetic background of varieties assigned to respective centers (DRR-MTU 1010 and Improved Sambha Mahsuri, TNAU-ADT43 and ASD16), is currently available. In addition, several advanced backcross derived lines (BC_3F_3) in the genetic background of IR 64 and IR 36, developed by IRRI using GR-2 R event as donor, have been made available to the Indian Network for further evaluation. (Parida 2010, personal communication)

Golden Rice and IPR

Golden Rice is a good example of how a genetically engineered product can become tangled in a web of Intellectual Property Rights (IPRs) belonging to diverse agencies. Once Golden Rice took the shape of a product that could be distributed, this tangle of IPRs had to be sorted out before the product could reach farmers fields. The most relevant IPRs found associated with Golden Rice were 15 Technical Property (TP) claims and 70 patents owned by 31 agencies. In a detailed analysis, Kowalski (2002) has examined the four major components of IPR related to Golden Rice. These are;

1. The seed source which is a japonica rice variety;
2. Gene construct parts like cloning vectors and plant transformation vectors
3. The process of genetic engineering which in this case is Agrobacterium-mediated as well as tissue culture, plantlet regeneration and other techniques;
4.The polymerase chain reaction (PCR) to amplify DNA and the"Taq" polymerase enzyme that catalyzes this reaction.

To give an idea of the complexity of the IPRs that had to be managed in the case of Golden Rice, let us consider just one example, the plant transformation vector pBin19hpc. This vector is a complex construct, with numerous subcomponents. These include the plant gene promoter CaMV35S; the seed endosperm specific gene promoter Gt1; the selectable marker nptII (kanamycin resistance); the pea Rubisco small subunit transit peptide (DNA); the selectable marker aphIV (hygromycin resistance); the carotenoid biosynthetic gene psy (phytoene synthase); the carotenoid biosynthetic gene crtI (phytoene desaturase); Agrobacterium-mediated transformation; and cotransformation technology (taken from Kawolski 2002). Each of these components could have an IP or TP right attached to it with the potential to constrain the deployment of Golden Rice.

Kowalski also analyses four types of uncertainty that could contribute to further IPR complications.

1. *Original & subsequent patent holders* – In the case of Golden Rice, thirty-one patent holders were tentatively identified initially. However, since biotech companies have constantly been in a state of flux, it has not always been easy to figure out which company had the right to grant licenses for a particular product or process at any given time. As companies re-structure, sell/assign patents, or grant licenses,(with or without the right to sub-license) the degree of uncertainty increases.

2. *Absence of Material Transfer Agreements (MTA) for the Technical Property (TP).* The absence of an MTA for a specific TP component does not necessary mean that component can be freely used. Researchers often overlook technology transfer processes especially since IPR conditionalities are new and scientists, particularly those in the public sector have long exchanged TP components like the plasmid construct, gene promoters, antibodies etc freely with one another. In the post WTO IPR climate, every such instance of free and open sharing of research materials could land the researcher in problems if MTAs have not been executed, since these are likely to be registered as TPs.

3. *Cross border issues.* The potential impact of Golden Rice crossing national boundaries adds another complication to the Intellectual Property (IP) landscape. In the case of the US, if a product is made outside the US using an unlicensed U.S. patented process, U.S. law prohibits the re-entry of such products. As the IP landscape evolves biotechnology IPRs involved in trade of biotech products will need to be tracked.

4. *Current and future IPR Scenarios* – In the case of Golden Rice, it came up that since most of the IPR involved was not protected in the majority of the developing world where it is to be distributed. Negotiating IPR licenses or MTA was not an issue. (Binenbaum 2000)

However, while this may be true in some cases today, given the speed with which IP regimes are changing, the situation regarding valid IPR in different countries is likely to become an impediment to the deployment of Golden Rice.

Freedom to Operate (FTO)

Given all this, how does one create a situation, wherein the development and distribution of agri-biotech products such as Golden Rice could be facilitated? What could be the mechanisms that provide “Freedom to Operate” in the face of such patent thickets?

Legal researchers have proposed a series of options that would allow agencies to navigate through patent thickets.

1. *Inventing Around*: in some cases existing patents can be circumvented by an alternative research approach, using different genes with similar functions.

2. *Re-Design Constructs:* the genetic constructs can be redesigned to avoid or minimize using the number of patented products and processes. This could mean using different markers or promoters. This option has the potential to reduce the number of TP involved since many genes can be synthesized at low cost and plasmids available in the public domain can be used.

3. *Convincing IP/TP owners to relinquish claims:* All right holders could theoretically relinquish their rights over components involved in producing the agbiotech product. This could happen through royalty free licenses or agreements or indemnity clauses which would relieve right holders from any liabilities that might result from using or selling the product by the recipient. In case of Golden Rice with multiple shareholders, this option would still include substantial Freedom to Operate negotiations in each country where the product is to be used.

4. *Ignore all IP/TP* rights and go ahead with producing the product. This low cost option involves some risk depending on the degree of enforcement that individual property right holders decide to exercise. Attractive as this option is, executing it could jeopardize any future collaboration with the IP holders.

5. *Acquire licenses for all IP/TP involved:* This licensing approach would require all IP/TP right holders to be identified and individual contracts negotiated, which requires substantial management effort and

expense. This model has the attraction of being most effective in terms of capacity building among the licensees for future work, specially if the transfer of rights is accompanied by transfer of know-how.

6. *A mix of all options listed above.* This represents a comprehensive and pragmatic, approach to obtaining full FTO for Golden Rice or any other agbiotech product. Taking advantage of the many available options grants flexibility and makes this the most effective route for the distribution of products like Golden Rice which have a slew of IPRs and TP claims associated with them. This approach still requires that all concerned parties understand and accept the issues that are involved. (taken from Kryder et al 2000)

2.2 Regulation of GM crops

Regulation of GM crops in India is done through the Environment Protection Act [1986]'s 1989 Rules (Ministry of Environment and Forestry 1989-http://dbtbiosafety.nic.in/act/ Annex-4.Htm). These rules are called the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-Organisms, Genetically Engineered Organisms or Cells.

Competent Authorities under the Rules of 1989 are the following:

(1) Recombinant DNA Advisory Committee (RDAC)

This committee shall review developments in biotechnology at national and international levels and shall recommend suitable and appropriate safety regulations for India in recombinant research, use and applications from time to time. The committee shall function in the Department of Biotechnology.

(2) Review Committee on Genetic Manipulation (RCGM).

This committee shall function in the Department of Biotechnology to monitor the safety related aspect in respect of on-going research projects and activities involving genetically engineered organisms/hazardous microorganisms. The Review Committee on Genetic Manipulation shall include representatives of (a) Department of Biotechnology, (b) Indian Council of Medical Research, (c) Indian Council of Agricultural Research, (d) Council of Scientific and Industrial Research, (e) other experts in their individual capacity. Review Committee on Genetic Manipulation may appoint sub groups.

It shall bring out manuals of guidelines specifying procedure for regulatory process with respect to activities involving genetically engineered organisms in research use and applications including industry with a view to ensure environmental safety. All ongoing projects involving high-risk category and controlled field experiments shall be reviewed to ensure that adequate precautions and containment conditions are followed as per the guidelines.
The Review Committee on Genetic Manipulation shall lay down procedures restricting or prohibiting production sale importation and use of such genetically engineered organisms of cells as are mentioned in the schedule.

(3) Institutional Biosafety Committee (IBSC).
This committee shall be constituted by an occupier or any person including research institutions handling microorganisms/genetically engineered organisms. The committee shall comprise the head of the institution, scientists engaged in DNA work, a medical expert and a nominee of the Department of Biotechology. The occupier or any person including research institutions having microorganisms/genetically engineered organisms shall prepare for the assistance of the Institutional Biosafety Committee (IBSC) an up-to-date on-site emergency plan according to the manuals/guidelines of the Review Committee on Genetic Manipulation (RCGM) and make available copies to the District Level Committee/State Biotechnology Coordinating Committee and the Genetic Engineering Approval Committee.

(4) Genetic Engineering Approval Committee (GEAC)

This committee shall function as a body under the Department of Environment Forests and Wildlife for approval of activities involving large scale use of hazardous microorganisms and recombinants in research and industrial production. The Committee shall also be responsible for approval of proposals relating to release of genetically engineered organisms and products into the environment including experiment field trials.

The composition of the Committee shall be

(i) Chairman-Additional Secretary Department of Environment Forests and Wild life
Co-Chairman Representative of Department of Bio-technology

(ii) Members: Representatives of concerned Agencies and departments namely Ministry of Industrial Development, Department of Biotechnology and the Department of Atomic Energy.

(iii) Expert members: Director General-Indian Council of Agricultural Research, Director General-Indian Council of Medical Research, Director General-Council of Scientific and Industrial Research, Director General Health Services, Plant Protection Adviser, Directorate of Plant Protection, Quarantine and storage, Chairman, Central Pollution Control Board and three outside experts in individual capacity.

(iv) Member Secretary: An official of the Department of Environment, Forest and Wildlife.

The Committee may co-opt other members/experts as necessary.

The committee or any person/s authorized by it shall have powers to take punitive actions under the Environment (Protection) Act.

(5) State Biotechnology Co-ordination Committee (SBCC).

There shall be a State Biotechnology Coordination Committee in the states wherever necessary. It shall have powers to inspect, investigate and take punitive action in case of violations of statutory provisions through the Nodal Department and the State Pollution Control Board/Directorate of Health/Medical Services. The Committee shall review periodically the safety and control measures in the various industries/institutions handling genetically engineered organisms/hazardous microorganisms.

(6) District Level Committee (DLC)

There shall be a District Level Biotechnology Committee (DLC) in the districts wherever necessary under the District Collectors to monitor the safety regulations in installations engaged in the use of genetically modified organisms/ hazardous microorganisms and its applications in the environment.

The District Level Committee/or any other person/s authorized in this behalf shall visit the installation engaged in activity involving genetically engineered organisms, hazardous microorganisms, formulate information chart, find out hazards and risks associated with each of these installations and coordinate activities with a view to meeting any emergency. They shall also prepare an off-site emergency plan. The District Level Committee shall regularly submit its report to the State Biotechnology Co-ordination Committee/Genetic Engineering Approval Committee.

Comment

The Genetic Engineering Approval Committee (GEAC) has been authorized as the inter-ministerial body under the Indian Ministry of Environment and Forests to be the authority to permit any manufacture, use, import, export and storage of hazardous microorganisms and genetically modified organisms or cells. In practice, it is the Review Committee on Genetic Manipulation (RCGM) under the Department of Biotechnology that is currently authorizing research up to limited field trials and also imports of GM material for research purposes.

In addition to these rules, guidelines have been prepared by the regulators for the actual experimentation and release. There are specific formats prescribed for various applications for GM imports and use to be received by the regulators.

Under the Indian Ministry of Health, the Indian Council of Medical Research (ICMR) stated its own views on the regulatory regime and the way ahead for genetically modified foods in the country (Indian Council of

Medical Research 2004). The Indian Council of Medical Research view is that the safety assessment of GM foods should be as per Codex Alimentarius (India follows OECD guidelines for most tests under safety assessment as of now).

2.2.1 The Biotechnology Regulatory Authority of India Bill, 2009

The Government of India (GoI) has responded to demands from the seed and pharmaceutical industry to make regulation of Genetically Modified Organisms (GMOs) simpler and to set up a single window clearance facility in place of the multi agency regulatory system in place today.

In 2008, the Government of India decided to replace the current regulatory regime by introducing a bill known as the National Biotechnology Regulatory Authority of India Bill. Under the bill, the Central Government proposes to set up a Biotechnology Regulatory Authority to act as a single window fast track window clearance body.

The bill was heavily criticized by scientists and civil society on the grounds of being vague and incoherent. This led to a subsequent bill known as the Biotechnology Regulatory Authority of India Bill ("Bill") being introduced in 2009 by the Central Government. However, the new Bill still does not address the major concern regarding the environmental and health impacts of genetically modified crops. The Bill is likely to be tabled anytime soon in Parliament and is being vehemently opposed by activists and scientists alike.

The Bill is structurally flawed as it proposes the creation of too many authorities without prescribing or defining the functions and powers of each authority or advisory board. The Bill proposes the setting up of the Biotechnology Regulatory Authority of India (BRAI) as the main authority to regulate the research, transport, import, manufacture and use of organisms and products of modern biotechnology in order to promote the safe use of modern biotechnology. However, the BRAI has been empowered to constitute and set up other authorities/advisory boards to assist it in discharging its functions. But the roles of the advisory bodies constituted under the Bill are undefined and unclear leading to confusion and a complete lack of responsibility and accountability. It has merely been stipulated that the functions of the Advisory Boards may be 'as may be prescribed'. Therefore, it is clear that there is no clarity on either the functions of the various Advisory Boards or where their functions will be prescribed and who will prescribe them.

The Bill further adds to the confusion by empowering the BRAI to provide scientific advice and technical support to the Central Government and State Government and to constitute one or more scientific advisory panels to provide scientific advice, information and recommendations on biotechnology issues. The reason for assigning the power to provide scientific advice to the BRAI and for empowering the BRAI to constitute another scientific advisory panel is not clear in light of the fact that the Advisory Boards have been created for the same purpose. There is so much overlapping of the functions and roles that there is utter confusion in the way the authorities/advisory boards have been constructed and a complete lack of understanding of the functions and responsibilities of each authority.

Further, even the functions of the BRAI have not been enumerated properly and clearly in the Bill. It has merely been stated that the function is to regulate, transport, import, manufacture and use of organisms and products of modern biotechnology in order to promote the safe use of modern biotechnology. But what measures will be taken into consideration by the BRAI to regulate has not been mentioned anywhere in the proposed Bill. The Bill only mentions the fact that the measures will be enumerated in the regulations (which have still not been framed). Thus, the BRAI has been vested with complete discretion and unfettered powers which may lead to arbitrary action by the BRAI.

The Bill attempts to stifle dissent and any form of opposition. Section 63 is a draconian provision which provides for imprisonment for anybody who tries to mislead the public about the safety of the organisms and products. This is a completely unconstitutional attempt to prevent activists, farmers and other public interest groups from voicing any form of dissent or disapproval. The concerns regarding this section were raised when the earlier bill was introduced, however, the concerns have still not been addressed and taken into account. The provision will be used as a tool to harass activists and members of public interest groups to prevent them from critiquing and voicing dissent. Such a provision has no place in a democratic society and it goes completely against the constitutional provisions.

