Agricultural Biotechnology and Biosafety in India:
Expectations, Outcomes and Lessons

A. Indira, M. R. Bhagavan and I. Virgin

CBPS
Centre for Budget and Policy Studies
Bangalore, India

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A. Indira#, M. R. Bhagavan* and I. Virgin*
Centre for Budget and Policy Studies (CBPS), Bangalore and
Stockholm Environment Institute (SEI), Stockholm

aindira1@rediffmail.com and cbps@indiatimes.com
* malur.bhagavan@sei.se
* ivar.virgin@sei.se

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STOCKHOLM ENVIRONMENT INSTITUTE

Stockholm Environment Institute
Lilla Nygatan 1
Box 2142
SE-103 14 Stockholm
Tel: +46 8 412 1400
Fax: +46 8 723 0348
E-mail: postmaster@sei.se
Web: www.sei.se

Communications Director: Arno Rosemarin
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Government of India, New Delhi:

- Department of Science and Technology, MoST
- Indian Council for Agricultural Research
- Council for Scientific and Industrial Research
- Ministry of Agriculture
- Ministry of Environment and Forestry (MoEF)
- Ministry of Health
- Ministry of Law and Justice

Karnataka State Government, Bangalore:

- Department of Agriculture
- Taskforce on Agriculture

Public Sector R&D Institutions:

- National Research Centre on Plant Biotechnology, Indian Agricultural Research Institute, Pusa, Delhi

-University of Delhi, South Campus:
    Centre for Plant Molecular Biology
    Department of Biochemistry
    Department of Genetics
    Department of Microbiology
    Department of Plant Molecular Biology

- Jawaharlal Nehru University, New Delhi:
    Centre for Plant Molecular Biology
    National Centre for Plant Genome Research
    School of Life Sciences

- Centre for Plant Molecular Biology, Tamil Nadu Agricultural University, Coimbatore

- Madurai Kamaraj University, Madurai, Tamil Nadu:
    Centre for Plant Molecular Biology
    Department of Plant Biotechnology

- Indian Institute of Science, Bangalore
- University of Agricultural Sciences, Bangalore
- University of Agricultural Sciences, Dharwar, Karnataka
- Indian Horticultural Research Institute, Hesarghatta, Karnataka
- Centre for Plant Molecular Biology, Osmania University, Hyderabad
- Department of Biotechnology, University of Hyderabad
- Directorate of Rice Research, Hyderabad

Private Sector Companies:

- Monsanto, Bangalore
- Maharashtra Hybrid Seed Company (MAHYCO), Bangalore and Dharwar
- ProAgro-PGS, New Delhi and Bangalore
- Indo-American Hybrid Seeds, Bangalore
- Biocon, Bangalore
- Genei, Bangalore
- Vittal Mallya Scientific Research Foundation, Bangalore

Civil Society Organisations (Non-Governmental Organisations):

- Gene Campaign, New Delhi
- All India Biotechnology Association, New Delhi
- Centre for Science and Environment, New Delhi
- Confederation of Indian Industries, New Delhi
- Karnataka Farmers' Association *(Karnataka Krishak Samaj)*, Bangalore
- Federation of Karnataka Chambers of Commerce and Industry, Bangalore
- Farmers' Association, Hyderabad
- Deccan Development Society, Hyderabad
- Institute for Public Enterprise, Hyderabad