Another area of concern is the attempt to restrict the scope of the Right to Information Act and curb transparency. Section 27 states that in case the application under section 24 or section 26 requires the disclosure of confidential commercial information, such information shall be retained as confidential, notwithstanding the provisions of the Right to Information Act, 2005. Though Section 27 relates only to confidential commercial information but the problem arises due to the fact that the term confidential information has not been defined and could encompass all types of information. The term confidential commercial information should be clearly defined and restricted to include only that information which relates to the innovative component. It cannot include information, which has a bearing on the environment, an impact on human or animal health or a socio-economic impact.

For instance when Gene Campaign and Greenpeace asked three years ago under the Right to Information Act, for data on allergenicity and toxicity tests conducted on Bt eggplant, the Department of Biotechnology refused to provide the information saying it was the confidential information of the company and could not be released. Data that could have implications for public health was being treated as proprietary information by the regulatory agency. It was only after an appeal to the Supreme Court under Gene Campaign's ongoing (since 2004) writ petition in the Supreme Court 16, that the Court directed the Government to provide the information (Gene Campaign 2004).

Similarly, the Bill does not provide for public participation. There is no provision in the Bill, which requires the BRAI to hold discussions/consultations with stakeholders and affected members of society before granting authorization. This goes against the current climate of consultations and participatory policy formulation of does not provide for any comprehensive debate and discussion on the proposals and involvement of the primary stakeholders. This omission shows that the Bill has been framed keeping in mind only the interests of the agencies interested in promoting genetically modified products and not farmers, consumers or the society at large. It is clear that the Bill has been framed to appease the biotechnology industry at the expense of the security, health and environment of the nation. The State Governments have also been completely left out of the decision making process and have been assigned a mere advisory role allowed for State Governments in decision making and therefore it completely ignores the interest of the State Governments.

Interestingly, the Bill gives the Central Government the power to supersede the BRAI for a period not exceeding six months. This power is completely unacceptable and should be deleted. Further, the Central Government has been given the power to issue directions on the question of policy, other than those relating to technical and administrative matters and the authority is bound by the said direction. This provision seeks to defeat the purpose of the law by encroaching on the independence of the BRAI. The BRAI is a scientific body dealing with technical issues and the Central Government does not have the expertise to give directions to the BRAI.

The Central Government has been given sweeping powers to override the other existing regulations. This should not be permitted and the provisions of the Bill should be in addition to and not in derogation of the existing laws. The Central Government has also been granted the power to amend the first schedule after consultation with the BRAI. This is totally unacceptable and must be deleted. If the Central Government proposes to undertake any changes in the first schedule, it should only do so after a broader consultation is undertaken by the BRAI.
The composition of the BRAI is also flawed. It only comprises of members from the scientific community. There is no representation from members of the farming community, women or other public interest groups. This needs to be rectified to ensure that the BRAI is broad-based comprising of experts from diverse fields, representative of the farming community, with adequate representation of women and public interest groups. Another major lacuna in the Bill is that even if there is a defect in the constitution of the BRAI, the proceedings initiated by the BRAI shall not be invalidated. This provision is liable to be greatly misused/abused as it can result in the authority being run by a single member. This should not be allowed as the BRAI is a technical body performing important functions and such a provision leaves much space for unscientific, undemocratic and corrupt functioning with very little checks and balances.

The penal provisions provided for in the Bill are very weak. The focus of the Bill does not seem to be risk management, but ensuring greater latitude for the agencies promoting genetically manufactured products. The penal provisions have been laid down in chapter XIII of the Bill. The complaint provision of the Bill is completely flawed and baseless. As per section 70, cognizance of the offence can be taken only on the basis of a complaint made by the BRAI or any person or officer authorized by it. It does not provide for any mechanism for a private individual to file a complaint. Therefore if the offence is committed by a government department, the BRAI may not file any complaint. This provision is completely against the grain of a liability regime as there is absolutely no mechanism to redress an offence committed by a government department. Considering the fact that some of genetically manufactured products are promoted by government departments, such an omission raises important questions on the objectivity of the liability provisions. Further, there are no penal provisions provided for concealment of information on the safety/health hazards of the products. The Bill neither provides for any revocation of authorization or measures for providing compensation nor does it provide for any measures to provide for post-authorization surveillance of the products. The enforcement provisions laid down in the Bill are weak and not at all satisfactory. The enforcement of the provisions of the Bill have been given to the monitoring officers (who are to be appointed by the BRAI). The functions and powers of the monitoring officer have been provided under section 38 and 39 respectively. But as has been seen in the previous sections, no specific guidelines have been provided defining the parameters of the monitoring. Secondly, there is no provision for any penalty to be imposed on the monitoring officer in the event they fail to discharge their duties.

There are other provisions in the proposed Bill, which are also of concern. As per the Bill the BRAI is required to constitute a Risk Assessment Unit to undertake a science based assessment. However, as like in the previous provisions of the Bill the manner in which the assessment is to be carried out has not been specified. It has merely been stated that the manner of assessment will be specified in the regulations. There is also utter confusion in some of the provisions of the Bill. The provisions given in section 24 (2) (a) to(c) are repetitions as the same provisions have also been given in section 26 (4) (a) to (c). There is also apparent conflict between the two sections. Section 24, lays down the procedure for obtaining the authorization for the research, transport or import of organisms and products as specified in parts I, II and III of schedule I. It is provided that after the report of the risk assessment unit is submitted to the BRAI, who will then take a decision after considering all other relevant matters in addition to the assessment report. Whereas section 26 lays down the procedure for grant of authorization for manufacture or use of organism and products. The section provides that the evaluation of the application by the risk assessment unit shall be forwarded by the BRAI to the product ruling committee to look into all the relevant matters. There are no guidelines prescribed in the Bill on the basis of which the BRAI or the product ruling committee are required to determine the relevant factors and there is also no clarity on the rationale behind segregating the two application procedures.

The provisions of the Bill need to be amended to rectify the above flaws and to ensure that the focus of the Bill is not appeasement of the biotechnology industry, but the protection and conservation of biodiversity, environment, health and farmers right to livelihood. For detailed suggestions on improving the draft law, see Appendix 2.

2.3 Intellectual Property Rights framework

The relevant Intellectual Property Rights (IPR) laws governing the field of genetically modified organism are the Patent (Amendment) Act, 200517 and the Protection of Plant Varieties and Farmers Rights Act, 2001 (PPV-FR) (Patents (Amendment) Act 2005, Protection of Plant Varieties and Farmers’ Rights Act 2001).

Indian law does not allow the patenting of plant varieties. According to the PPV-FR, plant varieties can be protected by the breeder by Breeders Rights. The Breeders Rights for plant varieties is valid for 15 years, and for trees it is valid for 18 years. Farmers also have rights, principally, the right to save seed from their harvest to plant the next crop. Farmers Rights goes beyond this, it allows the farmer to sell seed obtained from the harvest of a crop planted with a breeder certified seed, provided the seed is not branded and is not sold commercially. This clause has caused concern in the seed industry but it has been included to allow local farmers to access seed from their neighbours if they have lost their own seed. Restricting the right of the farmer to sell such seed ensures the rights of the plant breeder who in any case has complete control over all commercial transactions and over import and export of the plant variety that is protected by a Breeders Right.

According to the Patent Act, plants, animals and parts thereof, excluding mircroorganisms, cannot be patented. Microorganisms can be patented. Parts of plants and animals also means genes, genetic sequences and other DNA material, which cannot be patented according to the law. However, there are reports that lawyers representing the biotech industry and the GM seed industry are presenting the case that genes are products and since the patent law allows products to be patented, genes should be patentable subject matter. There is considerable pressure from the USA through the Indo-US Knowledge Initiative on Agricultural Research and Education to enable gene patents and either stronger Breeders Rights conforming to International Union for the Protection of New Varieties of Plants (UPOV) 1991 or patents on plant varieties. The EU is asking for Trade-Related Aspects of Intellectual Property Rights (TRIPS) plus conditions like compliance with UPOV 1991, in bilateral free trade agreements.

2.4 Funding for GM research

Currently, In India seven major agencies fund research in biotechnology, the bulk of which is in agbiotech. These are:

• Department of Biotechnology (DBT)
• Department of Science and Technology (DST)
• Indian Council of Agriculture Research (ICAR)
• Indian Council of Medical Research (ICMR)
• University Grants Commissions (UGC)
• Department of Scientific and Industrial Research (DSIR)
* Council of Scientific and Industrial Research (CSIR)

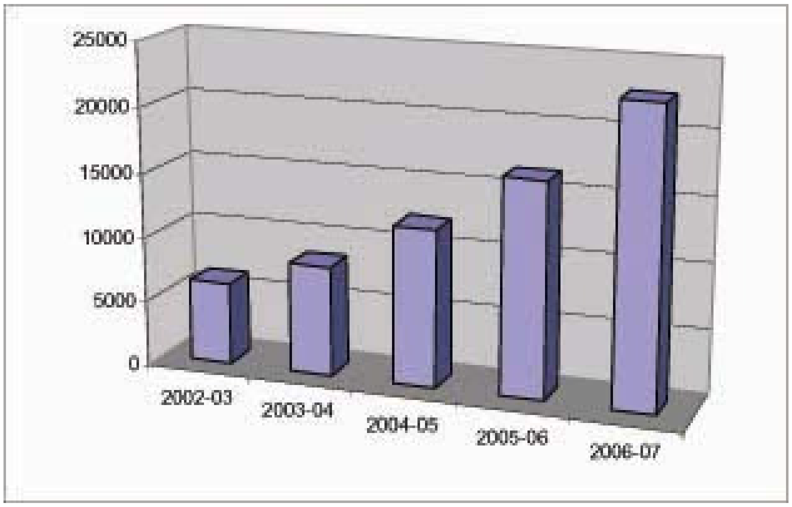
DBT, DST and DSIR are part of the Ministry of Science and Technology, while ICMR is with the Ministry of Health, ICAR with the Ministry of Agriculture and UGC with the Ministry of Human Resource Development. Their funding for selected years is given in Table 5.

Table 5: Budget Allocations of Major Biotechnology Funding Agencies in India (million USD)

Agency	1990-91	2000- 01	2002- 03	2003- 04	2004- 05
Department of Biotechnology (DBT)	135	160	267	293	358
Indian Council of Agriculture Research (ICAR)	667	1647	1667	1615	1934
University Grants Commissions (UGC)	720	1656	1774	1749	1832
Department of Scientific and Industrial Research (DSIR)	511	1142	1180	1219	1439
Department of Science and Technology (DST)	533	918	1150	1262	1420
Council of Scientific and Industrial Research (CSIR)	484	1073	1145	1184	1399
Indian Council of Medical Research (ICMR)	80	173	185	179	197
Total	3133	6768	7368	7501	8579

Source: Chaturvedi (2006).

Figure 3: Investment in Biotech Industry, 2002-07 (INR million)



Source: Gupta (2007).

The Department of Biotechnology supported the establishment of seven Centres for Plant Molecular Biology throughout the country. Today, there are about 50 public research units in India using tools of modern biotechnology for agriculture, especially techniques for cell and tissue culture. The Indian government allocates an estimated US$15 million annually on plant biotechnology research, while the private sector contributes about US$10 million (Huang, Rozelle, Pray, & Wang, 2002).

Monsanto has provided a research grant to the Indian Institute of Science in Bangalore, a move that was widely criticized specially since the Indian Institute of Science is a well-funded institute and did not need supporting funds. The critics were apprehensive that such funding support would lead to the corporatisation of research as has happened elsewhere when corporate money has been invested in public sector institutions, including international research organizations like those of the Consultative Group on International Agricultural Research (CGIAR).

In addition to direct funding support from the corporate sector, the Indo-US Knowledge Initiative on Agricultural Research and Education has opened up channels of investment in transgenic research and product development through the USA Government and US corporates. There are concerns in India about the manner in which the agreement with the USA will play out. For instance, how will the products of research and the profits be shared? Will benefit sharing include technology transfer and payment for gene use as provided in the Indian legislation? Will India be able to have free access to the public sector technology and research in US universities and research institutions? Will privately owned US technologies be made available to India for free or at concessional rates? If not, then what is the point of a deal? How are farmers going to benefit from programs of the agriculture deal? When a new variety is produced from the Indian genetic material, will it be freely available to them? Will the improved varieties be made available to farmers through public research institutions as done during the Green Revolution or will they be given to the private sector for commercialisation?

Funding support for the biotechnology sector

Apart from the funding for research, generous plans have been made in the National Biotechnology Development Strategy to fund the development of the biotechnology sector per se, especially the biotechnology industry. Clear government policies for promotion of innovation and commercialisation of knowledge is proposed to propel the growth of the biotechnology sector.

It is proposed to create several national/regional technology transfer cells (TTCs) to provide high caliber, specialised and comprehensive technology transfer services. The services would include: evaluating technology and identifying potential commercial uses, developing and executing and intellectual property protection strategies identifying potential licensees and negotiating licenses. Each technology transfer cell would service a cluster of institutions in a region or a large city.

Fiscal and trade policy initiatives

Government support, fiscal incentives and tax benefits are seen as critical to this sector and these measures will be taken to help capitalize on the inherent cost effectiveness of the Indian biotech enterprises. The proposed interventions include:

- Exemption of import duties on key research and development, contract manufacturing / clinical trial equipment and duty credit for research and development (R&D) consumer goods to enable small and medium entrepreneurs to reduce the high capital cost of conducting research.
- Extending the 150 % weighted average tax deduction on R&D expenditure under income tax law and to permit international patenting costs under this provision.
- Enable lending by banks to biotech companies as priority sector lending. Currently banks are almost averse to lending to young biotech companies.
- Rationalization of import and export of biological material to facilitate clinical research and business process outsourcing.
- Simplification and streamlining of procedures for import, clearance and storage of biologicals, land acquisition, obtaining environmental and pollution control approvals would be simplified and streamlined within shorter time frame lines through consultations with various Central and State Government departments.
- International trade opportunities would be promoted to guide R&D investment in Indian biotech companies.
- Efforts would be made to remove hurdles for contract research especially for input output norms and tax on revenue generated through contract research/R&D.

Public investment for promotion of innovation and knowledge commercialisation

To make available financial support for early phase of product development to establish proof-of-principle it is proposed to institute a Small Business Innovation Research Initiative (SBIRI) scheme through the Department of Biotechnology. SBIRI will support small and medium size enterprises with a grant or loan. Companies with up to 1000 employees will be eligible. The SBIRI scheme will operate in two phases of innovation and product development.

Phase I: Here funding will be provided for highly innovative, early stage, pre-proof-of-concept research. Preference will be given to proposals that address important national needs. The maximum amount of funding to an enterprise will be limited to Rs. 5 million with not more than 50% of it going as grant and the remaining as an interest free loan.

Phase II: Once proof-of-concept is established, projects will be eligible for Phase-II funding. Some projects could be eligible for direct phase-II support. It is proposed to provide soft loan at this stage for product development and commercialisation at an interest rate of 2%.

2.5 Current transgenic research and its relevance for food security

If transgenic crops are to contribute to overall food security, their main objective will have to be raising the productivity of crop plants. Agricultural productivity is low in India for a variety of reasons, the most significant of which are inadequate water, poor soils , lack of access to seed and agrochemicals in adequate amounts and at the right time. In addition, the poor financial situation of small farmers, exacerbated by a near non-existent access to official credit, creates conditions in which the farmer is unable to get the most basic inputs for cultivation. It is true that there is also the problem of pest and disease which are the biggest focus of GM crops but these can be controlled by traditional practices, plant based pesticides and integrated pest management.

It is difficult to see how transgenic technology which is today dominated by insect resistant crops or those that are tolerant to herbicides , will contribute to raising farm productivity in any significant way. Most of the time, farmers are unable to extract even half the genetic potential for yield that is contained in the seeds they are using currently because they do not have access to the most basic factors of cultivation like water and soil nutrients.

In order to assess first hand what the farmers identify as their main problems in agriculture which are impediments to raising production, and in which sectors they want government intervention, Gene Campaign conducted a survey in the western plateau region of Jharkhand.

The eastern Indian state of Jharkhand is a backward state in India where agriculture is rainfed and productivity is low. It is a problematic backward state where the government needs to intervene to raise agriculture production. High priorities of the government's proposed interventions are water and transgenic crops. The main findings of the Gene Campaign survey are presented briefly in the Table 6. They offer a sharp contrast to the government's planning with high tech solutions like agricultural biotechnology to raise productivity, whereas the farmers want completely different interventions to raise production and improve food security.

Table 6: Main Problems identified by Jharkhand farmers

Rank	Main problems	Percentage
1	Irrigation	92 %
2	Fertilizer	85%
3	Seed	82-100 %
4	Credit	90 %
5	Roads	40 %

According to farmers, their main problems are water, seed and credit and this is where they want government to help. The situation with water is critical because almost no effort has been made in this water starved region, to conserve rain water which now comes only once a year, during the monsoon (July-September). Farmers are unable to plant a second crop in the winter season because there is no water to irrigate the crops.

A short survey of water conservation efforts on the ground in Jharkhand (see Table 7) shows that barring a few locations, where some water conservation has taken place, water conservation has not been prioritised and irrigation is not available to farmers. In such a situation it is hard to understand how GM crops will help farmers raise their productivity. Jharkhand is not the only monsoon dependent state in India, about 60 to 70 percent of Indian agricultural land is monsoon dependent, often with no secondary source of water.

Table 7: Block wise break up of water conservation and irrigation facilities

Sl. No.	Name of Block	Water Conservation (In %)		Sufficient Irrigation (In %)	
		Yes	No	Yes	No
1	Tamar	00	100	00	100
2	Bundu	00	100	00	100
3	Sonahatu	00	100	00	100
4	Bero	54.54	45.45	9.9	90.2
5	Lapung	00	100	7.69	92.3

6	Mandar	31.25	61.53	00	100
7	Burmu	00	100	12.5	68.75
8	Angara	13.33	100	-	100
9	Silli	21.42	78.57	-	100
10	Khijri	00	100	-	100
11	Ormanjhi	00	93.33	-	93.33
12	Chanho	00	100	8.33	75
13	Kanke	00	100	00	100
14	Ratu	00	100	00	100

It is evident that farmers face a range of problems with respect to their food and livelihood security that cannot be addressed by GM technology. Placing the kind of emphasis that the government does on transgenic technology is clearly misplaced from the standpoint of food security. Transgenic crops are not a panacea for the food and hunger problem. They can at best offer solutions to certain problems if the research is well targeted. This can only happen if a proper needs assessment exercise is undertaken to identify the real problems of agriculture, especially those faced by small farmers. After this, an evaluation should be done to see which problems can be effectively solved by conventional methods and which may require the intervention of GM technology.

2.6 Implementation of GM technology: translating GM technology to GM products

India has a strong public sector program on agriculture biotechnology. Several universities and research stations are engaged in research on GM crops, including Bt cotton. However barring a recent approval given to a public sector Bt cotton variety produced by the Central Institute of Cotton Research (CICR) in Nagpur, all other Bt cotton hybrids that have been approved are from private companies. Nearly all the Bt cotton in the market is transformed using the Bt gene set from Monsanto. The sole exception is the Bt cotton being produced by Nath Seeds which uses the Bt gene licensed from China (IGMORIS 2010).

Most public sector labs are facing problems in translating their research into commercial products. In order to overcome this bottleneck, the Government of India decided to establish a platform to help public and private sector institutions engaged in transgenic research, to bring their products to market.

Accordingly, the Department of Biotechnology (DBT) and ICRISAT, an institution of the CGIAR system, located in Hyderabad, India, decided to establish a Platform for Translational Research on Transgenic Crops (PTTC) with the goal of facilitating the creation of GM crops from laboratory research projects (ICRISAT 2009).

In the backdrop of the major bottlenecks in successful translation of GM technology from lab to land, “ICRISAT proposes to leverage its existing excellence in the areas of transgenic research on crop plants, molecular plant sciences and plant breeding to improve its ability to enhance the delivery of transgenic crops in agriculture” says the ICRISAT statement.

The PTTC is planned as a ‘clearing’ house for innovative ideas and technology in crop genetic engineering that could positively impact agriculture, with an objective of providing expertise and facilities for the development, assessment and deployment of transgenic crops. The idea is to establish an entity that serves to evaluate potential new genetic engineering options and then advance these, in a focused way, to meet specific objectives in agriculture. Besides acting as a clearing house for technology inputs, transgenic research leads and prototypes with proof of concept derived from research institutions, the PTTC would help evaluate the concepts, ideas, and technologies and promote advancement of the most promising concepts by prioritization through a well-coordinated approach arising from networking among research institutions, industry and the government. It would also create specific projects with defined milestones and endpoints and their effective management. These ‘evolved’ technologies could then be transferred to the private or public sector for advancement to the farmers.

According to the DBT, India has one of the world’s largest numbers of highly trained plant breeders who have developed many improved seed varieties that lie at the core of the Green Revolution. Transgenic research in the agricultural sector can bring another revolution, the “Gene Revolution”, in food production. The development of transgenic varieties, however, requires much more than the existing expertise. The basic infrastructure needed for this purpose is the creation of accredited laboratories that will offer facilities for effective evaluation, validation and testing for safety to human health and the environment. The aim of establishing PTTC is to facilitate a collaborative and coordinated approach for translation of existing genetic engineering technologies in development of transgenic crop varieties that can be efficiently taken through product development to commercialisation. The stated mission of PTTC therefore, is “to translate transgenic science and technology and harness its products to meet the needs of agricultural growth”.

The major activities of the PTTC will be as follows:

• Contract research to develop transgenic events in crops based on proof of concept from public and private sectors.
• Genotypic and phenotypic evaluation of trait-specific transgenic events of agriculturally important crops, produced by various public and private sector institutes, under contained greenhouse and field conditions.
• Introgression of sellable (for commercial purposes) transgenic events into agronomically acceptable varieties and their validation.
• Facilitate the conduct of multi-location and large-scale field trials in collaboration with the Indian Council of Agricultural Research (ICAR) institutes.
• Detailed examination of Intellectual Property Rights issues associated with transgenic technology selected for product development.
• Development of biosafety dossiers for commercialisation of the product based on selected transgenic event/s.
• Coordination and conduct of thorough evaluations of transgenic events for possible food, feed and environmental safety studies with external agencies such as the Indian Council of Medical Research (ICMR) and the Research Committee on Genetic Modification (RCGM).
• Identification of partnerships for seed registration and marketing of the final “product”.
• Obtaining permission for growing cultivars derived from transgenics in open fields following the Research Committee on Genetic Modification (RCGM) and Genetic Engineering Approval Committee (GEAC) guidelines.
• Provide training on development and deployment of transgenic crops and their products.

The PTTC proposes to offer a range of services like

a) Contract research

i. Tissue culture & transformation services:
A “high throughput transformation facility” will be set up to facilitate plant transgenic research with a range of facilities, skills and experience to carry out plant tissue culture and transformation services. This would include state-of-the-art facilities such as sterile tissue culture units (laminar flow hoods), a range of plant transformation equipment, controlled environment culture rooms, containment glasshouses, a comprehensive range of molecular biology and biochemistry technologies. The transformation facility will undertake projects involving development of a specified number of (100- 150) transgenic events carrying any desired gene construct and their seed multiplication activities within a time span of one-and-a-half to two years.

ii. Product development on the value chain:
Contract research at PTTC will be undertaken primarily to assist agri-biotech companies on transgenic research, testing and approval processes of transgenic products. Small seed companies do not have adequate infrastructure to adopt physiological, molecular, genetic and immunological tools required for efficient development, screening and selection of the desired transgenic lines. PTTC will provide contract services throughout the value product chain to the private as well as public sector in order to facilitate the conversion of a desirable transgenic event to a ‘marketable product’. Rights and intellectual property would

be negotiated prior to signing of the contract. Besides, a “Confidentiality Agreement” with the private sector companies will be executed to ensure privacy and confidentiality.

b) Consultancy services

Genetic engineering technologies are intensively knowledge driven, which makes it difficult for a majority of small seed companies to undertake research activities on genes and transformation technologies. Similarly, researchers/scientists carrying out transgenic research in universities and institutes find it difficult and cumbersome to handle and analyze the associated IPR issues and deal with regulatory departments. Keeping in view these limitations, PTTC would actively provide consultancy services in areas related to plant tissue culture and transformation, agricultural biotechnology protocols and the like. From advice on laboratory procedures and troubleshooting to whole laboratory design, event selection, field trials and eventually commercialisation, these services would pave the way for both public as well as the private sector to benefit from a range of scientific and regulatory expertise at PTTC.

c) Intellectual property management and advisory cell

PTTC aims to establish a single window advisory service for providing advice on IPRs pertaining to transgenic research in both public and private sector research institutes and universities.

Organisations have a great deal of flexibility in using the services of the PTCC, they do not have to participate from beginning to end. Organisations could enter and exit the PTCC process at any of the following stages:

i. Discovery stage
The discovery stage is for basic and applied research. Under the discovery stage activities such as traits and genes are identified that can be used for various purposes. It may also include transgenics, molecular analysis, seed set and laboratory testing. Tissue culture and green house testing can also be done at this stage.

ii. Development, validation and biosafety
The development biosafety deals with development of transgenics, verification and validation of the crops, and ultimately development of breeding lines. The development biosafety involves limited field trials, toxicity and allergenicity, and environmental impact assessments under stringent biosafety norms.

iii. Commercialisation
The commercialisation process starts with conducting field trials, varietal registration, certification and finally marketing. After large-scale field trials the variety is released with Breeder, Foundation and Certified Seed.

2.7 Policy on biotechnology

India had engaged in biotechnology research including research on transgenic crops for years in the absence of a biotechnology policy. Sporadic informal comments had been made by various people that India needed a policy, but no specific effort was made in this direction till 2003.

In November 2003, Gene Campaign organised a national conference on the relevance of GM technology to Indian agriculture and food security. People with all shades of opinion were invited to this first ever national consultation to debate if GM technology could play any role in improving agriculture in developing countries. Participants included representatives of the multinational sector, government departments, seed industry, civil society, scientists and academics, students, activists and NGOs, UN organisations and international organisations and foundations as well as representatives from select embassies.

After two days of presentations and discussions, several recommendations were made. There was an almost unanimous view among the participants that the regulatory system in India was technically incompetent and non-transparent and that the country urgently needed a biotechnology policy. These views were shared equally by those opposed to agricultural biotechnology as those strongly in favour of it.

The following twenty consensus recommendations were those on which everyone agreed and these were forwarded to the DBT for consideration (Sahai 2003). The DBT rebutted each one, saying no action was needed on any of the suggestions made. Following this refusal of the DBT to engage in dialogue, Gene Campaign decided to file a Public Interest Litigation (PIL) in the Supreme Court of India in 2004.

Table 8: Consensus recommendations

Recommendations from National Conference on GMOs - 2003	***Response from Government of India (DBT)***
A comprehensive biotechnology policy should be developed in consultation with all stakeholders.	**It is not felt necessary that a separate National biotech policy should be developed. The National Science and Technology Policy-2003, is already in place.**
A statutory National Bioethics Commission must be set up. There should be a consultative and participatory process to prioratise crops and traits for genetic improvement through biotechnology with the goal of addressing the needs of small farmers and Indian agriculture.	Setting up of a Statutory National Bioethics Commission is not felt necessary**.** The Ministry of Agriculture has already set up a task Force to look into the issues**.**
India must develop a policy for transgenic varieties of crops for which it is a Centre of Origin and Diversity. Commercial cultivation of GM rice should not be allowed until the nature of gene flow and its impact is understood.	The issue of “Policy for transgenic varieties of crops” especially the rice has already been taken care in the agri-biotech research. The elite class of rice varieties like Basmati and Pusa are used only for standardization of transformation techniques and not for commercial preparation of transgenic varieties. The Indian scientists and the Government is well aware on the importance of the Indian rice germplasm protection.
A cost and risk benefit analysis must be conducted before deciding on a GM product. **Develop a stringent protocol to assess environmental and ecological impact.**	The cost and risk benefit analysis is the basic fundamental of seed business and there should not be any apprehension with such GM crops. **The Protocol to assess environmental and ecological impact for risk assessment and risk management are already inbuilt in the EPA and they are not less stringent than anywhere in the world.**
Have a policy to deal with bio terrorism urgently. ****A new statutory, independent National Biotechnology Regulatory Authority must be established.**	The policy to deal with bio-terrorism is not a grave issue at present in our country. The present functioning of the regulatory system has been well accepted. ****A New Independent National Biotechnology Regulatory Authority would not be solution to various issues faced by the industry.**
Make GEAC more competent, transparent and accountable. Post data on research and development of GM crops and products on websites and local newspapers.	GEAC is comprised of all stakeholders pertaining to various administrative ministries and is thus competent. Posting of data on R&D on GM crops and products on website is not a practical suggestion.