ACRONYMS

Bt Bacillus thuringiensis
CBD Convention on Biological Diversity
CGIAR Consultative Group on International Agricultural Research, which comprises 16 International Agricultural Research Centres (IARCs)
CIMMYT International Research Center for Maize and Wheat (part of the CGIAR group of IARCs)
CPB Cartagena Protocol on Biosafety
CPMB Centre for Plant Molecular Biology
CSIR Council for Scientific and Industrial Research
CSO Civil Society Organisation
DBT Department of Biotechnology, under the Ministry of Science and Technology
DLC District Level (Biotechnology and Biosafety) Committee
DNA Deoxyribonucleic acid
DST Department of Science and Technology, under the Ministry of Science and Technology
EU European Union
FAO UN Food and Agriculture Organization
FCI Food Corporation of India
GEAC Genetic Engineering Approval Committee, under the Ministry of Environment and Forestry
GM Genetically modified
GMO Genetically modified organism
GoI Government of India
GURT Gene use restriction technology (the so called 'Terminator Technology ')
IBSC Institutional Biosafety Committee
ICAR Indian Council for Agricultural Research
ICSSR Indian Council for Social Science Research
IFPRI International Food Policy Research Institute (part of the CGIAR group)
IMRC Indian Council for Medical Research
IPR Intellectual property rights
IPRB International Program on Rice Biotechnology
IRRI International Rice Research Institute (part of the CGIAR group)
ISAAA International Service for the Acquisition of Agri-Biotech Applications
ISNAR International Service for National Agricultural Research (part of the CGIAR group)
LMO Living modified organism
MEC Monitoring and Evaluation Committee, under DBT
MoA Ministry of Agriculture
MoC Ministry of Commerce
MoEF Ministry of Environment and Forestry
MoH Ministry of Health
MoLJ Ministry of Law and Justice
MoST Ministry of Science and Technology
NGO Non-governmental organisation
OECD Organisation for Economic Co-operation and Development
PVP Plant Variety Protection
RCGM Review Committee on Genetic Manipulation, under DBT
R&D Research and Development
TNC Transnational Corporation (Multinational Corporation)
TRIPS Trade Related Intellectual Property Rights
SBCC State (Level) Biotechnology (and Biosafety) Co-ordination Committee
UAS University of Agricultural Science
UGC University Grants Commission
UNDP United Nations Development Programme
UNEP United Nations Environment Programme
UPOV International Union for the Protection of New Varieties of Plants
WTO World Trade Organization

GLOSSARY

Sources:

• Nuffield Council on Bioethics (2004) *The use of genetically modified crops in developing countries: A Follow-up Discussion Paper.* Nuffield Council on Bioethics, London. www.nuffieldbioethics.org/gmcrops

• Steinberg, M. L. and Cosloy, S.D. (2001) *The Facts on File Dictionary of Biotechnology and Genetic Engineering.* Checkmark Books, New York

Abiotic stress: Environmental stresses, which can reduce the productivity of a crop. These include weather conditions such as excessive or untimely frosts, and extended droughts and adverse soil conditions such as high levels of salt or aluminium.

Agrochemical: A chemical, such as a fertiliser, a herbicide or an insecticide, that improves the productivity of crops.

Amino acids: Molecules which, when linked together, form proteins.

Biodiversity: The number and variety of plants, animals and other organisms that exist in nature genetic data.

Biotic stress: Stress resulting from attack by organisms capable of causing disease.

Bt: The bacterium *Bacillus thuringiensis* which produces proteins that are toxic to some insects.

Centre of diversity: A centre of diversity would often contain a variety of cultivars and their wild relatives. Such areas often harbour a wide range of natural genetic variation for a particular crop.

Chromosomes: The thread-like structures in cells that carry DNA, on which genetic information is arranged.

Crossing: Cross breeding different varieties of a crop species or, occasionally, varieties of closely related species.

Cultivar: A genetically defined plant variety which has been selected to be adapted for agricultural use.

Disease resistance: The capacity of a plant, usually determined by one or a few genes, to suppress or retard the activities of a disease-causing organism.

DNA: The biochemical substance from which the genetic material of cells is made. DNA has a thread-like structure. The DNA in a plant or animal cell is in several long lengths called chromosomes, each of which contains many genes.

Gene: A linear fragment of *DNA* which contains the information needed to make proteins.

Geneflow: The transfer of genes via pollen to or from a cultivated crop to other crop plants, wild relatives, other plant species or other organisms.

Genetic modification: A technology which allows selected individual genes to be transferred from one organism into another, including genes from unrelated species. The technology can be used to promote a desirable crop characteristic or to suppress an undesirable trait.

Genetic engineering: The manipulation of genes through the use of recombinant DNA techniques for the purpose of modifying the function of a gene or genes for a specific purpose.

Genetics: The study of the process by which traits are transmitted from parent to offspring; the study of inheritance.

Gene use restriction technology (GURT):A technology which genetically compromises the fertility or the performance of a cultivar so that harvested grains cannot germinate without agrochemical treatment. The technology is intended to prevent undesired geneflow and/or to protect the market of the seed producer.

Genome: The entire complement of DNA (genes plus non-coding sequences) present in each cell of an organism.

Germplasm: Tissue from which new plants can be grown, for example seeds, pollen or leaves. Even a few cells may be sufficient to culture into a new plant.

Herbicide: A substance that kills plants and is used to control weeds. Herbicides vary in their specificity. Some kill a broad spectrum of plant species, while others kill only specific species or groups of species.

Herbicide tolerance: This allows a plant to tolerate a herbicide that would otherwise kill it. This can be achieved by means of either genetic modification or conventional plant breeding.