An annual review of all decisions on GM products must be presented to Parliament Organise a series of public debates across the country to elicit the views of the people, to channel it into policy making. The government should fund this exercise.	Submission of GEAC decisions to Parliament is not a practical exercise The policy making on the GM products is always channelised through public debates across the country involving CII, FICCI, ASSOCHAM, Indian seed industry, All India Biotech Association, NGOs etc.
There should be a moratorium on *commercial cultivation* of GM crops until the regulatory system is demonstrably improved. Research on GM crops, however, should continue.	There is no need for a moratorium on commercial cultivation of GM crops as research in this field aims at benefit to the farmers at large with benefit to the society. The regulatory procedures that exist today are good enough to meet the biosafety requirements.

** A request for a reformed regulatory system which was simplified, technically competent, accountable and inclusive was made at the conference. It was recommended that an independent National Biotechnology Regulatory Authority be established. The DBT had rejected this recommendation at the time but gave in later to draft an NBRA Bill which is confused, pro-industry and severely criticized (see chapter 2.2.1).

Source: Sahai, S., (ed) 2003. Relevance of GM technology to Indian agriculture and food security, Gene Campaign, ISBN 81-901009-8-X, 137-159.

Following the PIL filed by Gene Campaign, the Government of India decided to establish an Expert Committee in 2005 to frame a national biotechnology policy. Dr Suman Sahai was the only NGO member invited to serve on the Expert Committee. The Expert Committee refused to take on board the repeated submissions made by Dr. Sahai for a more open and inclusive consultation process, leading Sahai to resign from the Committee that framed the National Biotechnology Development Strategy in 2007 (DBT 2007).

Although the Government says in its policy document that "It is imperative that the principal architects of this sector along with other key stakeholders play a concerted role in formulating such a strategy to ensure that we not only build on the existing platform but expand the base to create global leadership in biotechnology by unleashing the full potential of all that India has to offer", in actual fact stakeholder consultations (barring the inclusion of Dr Sahai in the Expert Committee and one meeting with stakeholders) did not really take place and a heavily criticized national policy was adopted in 2007.

The National Biotechnology Development Strategy

The key policy recommendations of the National Biotechnology Development Strategy address six broad fields. These are: Human resource development; Infrastructure development and manufacturing; Promotion of industry and trade; Biotechnology parks and incubators; Regulatory mechanisms as well as public communication and participation. The priority areas of intervention in the national biotech policy document are the following:

1.Agriculture & Food Biotechnology

•A comprehensive and integrated view to be developed of r-DNA and non r-DNA based applications of biotechnology with other technological components required for agriculture as a whole.

•Use of conventional biotechnologies (e.g. biofertilizers, biopesticides, bioremediation technologies, molecular assisted grading, plant tissue culture etc.) to continue to be encouraged and supported. A precautionary, yet promotional approach should be adopted in employing transgenic R&D activities based on technological feasibility, socio-economic considerations and promotion of trade.

•Public funding should be avoided to research areas of low priority or those that could reduce employment and impinge the livelihood of rural families.

•Regulatory requirement in compliance with Cartagena Protocol, another international treaty and protocol for biosafety, germplasm exchange and access and the guiding principles of codex alimentarius will be implemented through inter ministerial consultative process.

•Transgenic plants should not be commercialised in crops/commodities where India's international trade may be affected. However, their use may be allowed for generation of proof of principle, strictly for R&D, their alternate systems are not available or not suitable.

•In a long term perspective basic research for development of low volume, high value secondary and tertiary products through enabling technologies of genomics, proteomics, engineering of metabolic pathways, RNAi, host pathogen interaction and others. Research and support of biosafety regulation would need support.

•It is proposed to do away with the large-scale field-testing of the released transgenic events and make it compliant to agronomic test requirements.

Within Agriculture and Food Biotechnology, the following sectors would be prioritized:

(a) Crop

Priority target traits in crop plants would be yield increase, pest and disease resistance, abiotic stress tolerance, enhanced quality, and shelf life, engineering male sterility and development of apomixis. Crops of priority should be rice, wheat, maize, sorghum, pigeon pea, chickpea, moong bean, groundnut, mustard, soybean, cotton, sugarcane, potato, tomato, cole crops, banana, papayas and citrus. In priority crops equal emphasis should be given to GM hybrids and new varieties. The varieties in contrast to hybrids, are preferred by small farmers as they can use their own farm saved seeds for at least three or four years. In case of hybrids, research on the introduction of genetic factors for apomixis would be supported so that resource-poor farmers can derive benefits from hybrid vigour without having to buy expensive seeds every cropping season.

(b) Livestock

Priority target traits in livestock would be enhanced fertility and reproductive performance, improved quality, resistance to diseases for reduced drug use, production of therapeutically useful products and quality feed. Livestock of priority would be buffalo, cattle, sheep and goat. Emphasis would be given to animal healthcare, nutrition, development of transgenics and genomics. It is proposed to set up an autonomous institution for animal biotechnology.

(c) Aquaculture and marine biotechnology

Application of biotechnology would be crucial in disease resistance, enhanced productivity, fertility and reproductive growth, use of aquatic species as bioreactors for production of industrial products, value added products from sea weeds and other marine taxa and biosensors for pollution monitoring. Species of priority in fisheries would be carps, tiger shrimps and fresh water prawns. It is proposed to set up under the auspices of DBT an autonomous centre for marine biotechnology

(d) Food and nutrition

R&D would be focused on: development of biotechnology tools for evaluating food safety, development of rapid diagnostic kits for detection of various food borne pathogens; development of analogical methods for detection of genetically modified foods and products derived there from; development of nutraceuticals / health food supplements/ functional foods for holistic health; development of pre-cooked, ready-to-eat, nutritionally fortified food for school going children; development of suitable pro-biotics for therapeutic purposes and development of bio food additives. It is proposed to set up (under the auspices of Department of Biotechnology) an autonomous institute for nutritional biology and food biotechnology.

(e) Biofertilizers and biopesticides

Priorities would include screening of elite strains of microorganisms and / or productions of super-strains, better understanding of the dynamics of symbiotic nitrogen fixation, process optimization for fermentor – based technologies, improved shelf life, better quality standards, setting up accredited quality control laboratories and standardization of Good Manufacturing Practice (GMP) guidelines. Integrated nutrient management system would be further strengthened.

2. Bioresources

Attention will be paid to plant, animal, microbial and marine resources with a focus on the following strategic actions :

• Support to capacity building in microbial taxonomy through intensive training programmes at graduate and post-graduate levels.

• Promotion of horizontal networking between remote sensing experts, field biologists and computer specialists for inventorisation of bioresources based both on primary and secondary sources of information.

• Promotion of closer and effective interaction between biotechnologists, foresters, oceanographers and field biologists.

• Ensuring the use of bioresources is sustainable by regulating the harvesting of medicinal plants.

• Formulating a policy to regulate the procurement and sale of medicinal plants in India. Introduce regulatory norms prescribed by DCGI that evaluate the efficacy, safety, and quality of herbal products, which currently are exempt from the scope of any regulation of the DCGI.

• Establish a close working relationship between field scientists, pharmacologists and clinicians so that an all round integration is achieved.

• Promote Public-Private Partnerships for product generation.

• Creation of a gene bank for maintaining 'mined' genes.

• There is, as on date, only one international depository authority (IDA) in the country at the Microbial Type Culture Collection (MTCC) at IMTECH, Chandigarh; however, for securing national IPR interests, we need to initiate steps to establish a few more centres as IDAs.

• Currently, MTCC does not accept biological materials such as cell lines, cyanobacteria, viruses etc. as it has no expertise or facilities for this purpose. Yet, these are essential for filing patents. IDAs in other countries may refuse to accept such material as they may be potentially hazardous or the shipments may have restrictions. In view of this, the scope of MTCC needs to be expanded by upgrading the existing expertise and infrastructure. Alternately, IDAs should be set up where such expertise and infrastructure are available.

• Testing end products from bioprospecting for a variety of parameters before commercial production can begin. There is a need to set up appropriate facilities for such late stage testing of products.

• An autonomous Centre for Marine Biotechnology is proposed to be set up under the auspices of DBT.

• An autonomous Institute for Biotechnology for Herbal Medicine under the auspices of DBT is proposed to be established.

Other focus areas identified for strategic intervention in the policy document, are

- Environment,
- Industrial Biotechnology;
- Preventive & Therapeutic Medical Biotechnology;
- Regenerative & Genomic Medicine;
- Medical Diagnostics ;
- Bio-engineering & Nano Biotechnology;
- Bio-informatics and IT - enabled Biotechnology;
- Clinical Biotechnology and Research Services and

- Intellectual Property & Patent Law.

Comment

A striking feature of the Biotechnology Strategy document is the exclusion of NGOs from any aspect of decision making or implementation of biotechnology. A single reference exists to the farming community (included in an inter-ministerial group) but NGOs are not involved in any way. The most problematic parts of the National Biotechnology Development Strategy relate, to the most contentious areas of biotechnology, agricultural biotechnology, regulatory mechanisms and public participation. Here was an opportunity to demonstrate confidence and inclusivity by bringing in a fresh view on an old controversy and open the doors to consultations, but this was not done. The report has elected instead to follow a clearly pro-industry line on both content and regulation.

In its recommendations, the biotech strategy report follows the American view on risk assessment, making liberal use of the 'science-based' approach promoted by the GM lobby and by the USA. Despite their being mentioned in the Convention on Biological Diversity and the Biosafety Protocol, nowhere does the biotechnology strategy report acknowledge the special developing country concerns like the Precautionary Principle, socio-economic concerns relating to small farmers and consumers and the right of the public to participate in decision making.

India is a biodiversity rich region from where major crop plants like rice have originated. It is therefore an important center of origin, where unique genetic wealth and diversity is found. There is global concern on GM crops being grown in their centers of origin and diversity because of the threat to this unique gene pool from contamination by foreign genes. Such contamination has already been found in Mexico's corn and the authorities there are scrambling to find a way to contain the problem. The policy document is silent on this crucial issue of particular relevance to India and ultimately to the world, since rice is the staple food of almost half of mankind. Similarly, there is no acknowledgement of other concerns being discussed on international platforms, for instance socio-economic impact of GM crops, their likely impact on traditional farming practices and on indigenous knowledge. It is universally recognized that there can be social and economic impacts on farmers, especially small farmers, resulting from the application of GM technology in agriculture.

Suggestions for a policy framework on transgenic research

In a 2003 paper (Pental 2003), Deepak Pental, then at the Department of Genetics, Delhi University captured informal discussions on policy guidelines for research using transgenic technology. Pental is currently Vice Chancellor of the same university. The major recommendations made for a policy framework for transgenic research are as follows:

1. Transgenic technologies are not a substitute for conventional methods of plant breeding. Pure line breeding to diversify varieties and to select transgressive sergeants for important traits must continue. Component breeding through marker-aided selection must be provided adequate funding. The development of heterotic pools in some of the important crops like wheat and rice has so far been given little attention. This needs to be rectified as it is essential for enhancing productivity.

2. The most important contribution of transgenic technologies will be in the areas of developing varieties resistant to pests and pathogens. A major effort should be launched to develop transgenics that contain resistance to pests and pathogens.

3. For pests, discovery of new insecticidal proteins encoding genes both from microbes and plants should be given high priority. Currently, there is no work on search for new Bt Cry proteins or VIPS. At least three laboratories should be given the charge of collecting new strains from different ecological regions of the country so as to identify new insecticidal proteins. Existing and new genes should be tested on the most devastating insect pests of crops grown in India. *Heliothis armigera*, that affects at least three major crops should receive high priority.

4. Variability at the molecular level needs to be studied for viral pathogens; otherwise strategies based on pathogen-derived resistance would be ineffective. Work on variability analysis should be initiated at the earliest.

5. Some of the major bacterial and fungal pathogens need to be more intensively studied, both for variability at the molecular levels.

6. Indian labs should participate in structural and functional genomics work through international collaborations. Such participations should focus on sequencing genomes of model legume species and some of the important pathogens of crop plants.

7. In functional genomics, top priority should be given to identification and isolation of genes conferring resistance to pest and pathogens. India should sequence the genome of a wild relative of rice for allele mining.

8. Development of transgenics for resistance to pests and pathogens would require strong multidisciplinary groups or collaboration among laboratories specialising in genome sequencing, plant pathology, breeding and genetic transformation. Such groups can be assembled in a crop-wise manner.

9. As each crop requires inputs of a number of genes, there should be a crop-wise strategy for gene stacking. Technologies for the removal of marker genes should be used so that transgenics could be protected from homology-based silencing and do not contain a surfeit of marker genes.

10. In India, transformation protocols are available only for a few crops. There is great urgency in developing routine transformation protocols for crops like pigeonpea, chickpea, safflower, mungbean and wheat. Some new and innovative approaches will have to be supported as little success has been achieved to-date with some of these crops.

11. Heterosis breeding would require development of elite heterotic pools and sterility/fertility restoration systems. In many cases, data on heterosis are on a limited population size and, therefore, are not reliable.

12. Development of transgenics for reducing post-harvest losses should be given high priority. Basic work on senescence retardation will have to be supported.

13. For each crop, a thorough study needs to be undertaken on technological options that are available to meet the identified breeding goals. In areas where knowledge is not adequate or new strategies are required, basic research work should be funded.

14. A major effort needs to be made in training and retaining scientists who are competent to handle genomics and gene discovery work. Efforts should be made to attract scientists trained abroad in the key areas of genomics, gene discovery and molecular plant pathology.

15. A major initiative will be required to attract talented students to agricultural biotechnology. At the undergraduate and postgraduate levels, curricula are outdated. These need to be changed.

16. Seed industry could be helped by putting up trials on transgenic material through agricultural universities and the coordinated trial system of ICAR. Seed industry should be also provided germplasm without any restrictions.

17. Indian fertilizer industry should be given incentives to enter the business of producing and delivering quality seed of both hybrids and pure lines to the farmers. With their strong distributional networks and ties with the farmers, the fertilizer companies may be able to bring about a rapid turnaround in the seed sector.

18. The current process of clearance through IBSC, RCGM and GEAC should continue. However, the RCGM should be given the powers to receive reports from ICAR on yield and field behaviour, and ICMR on nutrition, toxicology and allergenicity. Special cells should be created in ICAR and ICMR for organising these studies.

19. It would be difficult to label GM and non-GM foods in India as land holdings are very small and food is processed predominantly by the small-scale industry. Therefore, transgenics should be released after proper testing and evaluation.

20. All information on trials under RCGM should be put on websites so that the community at large is informed about the performance and the merits/demerits of the transgenic material.

None of these recommendations to give some direction to transgenic research have not been acted on yet. Certain controversial features like the carte blanche for the seed industry will certainly need to be debated. In the absence of a policy thrust for transgenic research, it is unlikely to address any real problems but is likely to give market shares to corporations for GM seeds that will be pushed by their developers. This is unlikely to help agriculture and food security but is likely to push farmers into further indebtedness as GM seeds are expensive.

2.8 Can GM and non–GM crops be segregated in India – Is coexistence possible?

Coexistence of GM and non-GM crops is being promoted as a way to resolve the conflict over genetically modified crops and create space for both in the same agricultural system. India has plans to cultivate several GM crops but has no policy on coexistence. Given below are some reasons why coexistence would be impossible to implement under Indian agriculture conditions (Sahai 2004).

Central to coexistence is the notion of stringent segregation and identity preservation. An identity preservation system or an IP system is a well-worked out, standardized system, the first prerequisite of which is certified seed of great purity. This can only be ensured in a system of agriculture where the certified seed is made freshly available to farmers for each round of cultivation. That will be impossible to implement in India where the majority of farmers save seed out of their harvest for sowing the next crop, even with high-yielding varieties. Up to 85% of the seed requirement of Indian agriculture is met by farmer-to-farmer sales, so the seed would not be pure in the manner required by the IP system.

Additionally, an IP system would impose intolerable financial burdens, especially on the small farmers, who could not incur the cost of having to buy fresh seed for every crop cycle. In order to qualify for an IP system, the fields have to be prepared in a specific way. They can not have grown a crop the previous year, as that could produce contamination, either through weeds or through volunteer plants.

Apart from stringent field preparations, farmers would have to maintain accurate records and field maps for IP certification so that the crop history could be traced backwards. The majority of Indian farmers have small land holdings. The level of literacy is low, and farmers who might be very wise in agricultural systems would on the other hand find record-keeping of this kind very difficult.

In addition to the preparation of the field, the specific manner of cultivation is also important in qualifying for IP certification. One of the most significant aspects is maintaining isolation from other crops during the cultivation period. Crops that are to be IP certified have to be isolated distinctly from those other crops that are not applying for IP certification. Avoiding the contamination of the IP certified field may be possible on very large agricultural holdings, but in small land holdings, which are closely packed together with narrow separating boundaries, isolating one crop from another would be almost impossible.

This kind of isolation for maintaining purity would only be possible if an entire region was cultivating a single crop aiming for IP certification. If IP certification was something that only a few farmers could afford to attempt, then their neighbouring farmers would become sources of contamination through cross pollination, via volunteer plants and weeds. Spatial isolation of such crops seems difficult to achieve. Isolation distances will also vary from crop to crop, depending on the kind of flower, sexual compatibility, pollen quantity, viability, and weather conditions, which would affect pollen dissemination. Isolation distances will be calculated differently for self-pollinating and cross-pollinating crops.

Whereas self-pollinating crops like wheat and rice would need smaller isolation distances, cross-pollinating crops, like mustard for example, would require isolation distances of as much as 3 to 4 kilometres. Under Indian conditions this would mean that if a farmer wanted IP certification of his mustard field he would have to make sure that all farmers within a radius of 3 to 4 kilometres of his field were also seeking IP certification. Either the entire region would have to maintain the rigorous system required, or no farmer could seek IP certification, since contamination from neighbouring fields cultivating a different crop would be inevitable. This would naturally require that all farmers in the region have the resources, the literacy and the wherewithal to go through the complex and expensive procedure of planting only pure certified seed, maintaining very strict field conditions which would permit almost no contaminating weeds or volunteer plants, having multiple year rotations and maintaining records and field maps. Given the farmer profile in India and other developing countries, this appears impossible to implement.

Mixture is also inevitable when the crop is being harvested. Harvesting of the wheat and rice crop in India takes place in two ways. The principal way is still manual harvesting and manual threshing though in certain parts of Punjab and western Uttar Pradesh, and in some other places where farmers have become resource-rich, harvesting and threshing is done by the harvester-thresher combine. When the rice is to be threshed manually, the harvested crop is taken to the threshing area in bundles. Threshing areas in the village are normally common areas where people stock their harvest. Usually there will be a central area, an open space where the ground has been prepared with mud and cowdung to make it hard. This is where threshing takes place. It is possible that two to three farmers are threshing their grain at the same time. Mechanical mixture at this stage is not just a possibility it is practically inevitable. The possibility of mixture continues further as the grain is bagged and stored.

In the case of mechanized harvesting and threshing too, the possibility of different crops getting mixed remains high since the same harvesting-threshing machine could harvest 5 – 10 fields a day, depending on their size. Harvesting is a continuous process from field to field without the harvester being cleaned in between the harvesting of two fields. Grains from several fields that the harvester combine has gone through will be mixed with each other. A figure from the 2003 rice harvest in Punjab shows an instance of mechanized harvesting where three to four farmers have harvested their crop with the Harvester-Thresher combine. Their produce will be divided in the right proportion, bagged and taken to the agricultural marketing centre for sale. Farmers also do transportation of the grain from the field to the marketing centre jointly, so mechanical mixture of grain happens at all stages.

Regarding the cost of implementing identity preservation, it is increasingly being recognized that the estimations done in the USA were not realistic and that IP costs were heavily underestimated. Especially in developing countries the operational costs of IP systems could be so significant as to actually put the food supply into jeopardy were it to be implemented. In other words, coexistence cannot be implemented in India. (Sahai 2004).

2.9 Problems with field trails: The case of Bt rice contamination in Jharkhand

The Mahyco seed company which is in a joint venture with Monsanto corporation, was conducting field trials of Bt Rice in Jharkhand in 2007-2008. The planting of genetically engineered rice in Jharkhand is of special concern since Jharkhand along with Orissa and Chattisgarh in Eastern India, is considered the center of origin, that is, the birthplace, of rice and the maximum genetic diversity of rice is found here. Any genetic contamination from foreign genes like the Bt gene can have highly detrimental effects on the genetic diversity of rice and this kind of contamination has the potential to cause serious long term damage to rice germplasm, affecting the future food security of large numbers of people (Gene Campaign 2008 and 2009).

The company has been conducting the field trials flouting every prescribed regulation and condition laid down for field trials of GM crops. Gene Campaign staff made visits to the site of the Bt rice trial and spoke to the farmers on location to get details of how the trial was conducted. The details are as follows:

1. Bt Rice hybrids belonging Mahyco seed company were planted on approximately one acre of upland fields.

2. Farmers had no idea what was planted in the trial field, they had never heard of Bt Rice or GM Rice. The company had told them nothing. The Agriculture Department of Jharkhand State had no information about the Bt rice trials.

3. Farmers told Gene Campaign that Mahyco staff came to observe the trials and sprayed the crop, farmers did not know with what.

4. There was no physical containment or any kind of isolation of the trial field. No containment of the crop was done by fencing or nets or physically isolating the trial site from rice fields- all steps mandated by law to prevent mixing of seeds/grains from GM crop fields.

5. The trial field was located in the midst of the agricultural area and is surrounded by farmers' fields on all sides. The boundaries of neighbouring fields are close together and it was impossible to prevent contamination of rice in other fields .

6. People walked egularly through the trial fields to other fields since this was on their way.

7. Since the trials were done on upland fields, the water flowed from there to lower fields, carrying soil, seeds etc to fields below, creating another source of contamination.
8. The trials were supervised by just one local farmer who was appointed as caretaker. Nobody from the company came to supervise the harvest and disposal of the crop residue which was found lying around.

9. The harvested GM rice seed was not secured in any way. The harvested Bt rice seed was kept in cloth bags in the caretaker's house. The straw was fed to his animals.

10. In its letter to the DBT, Mahyco had stated that the rice trials had been harvested and everything post harvest had been burnt. This was not the case.

11. Post harvest crop stumps had been left standing in the trialfField. These had thrown up secondary tillers and seed has already set in the tillers. These rogue Bt rice seeds had the potential to start the process of contaminating other rice crops in the region as they multiply in each crop cycle.

Such instances of gross violations in the implementation of the regulatory system while conducting trials of GM crops are a matter of great concern and once again raise the question whether the necessary systems are in place in India to ensure that the trials of GM crops are conducted with the caution that they deserve and according to the procedures laid down by the law.

The regulatory bodies, specially the GEAC, did not take any corrective action against the Mahyco company after receiving Gene Campaign's complaint, causing Gene Campaign to take the matter to the Supreme Court, where hearings on the original PIL are dragging on from 2004.

2.10 Consumer choice and GM foods - Indian policy on labelling

India has a Consumer Protection Act since 1986. According to this act, among others, the consumer has the right to safety and the right to choose, in all matters including food. In keeping with this, official Indian policy is for labelling GM foods (GoI 1986).

Labelling of GM foods in India is proposed under the Prevention of Food Adulteration Act, 2006. Labelling provisions under this act have still to be implemented. India has maintained a consistent position in the Codex Alimentarius negotiations that the country would implement mandatory labelling. The following are the details of the proposed rules to implement labelling under the Prevention of Food Adulteration Act, 2006 (Gazette of India):

(a) Labelling of genetically modified food – genetically engineered or modified foods means food and food ingredients composed of or containing genetically modified or engineered organisms obtained through modern biotechnology, or food and food ingredients produced from but not contained genetically modified or engineered organisms obtained through modern biotechnology;

In addition to the labelling provisions as prescribed under the proposed rules, the genetically modified food shall also conform to the following labelling requirements: a GM food, derived there from, whether it is primary or processed or any ingredient of food, food additives or any food product that may contain GM material shall be compulsorily labelled, without any exceptions;

(b) the label of all package (s) of GM food(s) or foods containing ingredients, derived from biotechnology or bioengineering or food additives or any food product that may contain GM material shall indicate that they

have been subject to genetic modification. These provisions will be applicable to all such products both imported or domestically produced;
(c) the label of imported GM food or derived there from, whether it is primary or processed or any ingredient of food, food additives or any food product that may contain GM material shall also indicate that the product has been cleared for marketing and use in the country of origin so that the verification, if needed can be taken up with that country without having to resort to testing.

(d) Restriction on sale of genetically modified food: No person shall except with approval of and subject to the conditions that may be imposed by the Genetic Engineering Approval Committee (GEAC) manufacture, import, transport, store, distribute or sell raw or processed food or any ingredient of food, food additives or any food product that may contain GM material in the country. In the case of imports, the importer must submit documents supporting the purported clearance at the time of import.

US interference in India's labelling rules

"The US has challenged the Indian attempt to formulate mandatory labelling laws for genetically modified foods. The challenge is posed unclear in the WTO committee on technical barriers to trade (TBT). This is not unexpected, as the US does not favour labelling of GM foods since it is of the view that GM foods are "substantially equivalent" to their non-GM counterparts and labelling of GM food would amount to "trade restrictive measures" (Financial Express 2006).

"The US has also said that India should refer its mandatory labelling norms for GM foods to WTO under the sanitary and phytosanitary (SPS) measures. This demand is totally misplaced. Simply labelling of GM food does not imply an SPS measure". (Financial Express 2006).

"Mandatory labelling is necessary to give consumers the right of choice and to check imports of unapproved GM foods. There are already reported cases of such unapproved GM foods entering the country. Many countries, including India have their own approval process for GM crops and foods, based on established scientific principles. India has so far approved only Bt cotton, which means that all other GM products entering the country are unapproved". (Financial Express 2006).

"The USA has also questioned the ambit of India's Genetic Engineering Approval Committee (GEAC). It said "The scope of the 1989 Rule under the 1986 Environment Protection Act is vague and appears to be broader than any other existing regulatory system in the world for biotechnology products, i.e. covering products such as cheese, wine, beer or other fermented products made using enzymes produced by genetically engineered bacteria." US interference through the Indo-US Knowledge Initiative on Agricultural Research and Education is causing concern and civil society is waiting to see how government will respond to these challenges." (Financial Express 2006).

2.11 Analysis of the engagement of political leaders with GMOs

An analysis of the questions asked by Members of Parliament (MPs) of all political parties regarding GM crops in the Lok Sabha and Rajya Sabha of the Indian Parliament, was done in order to understand the engagement of the political leaders with the issue. The Lok Sabha (House of the People), is composed of directly elected representatives of the people and the Rajya Sabha of members who are indirectly elected by the Legislative Assemblies of the various states.

The analysis showed that over the last seven years the issues concerning GMOs have been frequently debated both in the Rajya Sabha [http://www.indiagminfo.org/five/rajyasabha-GE-2001-07.pdf] and in the Lok Sabha [http://164.100.47.132/LssNew/psearch/qsearch14.aspx].

The questions raised nine issues related to GM food and technology are as follows:
1) The necessity for GM technology and for more information on GM
2) Government policies, rules and regulations relating to GM technology
3) Import of GM technology and implications for Indian farmers
4) Field trials of GMOs
5) Impact of GM on health/ environment/social/ economic conditions
6) Case of Bt cotton

7) Illegal and spurious GM seeds
8) Risk Issues of GM foods
9) Public reaction to GM in India such as farmer's protests, NGO advocacy and media reports.

Most questions asked for first level information on GM technologies, crops and the already implemented Bt cotton. Others were more nuanced and critical, indicating the comparative weightage given to the above themes and the glaring silence on certain issues in both houses.

1. Necessity for GM technology and for more Information on GM

This issue was very widely discussed and broadly covered in both the houses of the parliament. In the Rajya Sabha questions were raised seeking more information on the role of the government especially on introduction of GM technology, new policies and directions adopted by the government, ongoing field trials and/or banning of GMOs in the country and information on the policies and actions taken by the DBT and GEAC and other committees formed under the supervision of the government.

Importantly, it was in the Lok Sabha that the questions were directed towards the promotional aspect of GM technology. The members of the Lok Sabha mentioned the government's obligation to make GM technology available to the people. The Members of Parliament (MPs) asked about the steps taken by the government to promote GM technology in India. Some enquired about the implementation of various scientific reports such as the MS Swaminathan Report on Ag biotechnology. In the Lok Sabha, MPs are vocal about implementing GM technology and question the government about delays.

Both Houses of Parliament often mentioned the need for greater public awareness and dissemination of information regarding GM foods and its implications.

2. Government policies, rules and regulations relating to the introduction of GM technology

Government's policy on GM technology was more discussed in the Rajya Sabha than the Lok Sabha. Concrete issues related to specific foods such as GM eggplant, GM soy, Bt cotton and Golden Rice were discussed in the Rajya Sabha. Also discussed were which permissions had been granted by the government. The Rajya Sabha in addition, debated the concerns expressed over GM foods and regulation specific issues.

3. Import of GM technology and Implications for Indian farmers

The impact of GM technology was only very minimally discussed in the Lok Sabha (one question) and the Rajya Sabha. Questions remained focused on whether GM Foods had been imported into India.

4. Field trials

No questions were asked in the Rajya Sabha regarding field trials of GMOs and only two questions were asked in the Lok Sabha.

5. Impact of GM on health/ environment/social/ economic conditions

Few questions were asked on health impacts but the cost of GM seed was debated in both Houses.

6. Case of Bt cotton

Bt cotton was the most frequently debated subject, not surprisingly, since Bt cotton has been around since 2002 and a huge amount has been written in the media about it.

7.&8. Illegal and spurious seeds & risk Issues in GM food were minimally discussed.

9. Public reaction to GM crops in India such as farmer's protest, NGO advocacy and media reports

The Rajya Sabha gave more importance to themes on GMOs covered by the media. The MPs quoted reports and articles published in leading national newspapers and asked the government for answers on the issues raised by the public.

In the Lok Sabha questions were asked based on issues raised by NGOs such as Gene Campaign and Greenpeace who have been vocal in questioning government policy, the way field trials are conducted and overall implementation of GM technology.

2.12 Analysis of media reportage on GMOs

An analysis of selected national and print media [See Appendix 3] found that in the first three years (2001 – 2003) which marked the introduction of Bt cotton, the print media echoed the positive applications of Bt cotton by using descriptions like “Eco Friendly”, “Boon for Indian Farmers”, “Saviour for Farmer” interestingly such articles were also published alongside those which dealt with issues concerning food safety and food quality concerns in India. Articles dealing with concerns and apprehensions over the GM crops during these years were not mainly published as main articles of the newspaper and the speculations were based on purist arguments, which were voiced in articles like “Whose science, devil’s or God’s?” However, it was in the year 2006 that there was an increase in the momentum of write ups that dealt more with the negative impact of GMOs in India and the nature of such articles were inclined towards highlighting the voices of groups critical of GM crops.

This critical approach to GMOs was also at its peak for the year 2008 where reports of illegal cultivation of GM crops came up as a new issue for debate.

Reporting in the newspapers covered the following issues, in that order

1) Pros and cons of GM crops as expressed by different stakeholders
2) Perceived risks and benefits of genetic engineering
3) Case of Bt cotton - the first GM crop introduced in India
4) Illegal trials of GMOs on fields of farmers and illegal sale of Bt cotton seeds
5) Government’s position vis-à-vis regulation, information and sale of seeds
6) Implications of GMOs for perceived world hunger and food security
7) GMO and farmer suicides - Farmers’ movements against GM foods along with consumer mobilization.

In the initial years when Bt cotton was about to be introduced many articles reported on the benefits of GM crops in India, GM crops were seen as a “Boon” and “Saviour” for the Indian farmers. Reports like “*Benefiting from GE crops*”, strongly maintained that the GM crops would bring immense benefits to the Indian farmers. It is also seen that such views were mainly put forward from the scientist community, advocators of GM implementation in India who argue that GM crops and seeds are especially beneficial for Asian countries such as India as they imply positive health and nutritional benefits. Interestingly such articles were published along with others that talked about food safety and food quality concerns in India.

Media reports on the benefits and dangers of genetic engineering often provide detailed information about genetic engineering. They frequently list the benefits of GM technology in the fields of medicine and agriculture, saying GM technology can increase the production and nutritional value of fruits and vegetables, besides extending their shelf life and making them more appealing with respect to colour, shape and size. It is not unusual to find that risks of GM technology are also mentioned within the same report.

Later write ups mention risk assessment, saying that if the assessment of risk associated with GMOs is done properly then GM crops would bring immense benefits for Indian farmers. Such views are usually put forward by the scientific community and the seed industry people. The argument forwarded by the scientific community is that the acceptance/rejection of GMOs by society would be based on the current knowledge of assessment of risks. The issues of risk raised over GM technology touched on the failures and difficulties faced by cases like Bt cotton, Dolly the Sheep, Friesian Cow etc.

GM foods have also been presented in the context of health hazards for humans especially new born babies and pregnant women and the newspapers cite medical research done in this area. The lack of adherence to risk assessment protocols and the safety issues concerning GM crops undergoing tests in the country and its health effects on people were also raised.

A few reports said that a review of GM crops in India should not be done solely by the scientists but include members of civil society. Some reports have mentioned that risk communication and awareness is an essential feature of the regulatory framework. Transparent and credible decision-making involves communication of risks between all stakeholders in the risk management process.

1) Bt cotton

The commercial pages in newspapers tend to carry success stories of Bt cotton. The growth of cotton exports is attributed to the use of Bt cotton. But other reports mention other reasons for the success of the cotton crop such as the climatic and environmental conditions during the particular period, saying that cotton production increase was not solely due to Bt cotton.

2) Illegal trials of GMO's on fields of farmers and illegal sale of Bt cotton seeds

A report "*GM paddy runs into rough weather in TN*", highlighted the illegal cultivation of GM food crops on the agricultural lands especially in Tamil Nadu. "*Spurious Bt cotton seed being sold Agriculture Depatrment warns of action"*, also shows that unscrupulous traders have started cheating the farmers by selling them spurious seed of Bt cotton in Punjab and it is the newspaper that has highlighted this story and informed the State Government and Punjab Agricultural University that farmers have started visiting Rajasthan, Haryana and Gujarat in search of Bt cotton seed. Immense coverage of such incidences is found in both national and regional newspapers "*Unapproved Bt cotton seed on sale in Punjab*". Farmers are unaware of the trials being conducted in their fields as described in an article "*Concern over field trials of GM food*",

The importance of spreading this awareness regarding risks and GMOs was seen in the coverage on the "Navbharat scandal", where one aspect that stood out starkly was the practical difficulties faced by the State in testing and monitoring the use of GM seeds The farmers who were using the seeds neither knew whether they were genetically modified or not, nor were they aware of the implications of using them.

3) Government position

It is usually State Governments in particular that have shown a cautious attitude on the issue of GMOs. This can be seen in articles where the government has downplayed the over exaggerated claims by the Industrial sector on the success of Bt cotton. From 2006 more coverage of perceptions and opinions of state ministers and government officials on GM foods and crops is reported in the regional and national media. Political leaders from the states have made statements like "The government may issue a law banning GM crop trials. We hope the Centre will support us" (Tamil Nadu agriculture minister. The minister's reply came in the wake of severe concerns raised by legislators across party lines). A Congress leader is reported to have said: "GM crops will wipe out traditional crops" and another legislator said: "GM crops are being dumped in India to harm the farming sector."

4) GMO's and food security

Some newspaper reports question whether GMOs are really a solution to the problem of poverty and hunger across the world. Reports mention that farmers, especially in developing countries, face many problems that biotechnology does not address, much less solve, like lack of infrastructure, poor or unstable market access, volatile input and output prices, and so on.

On the impact of GMOs on food security, it is the scientific community that repeats that GM crops are especially beneficial for Asian countries such as India, and the anti- GM lobby should not oppose it as it implies positive health and nutritional benefits. Other articles point out that in the name of food security, India should not be made a dumping ground of GM foods and seeds that cannot be sold in the West.

The media appears to have highlighted the diverse views held by various stakeholders in the debate. Some newspapers have been more open in placing the GM debate on a wider public platform and have managed to convey the attitudes and perceptions of the scientists, academics, agriculturalists, activists and also farmers. A striking feature is the near absence of the views of consumers in the GM debate. This is probably because the consumer movement is not very strong in India and more so on this issue, it has not engaged with it the way consumers in other countries have. India is being perceived as a giant emerging market for GM foods with more than 1.1 billion consumers Therefore, it is important that consumer questions are addressed seriously, before GM foods are introduced in India. For that the consumer movement must express its views clearly.

3 FUTURE PERSPECTIVES

India has placed a heavy emphasis on agriculture biotechnology and the government sees this technology as the harbinger of a second Green Revolution, one that will bring about the same jump in food production that the original Green Revolution did. There are many reasons why this is unlikely to happen in the foreseeable future. For one, there seem to be little that Ag biotech has to offer to bring about significant yield increase. On the other hand, channeled properly and accompanied by stringent bio-safety testing, Ag biotech has the potential to solve certain specific problems in agriculture. Phenotypic traits that are dependent on single genes have a better chance of success than polygenic traits like drought tolerance.

There is more on offer than just transgenic technology in the field of agriculture. The future holds the promise of at least two new technologies that have the potential to make plant breeding more precise and effective as also to bring about an increase in food production. These two technologies are Marker Aided Selection (MAS) leading to Marker Assisted Breeding , the other is Apomixis. Still largely in the experimental stage (apomixis more than MAS), both are promising technologies without the baggage safety concerns.

MAS is a combination of molecular biology and traditional genetics which allows the selection of genes of interest by tracking the marker DNA to which the gene is linked. This makes plant breeding more precise thus saving time and allowing varieties to be developed quickly.

Apomixis which is essentially ‘freezing’ a hybrid biologically so that the advantages of hybrid vigor are perpetuated through the next generations, without segregating the way normal hybrids do. This means , once a hybrid with favorable traits is developed, it can be stabilized and farmers will be able to save seed for the next crop which they cannot do with the usual hybrids without losing the hybrid advantage.

Given the high cost and public distrust and rejection associated with Ag biotechnology as well as the difficulties of establishing biosafety, it would seem to be in India’s interest to go slow on this costly and controversial technology and invest heavily in MAS and apomixis to pave the way for a safer and more sustainable basis to food security.

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5 APPENDICES

Appendix 1: Transgenic crops under development and field trials 2006-2010

S.No.	Crop	Company Name	Trial	Trait	Gene/Event
1.	**(2006)** Brinjal (Eggplant)	Indian Agriculture Research Institute (IARI), New Delhi			*cry1Aa and cry1Aabc*
	Brinjal	Sungro Seeds Ltd, New Delhi			*cry1Ac*
	Brinjal	MAHYCO, Mumbai			*cry1Ac*
	(2007) Brinjal	MAHYCO, Mumbai	LST	Insect Resistance	*cry 1 Ac*
	Brinjal	University of Agricultural Sciences, Bangalore	MLRT	Insect Resistance	*cry 1 Ac*
	Brinjal	Sungro Seeds Research Ltd. New Delhi	MLRT	Insect Resistance	*cry 1 Ac*
	Brinjal	Tamil Nadu Agricultural University, Coimbatore	MLRT	Insect Resistance	*cry 1 Ac*
	(2009) Brinjal	Bejo Sheetal Seeds Pvt. Ltd. Jalna	BRL-I	Insect Resistance	*cry1Fa1* (Event 142)
	Brinjal	University of Agricultural Sciences, Bangalore	Seed multiplication	Insect Resistance	*cry1Ac*
2	**(2006)** Cabbage	M/s. Nunhems India Pvt. Ltd., Gurgaon, Haryana			*cry1Ba and cry1Ca*
	(2009) Cabbage	Nunhems India Pvt. Ltd. Haryana	Net house	Insect Resistance	*cry1Ba, cry1Ca* and *bar*
	(2010) Cabbage	M/s. Nunhems India Pvt Ltd, Haryana	Net house	Insect Resistance	6 events namely CF-3, CF-4, CF-5, CA-1, CA-2 and CA-6 of transgenic cauliflower and cabbage (3 events for cauliflower including hybrids of two of them and 3 events from cabbage including hybrids of two of them) containing *cry1Ba, cry1Ca* and *bar* genes.
	Cabbage	M/s. Nunhems India Pvt Ltd, Haryana	Event selection in net house under contained condition	Insect Resistance	*cry1Ba, cry1Ca* and *bar*
3.	**(2006)**	Directorate of			*cry1Aa and cry1Ec*

	Castor	Oilseeds Research (DOR), Rajendranagar, Hyderabad			
4.	**(2006)** Cauliflower	Sungro Seeds Ltd, New Delhi,			*cry1Ac, cry1Ba and cry1Ca*
	(2008) Cauliflower	Sungro Seeds Research Ltd, New Delhi.	BRL-I	Insect Resistance	*cry1Ac*
	(2009) Cauliflower	Nunhems India Pvt. Ltd. Haryana	Net house	Insect Resistance	*cry1Ba, cry1Ca* and *bar*
	(2010) Cauliflower	M/s. Nunhems India Pvt Ltd, Haryana	Net house	Insect Resistance	6 events namely CF-3, CF-4, CF-5, CA-1, CA-2 and CA-6 of transgenic cauliflower and cabbage (3 events for cauliflower including hybrids of two of them and 3 events from cabbage including hybrids of two of them) containing *cry1Ba, cry1Ca* and *bar* genes.
	Cauliflower	M/s. Nunhems India Pvt Ltd, Haryana	Event selection in net house under contained condition	Insect Resistance	*cry1Ba, cry1Ca* and *bar*
5	**(2006)** Corn	Monsanto India Ltd, Mumbai			*cry1Ab gene (Mon 810 event)*
	(2008) Corn	Monsanto India Ltd. Mumbai	BRL-I	Insect resistance and Herbicide tolerance	Stacked *cry2Ab2* and *cryA.105* (MON 89034) & *CP4EPSPS* (NK603)
	(2009) Corn	Monsanto India Ltd., Mumbai	BRL-I second year	Insect resistance and Herbicide tolerance	Stacked *cry2Ab2* and cryA.105 (MON 89034) & *CP4EPSPS* (NK603)
	Corn	Pioneer Overseas Corporation, New Delhi	BRL-I	Insect resistance and Herbicide tolerance	Stacked *cry1F and CP4EPSPS* (stacked event of TC1507XNK603)
	Corn	Dow Agrosciences India Pvt. Ltd.	BRL-I	Insect resistance	c*ry1F* (event TC1507)
	(2010) Corn	M/s. Dow AgroSciences India Pvt. Ltd. Mumbai	BRL-I second year	Insect resistance	*cry1F* (event TC 1507) gene
	Corn	M/s. Syngenta Biosciences Pvt. Ltd. Mumbai	BRL-I	Insect Resistance	*cry1Ab* gene (Event Bt11)
	Corn	M/s Monsanto India Ltd., Mumbai	BRL-I second year	Insect Resistance and Herbicide Tolerance	stacked *cry2Ab2* and *cry1A.105* genes (Event MON 89034) &

					CP4EPSPS genes (Event NK603)
6	**(2006)** Groundnut	ICRISAT, Hyderabad			*chitinase gene from rice (Rchit)*
	(2010) Groundnut	ICRISAT, Hyderabad	Event Selection in net house under confined conditions	Fungal Resistance 9	events namely RC-GN-12, RC-GN-23, RC-GN-24, RC-GN-27, RC-GN-29, RC-GN-30, RC-GN-31, RC-GN-36 and RC-GN-44
	Groundnut	ICRISAT, Hyderabad	Event selection in net house	Virus Resistance	11events namely GN TSV 3, GN TSV 9, GN TSV 30, GN TSV 31, GN TSV 33, GN TSV 40, GN TSV 41, GN TSV 48, GN TSV 50, GN TSV 94, GN TSV 101, control (JL 24) and control (TMV 2) containing coat protein gene of tobacco streak virus
	Groundnut	University of Agricultural Sciences, GKVK Campus, Bangalore	Event selection	Abiotic tolerance/drought resistance	Events namely 166-4 (A1), 187-3-1-1 (A2) and 296-12-4-4 (A4) over expressing *DREB1A* for stress tolerance (Drought tolerance)
	Groundnut	University of Agricultural Sciences, GKVK Campus, Bangalore	Event selection	Abiotic tolerance/drought resistance	Events namely 475-1-6-1 (B9), 505-7-5-6 (B11), 525-10-2-3 (B14), 537-6-6-1 (B15), 526-6-1-4 (B16) over expressing *DREB1B* for stress tolerance (Drought tolerance)
	Groundnut	M/s. Dow Agro Sciences India Pvt. Ltd. Mumbai	BRL-I second year	Insect resistance	*cry1Ac & cry1F* (WideStrike = Event 3006-210-23 and Event 281-24-236)
7.	**(2006)** Okra	MAHYCO, Mumbai			*cry1Ac, cry2Ab*
	(2007) Okra	MAHYCO, Mumbai	MLRT	Insect Resistance	*cry1Ac*
8.	**(2006)** Potato	Central Potato Research Institute (CPRI), Shimla			*RB gene derived from Solanum bulbocastanum*
	(2009) Potato	Central Potato Research Institute,	Event selection	Transgenic dwarf	*GA20 Oxidase1* (Events HP-600, HP-608, HP-609, HP-502, HP-504,

		Shimla		potato ---------------- Disease Resistance (late blight) ----------------- Reduction in cold-induced sweetening and chip colour improvement	HP-508, HP-401, HP-425, HP-431and HP-433) -------------------------- RB gene for conferring resistance to late blight disease ----------------------- vacuolar acid and invertase RNAi-transgenic events namely K.ChipInvRNAi-2214, K.ChipInvRNAi-2013, K.ChipInvRNAi-2311, K.ChipInvRNAi-2123, K.ChipInvRNAi-2262, K.ChipInvRNAi-2213, K.ChipInvRNAi-2015
9 .	**(2006)** Rice	IARI, New Delhi			*cry1B-cry1Aa fusion gen e*
	Rice	Tamil Nadu Agricultural University, Coimbatore			*rice chitinase (chi11) or tobacco osmotin gene*
	Rice	MAHYCO, Mumbai			*cry1Ac, cry2Ab*
	(2007) Rice	MAHYCO, Mumbai	MLRT	Insect Resistance	*cry1Ac*
	(2008) Rice	Bayer Bioscience Pvt. Ltd. Hyderabad	Event selection	Insect Resistance	*cry 1 Ab, cry 1C & bar*
	(2009) Rice	Bayer Bioscience Pvt. Ltd., Hyderabad	Event selection	Insect Resistance	*cry 1Ab, cry 1Ca & bar*
	Rice	Maharashtra Hybrid Seeds Co. Ltd. Mumbai	“	“	20 Bt Rice events namely 2Bt-1 to 2Bt-20 containing *cry2Ab*
	(2010) Rice	M/s. Bayer Bioscience Pvt Ltd., Hyderabad	Event selection	Insect Resistance	56 Bt rice lines events namely RICE1502-RICE1509, RICE1515, RICE1526, RICE1551-52, RICE1555, RICE1557-58, RICE1576, RICE2111-12, RICE2114, RICE3105, RICE3107, RICE3130, RICE3301-17, RICE3401, RICE3403-19 and LLRICE62 containing *cry1Ab, cry1Ca & bar* genes
	Hybrid rice SPT	M/s. E.I. DuPont India Pvt. Ltd,	Event selection	Male sterile female inbred	9 events namely DKC118, DKC45, JH02,

	maintainer	Haryana		rice lines.	JH04, JH11, JH15a, JH22, JH26b and JH34b containing Os-Msca1 gene
10.	**(2006)** Tomato	IARI, New Delhi			*antisense replicase gene of tomoto leaf curl virus*
	Tomato	MAHYCO, Mumbai			*cry1Ac*
	(2008) Tomato	Avesthagen Ltd. Bangalore	Event selection	Increased lycopene content	unedited *NAD9*
	(2010) Tomato	Indian Institute of Horticultural Research, Bangalore	Event selection	Virus Resistance	16 events namely PR 38-7, PR42-1, PR55-5, AS78-7, AS194-11, AV60-2, AV1-5, AVNv4A, AVNv4B, AM97-9, AM95-16, AM93-5, AM190-8, AM190-11, AM190-12 and AM190-14 30 events namely AM-188-4, AM188-26, AM-184-1, AM184-6, AM184-31, AM171-2, AM171-9, AM171-11, AM171-12, AM171-16, AM171-17, AM190-8, AM190-11, AM190-12, AM190-14, AS194-5, AS194-10, AS194-11, AS194-13, AS194-16, PR148-37, PR148-49, PR149-23, PR149-31, PR200-9, PR208-27, AV157-13, AV157-14, AV157-16, AV160-13, AV163-19 9 events namely ANMi, ANM2, ANM3, Av 225-7, ANV-9, ANV-1, PR130-13, PR 130-12, AS231-7
11.	**(2007)** Cotton	MAHYCO, Mumbai	MLRT	Insect resistance and Herbicide tolerance	stacked *cry1Ac, cry2Ab* (Event 15985) and *CP4EPSPS* (MON 88913)
	(2008) Cotton	Dow Agro Sciences India Pvt. Ltd., Mumbai	BRL-I	Insect Resistance	*cry1Ac & cry1F* (WideStrike = Event 3006-210-23 and Event 281-24-236)
	Cotton	JK Agrigenetics Ltd	BRL-I	Insect Resistance	*cry1Ac* (Event-1) and *cry1EC* (Event-24)
	Cotton	MAHYCO, Mumbai	BRL-I	Insect resistance	*cry1Ac & cry2Ab* (MON

				and Herbicide tolerance	15985) and *CP4EPSPS* (MON 88913)
	Cotton	Metahelix Life Sciences, Bangalore	LST	Insect Resistance	*cry1C* (MLS9124 event)
	Cotton	Central Institute for Cotton Research, Nagpur	LST	Insect Resistance	*cry 1Ac*
	(2009) Cotton	JK Agrigenetics Ltd, Hyderabad	BRL-I --------------- BRL-1 second year and F1 seed production in an area of 0.5 hectare	Insect Resistance	*cry1Ac* (Event-1) and *cry1EC* (Event-24)
	Cotton	Dow Agrosciences, Mumbai	BRL-1 second year ---------------- BRL-1 ----------------F1 experimental seed production	Insect Resistance	*cry1 Ac & cry1F* (Widestrike=Event 3006-210-23 and Event 281-24-236)
	Cotton	Central Institute for Cotton Research, Nagpur	Event selection	Virus resistance	30 events of Antisense Coat Protein (ACP), Sense Coat Protein (SCP) and Antisense Replication Protein (AReP) genes [(13 events of H-777 variety
	RRF cotton	Maharashtra Hybrid Seeds Co. Ltd., Mumbai	BRL-1 second year	Insect Resistance and Herbicide tolerance	Stacked *cry1Ac & cry2Ab* (MON 15985) and *CP4EPSPS* (MON 88913)
12.	**(2009)** Chickpea	ICRISAT, Hyderabad	Event selection	Abiotic tolerance/drought resistance	DREB1A gene derived from *Arabidposis thaliana* driven by the drought-responsive promoter of *rd29A* gene from *A. thaliana*
	Chickpea	NRC for Plant Biotechnology, Indian Agricultural Research Institute (IARI), New Delhi	"	Insect Resistance	*cry2Aa*
13.	**(2009)** Sorghum	National Research Centre for Sorghum, Hyderabad	BRL-1	Insect Resistance	*cry1B gene NRCSCRY1B event 4 and NRCSCRY 1B event 19*

	(2010) Sorghum	Central Research Institute for Dryland Agriculture, Hyderabad	Event selection	Abiotic tolerance/drought resistance	7genotypes with Events namely pCAMBIA 1300: *mtlD* CRIDA 1-6-1-8-4, *mtlD* CRIDA 2-9-3-3-5, *mtlD* CRIDA 4-7-1-7-4, *mtlD* CRIDA 26-1-11-6-1, *mtlD* CRIDA 75-2-21-2-1 and Events with pCAMBIA 1305.1: *mtlD* CRIDA 3-3-18-7-2 and untransformed control: SPV-462 containing *mtlD* gene
14	**(2010)** Watermelon	Indian Institute of Horticultural Research, Bangalore	Event selection	Virus Resistance	8 events namely AMa112a-1, AMa412-20, AMa432-6, AMa173-5, AMa545-1, AMa546-216, AMa547-230 and AMa548-10
15	**(2010)** Papaya	Indian Institute of Horticultural Research, Bangalore	Event selection	Virus Resistance	4 events namely TSolo4R, TSolo4Y, TSolo7-1and TSolo7-3 containing *PRSV* cp-gene
16	Sugarcane	Sugarcane Breeding Institute (ICAR), Coimbatore	Event selection	Insect Resistance	10 events namely Co 86032-Bt-7 (B), Co 86032-Bt-8 (B). Co 86032-Bt-10 (B), Co 86032-Bt-17(B), Co 86032-Bt-18(B), Co 86032-Apr-Bt-2(B), Co 86032-Apr-Bt-4(B), Co 86032-Apr-Bt-3(A), Co 86032-Bt-5(A), Co 86032- Bt-6(A)
17.	Maize	M/s. Pioneer Overseas Corporation, Hyderabad	BRL-I second year	Insect Resistance and Herbicide Tolerance	*cry1F & PAT* and *CP4EPS PS* genes (TC1507 x NK603 (DAS-01507-1 x MON-00603-6)

BRL-I: Biosafety Research Level-I

BRL-II: Biosafety Research Level-II

LST: Large Scale Trial

MLRT : Multi Location Research Trial

XX CGIAR institute
XX- Public sector institutions

Appendix 2: Recommendations to improve the Biotechnology Regulatory Authority of India Bill, 2009

Biotechnology Regulatory Authority of India Bill,2009	Recommendation for changes
Section 63 (Misleading public about organism and products): whoever, without any evidence or scientific record misleads the public about the safety of the organisms and products specified in Part I or Part II or Part III of the schedule I, shall be punished with imprisonment for a term which shall not be less than six months but which may extend to one year and with fine which may extend to two lakh rupees or with both.	**Old section 42.** **I**t Should be deleted. There is utter confusion in the way authorities are constructed. No understanding of functions and responsibilities.
Section 27 (Disclosure of confidential commercial information) The section 27 (1): In case an application to be submitted under sub-section (1) of section 24 or sub section (1) of section 26 require the disclosure of confidential commercial information, such information shall ,notwithstanding anything contained in the Right to Information Act,2005, be retained as confidential by the Authority and not be disclosed any other party. **(2)** If the Authority is satisfied that the public interest outweighs the disclosure of confidential commercial information or such disclosure shall not cause harm to any person, it may refuse to retain that the information as confidential commercial information.	Relates only to confidential commercial information but this CCI must be strictly defined
Section 3 (h) definitions: **confidential commercial information**	Should be clearly defined and restricted strictly to the innovative component; cannot include information which can have a bearing on the environment, human and animal health or socioeconomic impact
Section 5 composition of authority **Section 6** qualification appointment of chairperson and members	Authority must be broad based with experts from diverse fields, representatives of the farming community, with adequate representation of women and public interest groups
New bill section 18 Functions and power of Authority :	It is stated in Section 18 that BRAI shall have

	powers to regulate but by what measures the Authority shall regulate have not been mentioned either under the concerned Schedules or in the Bill itself. It has been said [vide Section 18(2)] that the Authority may, by regulations, specify measures to regulate the different items which have been given under (a) to (j). These measures, in fact, would establish the quality of regulations. They should have been put in the Schedule. It is surprising that while the Authority has been given the adjudicatory role, which ought to be independent, it has also been assigned (See Section 18(3)) advisory roles to the Central Government/State Governments. The said Authority, if its independence has to be maintained, cannot be assigned the role which has been mentioned under Section 18(3) or elsewhere in the Bill.

Section 13: No act or proceeding of the Authority shall be invalidated merely by reason of- (a) any vacancy in, or any defect in the constitution of ,the authority (b) any defect in the appointment of a person as a member of the authority; or any irregularity in the procedure of the Authority not affecting the merits of the case.	Section 13 should be deleted. Vacancy or defects in the constitution of the Authority or defect in the appointment of the members of the Authority are liable to be grossly misused /abused. This can result in the authority being run by one member alone. The authority should at all times consist of all members /functional bodies. There should be no tolerance of irregularity (section 8) specially in view of the important functions performed by the Authority

chapter III Inter-Ministerial Advisory Board And Biotechnology Advisory Council **Section 15(6)** the function of the Inter-Ministerial Advisory Board shall be to ensure co-ordination amongst various Ministries, Departments, and Councils, offices Directorate and Authorities on the matter of the policy relating to modern biotechnology and discharge such other function as may be prescribed. **Section 16(6)** the function of the Biotechnology Advisory Council shall be to advise the Authority on the relevant practices on the matter relating to modern biotechnology products, their uses, safety and effects and discharge such other function as may be prescribed.	The functions of the Inter-ministerial Advisory Board as well as Biotechnology Advisory Council, have not been mentioned, merely saying that they shall be **"as may be prescribed".** It is not clear where their functions will be prescribed: in rules, regulations or elsewhere. There is scope for arbitrary action if functions are not clearly prescribed.

Section 22 Risk Assessment Unit	Risk assessment unit should be composed of two bodies one for science based risks, the other for socio- economic risks. Risk Assessment unit should included Environment Impact Assessment which is missing from GEAC as well.

New bill Section 24: Procedure by Risk Assessment Unit for the research, transport, import, organism and product. **New bill Section 26:** procedure for grant of authorization for manufacture or use of organism and products	**CONFUSION !!** The provisions given in Section 24(2) (a) to (c) are repetitions: the same provisions have been given in Section 26 (4) (a) to (c). There is also apparent conflict between Sections 24 and 26. In Section 24, it is provided that after the report of the Risk Assessment Unit, a decision will be taken by the Authority whereas in Section 26, it is mentioned that the evaluation of the application by Risk Assessment Unit shall be forwarded by the Authority to the Product Rulings Committee to look into "all relevant matters". Neither it is mentioned what those "relevant matters" are nor is there any indication about providing them in the Rules/Regulations. It is said that on the basis of the report received from the PRC, a decision either to allow or reject the application shall be taken by the Authority. This confusion should be resolved and functions of the PRC should be specified.

Section 28 Scientific Advisory Panels and Roster of Experts	There is no need for section 28 separately. it should add with (Chapter iii),(Inter –Ministerial Advisory Board and Biotechnology Advisory Council)

Section 31, Delegation The Authority may, by general or special order in writing, delegate to the chairperson or any member or officer of the authority subject to such conditions or limitations, if any as may be prescribed in the order, such of its powers and functions (except the power to make rule under section 83 under this Act) as it may consider necessary.	The delegation to the chairperson or any other person should not be permissible because the authority consists of scientific experts and the tasks performed by the Authority cannot be given to a single individual.

Chapter ix: Enforcement Of Provisions Of Act: section 36 to39.	Though under Chapter 9, it is provided as to how the directions given by the Authority shall be monitored; no specific guidelines have been provided defining the parameters of such monitoring; no procedure to ensure accountability is provided for. The monitoring and reporting procedure should be clear, transparent and should be accessible to the people. Those who are accountable for monitoring should be dealt with severely, if they fail to discharge their duties.

Section 75 (power of central government to issue directions): without prejudice to the foregoing provisions of this Act, the authority shall, in exercise of its powers or the performance of its functions under this Act, be bound by such directions on question of policy,	The power given to the central government to give directions to the Authority, is totally unacceptable. The Authority is a scientific body and it is dealing with technical issues. The central Government cannot give directions or interfere with matters which are scientific and

other than those relating to technical and administrative matters, as the central government may give in writing to it from time to time: Provided that the Authority shall, as far as practicable be given an opportunity to express its views before any direction is given under this sub-section. (2) The decision of the central Government, whether a question is one of policy or not, shall be final	technical in nature. The authority should be independent of any pressure or interference from the central/state governments.

Section 79 protection of action taken in good faith No, suit prosecution or other legal proceeding shall lie against the Central Government .the authority and other bodies constituted under this Act or any officer of the Central Government, or any member, chief Regulatory Officers and other officers or other employee of such Authority and bodies or any other officer acting under this Act for anything which is in good faith done or intended to be done under this act or the rules made there under.	Presumption that government acts are done in good faith can no longer be accepted. Government agencies should stand on par with all citizens.

Section 81:Act to have overriding effect: save as otherwise provided, the provision of this Act shall have effect notwithstanding anything inconsistent therewith contained in any other law for the time being in force or in any instrument having effect by virtue of any law other than this Act.	The provisions of the Act should not have overriding effect. They should be in addition to other important enactments like the Protection of Plant Varieties and Farmers Rights Act, 2001; Biodiversity Act 200;.Environment (protection) Act, 1986.The act cannot override considerations pertaining to biodiversity and the environment.

Section 84 (power to amend schedule I): The Central Government, after consultation with the Authority and after giving, by notification in the Official Gazette, not less than three months notice of its intention to do so, may, by like notification, add to or otherwise amend the schedule I of this Act the purposes of the Act and thereupon the said Schedule shall be deemed to be amended accordingly.	This section is completely unacceptable and must be deleted. Any changes in the schedule can only be brought about by consensus after a broader consultation undertaken by the Authority.

OTHER RECOMMENDATIONS	
1. A separate chapter should be added on liability and redress.-disaster management and notification for recall of products.	
2. There should be separate and clear provisions on revocation of approval by the	

Authority at any junction, to prevent any possible harm to the environment/public health.	
3. Must provide for setting up a statutory National Bioethics Commission.	
4. Must provide for a consultative and participatory process to priorities crops and traits for genetic improvement through biotechnology with the goals of addressing the needs of smell farmers and Indian agriculture.	
5. Must prohibit commercialisation of GM crops for which India is a centre of origin(eg.rice)	
6. Must take a clear position proscribing the use of the Herbicide Tolerance trait, which will displace woman as wage labourers and destroy food, fodder and medicinal plants.	
7. Provide for a mandatory cost risk-benefit analysis before giving approval for a GM product.	
8. Must provide for post market surveillance and monitoring of GM product.	
9. Create provision to deal with bio-terrorism.	
10. Disallow edible vaccines /GM vaccines in food crops.	

There are no provision for liability and labeling in this new bill.

(For introduction to table see chapter 2.2.1)

Appendix 3: Media articles analysed

Article	Paper	Date	Links
Genetically modified food crops will not improve productivity’	The Hindu	Dec 8, 2009	http://www.hindu.com/2009/12/08/stories/2009120861450400.htm
“Farmers don’t agree Bt Cotton is a threat to rural life”	The Hindu	Dec. 4, 2009	http://www.hindu.com/2009/12/04/stories/2009120459621400.htm
Zero tolerance for GM foods in Europe	Business Line	Nov 02, 2009	http://www.blonnet.com/2009/11/02/stories/2009110250300900.htm
Bt brinjal: A lost cause?	Business Line	Oct 30, 2009	http://www.blonnet.com/2009/10/30/stories/2009103050140800.htm
On Bt brinjal	The Hindu	Oct 22, 2009	http://www.hindu.com/2009/10/22/stories/2009102255570802.htm
Brinjal and beyond	The Hindu	Oct 21, 2009	http://www.hindu.com/2009/10/21/stories/2009102155640800.htm
Bt brinjal gets biotech regulator's approval	Business Line	Oct 15, 2009	http://www.blonnet.com/2009/10/15/stories/2009101552130100.htm
Protests against nod for Bt brinjal today	The Hindu	Oct 16, 2009	http://www.hindu.com/2009/10/16/stories/2009101654730700.htm
Centre seeks public feedback on Bt brinjal	The Hindu	Oct 16, 2009	http://www.hindu.com/2009/10/16/stories/2009101659991200.htm
Bt brinjal: No outstanding bio-safety issues	Business Line	Jul 18, 2009	http://www.blonnet.com/2009/07/18/stories/2009071850631602.htm
Environment protection authority on the anvil	The Hindu	June 7, 2009	http://www.hindu.com/2009/06/07/stories/2009060760091000.htm
GM crops in India	Business Line	May 11, 2009	http://www.blonnet.com/2009/05/11/stories/2009051150170800.htm
Bt brinjal awaits statutory nod for commercial release	Business Line	Apr 22, 2009	http://www.blonnet.com/2009/04/22/stories/2009042250931600.htm
Report sought on bt cotton cultivation	The Hindu	March 22, 2009	http://www.hindu.com/2009/03/22/stories/2009032260380500.htm
New concern over Bt brinjal plans	The Hindu	March 8, 2009	http://www.hindu.com/2009/03/08/stories/200903085

			6872000.htm
Brinjal Food Fest' to protect native varieties	The Hindu	March 3, 2009	http://www.hindu.com/2009/03/03/stories/2009030354600600.htm
A threat to human health or panacea for farming ills?	The Hindu	Feb 04, 2009	http://www.hindu.com/2009/02/04/stories/2009020459580300.htm
Bt. brinjal field trial annoys farmers	The Hindu	January 30, 2009	http://www.hindu.com/2009/01/30/stories/2009013050750300.htm
Caution sounded against GM foods and crops	The Hindu	January 21, 2009	http://www.hindu.com/2009/01/21/stories/2009012154630500.htm
Consumers must reject GM products'	The Hindu	January 19, 2009	http://www.hindu.com/2009/01/19/stories/2009011955190600.htm
India pips China, Japan in food safety confidence: study	The Hindu	January 16, 2009	http://www.hindu.com/thehindu/holnus/015200901161721.htm
Enhance crop productivity: expert	The Hindu	Jan 09, 2009	http://www.hindu.com/2009/01/09/stories/2009010954090300.htm
Playing with genes as well as life	The Hindu	Dec 15, 2008	http://www.hindu.com/thehindu/edu/2008/12/15/stories/2008121551270400.htm
GM brinjal: Coming soon to your veggie store	DNA	November 13, 2008	http://www.dnaindia.com/scitech/report_gm-brinjal-coming-soon-to-your-veggie-store_1206039
Chemical veggies making males sterile: Expert	The Tribune	October 14, 2008	http://www.tribuneindia.com/2008/20081015/jal.htm#1
Ban "field trials of GM rice"	The Hindu	September 19, 2008	http://www.hindu.com/2008/09/19/stories/2008091953530300.htm
Unsafe food Organic farming has a bright future	The Tribune		http://www.tribuneindia.com/2008/20081006/edit.htm#6
GM field trials: leaving no room for assessment	The Hindu	July 03, 2008	http://www.hindu.com/seta/2008/07/03/stories/2008070350751500.htm
GM concerns in agriculture	The Hindu	June 11, 2008	http://www.hindu.com/2008/06/11/stories/2008061153320800.htm
GM Crops Concern voiced over GM foods	The Tribune	May 25, 2008	http://www.tribuneindia.com/2008/20080526/bathind

			a.htm
GM brinjal	Business Line	May 22, 2008	http://www.blonnet.com/2008/05/22/stories/2008052250440800.htm
Few checks to prevent entry of GM food	The Hindu	May 23, 2008	http://www.hindu.com/2008/05/23/stories/2008052359971300.htm
Farmers seek ban on GM crops	The Hindu	May 07, 2008	http://www.hindu.com/2008/05/07/stories/2008050760301200.htm
Farmers seek ban on GM crops	The Tribune	May 06, 2008	http://www.tribuneindia.com/2008/20080507/nation.htm#2
Greenpeace for ban on genetically modified food	The Tribune	June 19, 2008	http://www.genecampaign.org/kap/media-analysis-gmos.pdf
GM brinjals, boon or a curse?	DNA	June 10, 2008	http://www.dnaindia.com/mumbai/report_gm-brinjals-boon-or-a-curse_1170081
The colour purple	The Hindu	Jun 08, 2008	http://www.hindu.com/mag/2008/06/08/stories/2008060850110500.htm
Rain hits cotton growers hard	The Tribune	June 02, 2008	http://www.tribuneindia.com/2008/20080603/haryana.htm#1
Docs seek ban on genetic foods	The Tribune	June 02, 2008	http://www.tribuneindia.com/2008/20080602/ldh1.htm
Bt cotton doesn't hike yield: experts	DNA	February 27, 2008	http://www.dnaindia.com/india/report_bt-cotton-doesn-t-hike-yield-experts_1153149
Companies must address concerns about GM crops, says scientist	The Hindu	February 1, 2008	http://www.hindu.com/2008/02/01/stories/2008020154620700.htm
Charles GM remarks risk becoming political crisis	DNA	August 17, 2008	http://www.genecampaign.org/kap/media-analysis-gmos.pdf
Do not to recommend GM crops, TNAU told	The Hindu	Jul 11, 2008	http://www.hindu.com/2008/07/11/stories/2008071150360200.htm
Understand the economics behind technology, farmers told	The Hindu	Apr 19, 2008	http://www.hindu.com/2008/04/19/stories/2008041954270500.htm
Ban on genetically modified crops sought	The Hindu	April 12, 2008	http://www.hindu.com/2008/04/12/stories/2008041254400400.htm

Seed treatment best remedy Bt cotton faces fungal attack	The Tribune	June 21	http://www.tribuneindia.com/2007/20070622/ldh1.htm
Minister seeks explanation on 'unchecked entry' of GM foods	The Hindu	Dec 1, 2007	http://www.hindu.com/2007/12/01/stories/2007120162211800.htm
GM food: notice to Centre	The Hindu	Nov 20, 2007	http://www.hindu.com/2007/11/20/stories/2007112056461100.htm
Exporters join farmers' chorus against genetically	The Tribune	October 31, 2007	http://www.dnaindia.com/money/column_an-unsung-revolution-in-cotton-country_1117031
Evergreen revolution needed'	The Hindu	Sept 29 2007	http://www.hindu.com/2007/09/29/stories/2007092961991500.htm
Need to examine all aspects of genetically modified crops	The Hindu	July 21, 2007	http://www.hindu.com/2007/07/21/stories/2007072151120200.htm
An unsung revolution in cotton country	DNA	August 22, 2007	http://www.genecampaign.org/kap/media-analysis-gmos.pdf
India okays field trial of 1 GM food crop	DNA	August 18, 2007	http://www.dnaindia.com/india/report_india-okays-field-trial-of-1-gm-food-crop_1116248
India's biotech future	The Hindu	Aug 15, 2007	http://www.hindu.com/af/india60/stories/2007081550941100.htm
Plea for ban on GM crops	The Hindu	April 11, 2007	http://www.hindu.com/2007/04/11/stories/2007041115900500.htm
Importance of genetically modified crops underlined	The Hindu	Jan 15, 2007	http://www.hindu.com/2007/01/15/stories/2007011503420300.htm
Stringent laws suggested for transgenic seeds	The Hindu	December 31, 2006	http://www.hindu.com/2006/12/31/stories/2006123102111000.htm
GM paddy runs into rough weather in TN	DNA	December 11, 2006	http://www.ddsindia.com/www/fortnight/December-Ist%20frotnight.pdf
Crops on trial : The Bharatiya Kisan Union's movement against the field trials of Bt rice reopens the debate on GM crops.	The Hindu	December 1, 2006	http://www.hindu.com/fline/fl2323/stories/20061201003603000.htm
Modified food for thought	DNA	November 5,	http://www.genecampaign.

		2006	org/kap/media-analysis-gmos.pdf
Centre gives nod to Mahyco	The Hindu	Oct 31, 2006	http://www.hindu.com/2006/10/31/stories/2006103106011000.htm
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