Intellectual property: An intangible form of personal property. Copyrights, patents, and trademarks are examples of intellectual property. Intellectual property rights enable owners to select who may access and use their property, to protect it from unauthorised use and to recover income.

Living modified organism (LMO, as defined in the Cartagena Protocol on Biosafety):Any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

Marker-aided selection: The use of DNA markers to select a particular trait. Selection of a DNA sequence near the gene on a chromosome avoids time-consuming and expensive tests to select the ideal parent or offspring.

Pathogen: Any microorganism that causes disease or produces a pathological condition.

Precautionary principle/precautionary approach: A rule that permits governments to impose restrictions on otherwise legitimate commercial activities, if there is a perceived risk of damage to the environment or to human health.

Precautionary Principle (as defined in the Cartagena Biosafety Protocol):The principle that the lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

Recombinant DNA: A DNA that has become joined to another unrelated or foreign segment of DNA

Tissue culture: The growth of cells, tissues or organs in a nutrient medium under sterile conditions.

Traceability: The ability to trace and follow a food or feed through all stages of production, processing and distribution.

Transformation: The process by which foreign DNA is transferred and incorporated into a living cell.

Transgene: An isolated *gene* sequence used to transform an organism. The transgene may have been derived from a different species than that of the recipient.

1. INTRODUCTION

1.1 The push for agricultural biotechnology

Over the past two decades, the advances made in modern agricultural biotechnology (agro-biotechnology) have opened up new frontiers in agricultural production. The new techniques for understanding and modifying the genetics of living organisms have led to large investments in agro-biotechnology research and development (R&D). Most of this development has taken place in North America, Western Europe and East Asia, with the United States being far ahead of the others. Today, six transnational agro-chemical corporations (TNCs –Monsanto, Bayer, Syngenta, DuPont, Dow and BASF) dominate the global arena for GM-crops, from R&D to marketing. However, a number of public-sector universities and research institutions in the West have also been deeply involved, often in close collaboration with the TNCs. This situation, in concert with the ability to protect the intellectual property rights (through patents, etc.) of their GM-technologies and GM- innovations, has to a large extent vested the ownership and control of globalised GM-crops and GM-technologies in the globalised private corporate sector. The push by the TNCs has so far resulted not only in the commercial production of GM-varieties of some global crops (such as cotton, maize, soya bean and oilseed rape) in the leading grain exporting countries (USA, Canada, Argentina and Australia), but also in GM-cotton and GM-maize being commercially grown in several developing countries (e.g. China, India, Indonesia, the Philippines and South Africa).

However, a diverse range of developing countries, from the technologically advanced like Brazil, China, India, Malaysia and South Africa to the technologically less advanced like Egypt, the Philippines and Vietnam are also investing a significant part of their total R&D resources on agro-biotechnology. In striking contrast to the trend in the OECD region, the developing country R&D investments and activities are almost entirely in public sector universities and research institutions. These public sector R&D efforts are focused on local crops cultivated by small-scale farmers. In the short to medium term, this R&D work, and the subsequent commercialisation of the GM-innovations, will be dependent on the GM- technology of the private sector and thus on the intellectual property rights held by the private sector. But, in the longer term, and given the required resources and support, public sector institutions in many developing countries would be able to develop their own GM technology.

Intense debate is taking place in parts of the developing world about the potential benefits and risks associated with the introduction of GM-crops. Broadly speaking, while many government departments, agro-biotechnology R&D institutions, and seed breeding and marketing companies are firmly in the pro-GM camp, and environmental and consumer organisations make up the core of the anti-GM grouping, other major ‘stakeholders ’ such as farmers ’ associations and the media are split between the two sides. The principal issues of contention are the potential increases in yield, decreases in the use of pesticides and herbicides, impact on the physical environment (ecology and biodiversity), the health of human beings and animals (livestock), the livelihoods and socio-economic futures of small farmers, the ownership and control of genetic resources, and trade.

1.2 Meeting future global demand for food and livestock feed: What can technology do?

According to the United Nations, world population is estimated to increase from the current 6.3 billion to 7.5 billion by 2020 and 8.1 billion by 2030.Africa and Asia are expected to account for most of this increase, by factors of 1.3 and 1.7, respectively, over the next thirty years[1] .The demand for cereals in the developing world is expected to grow by about 560 million metric tons over the 23-year period 1997-2020 (from 1120 to 1680 million metric tons), while the demand in the developed world is

[1] *World Population Prospects: The 2002 Revision*, Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat (2003).

estimated to increase by about 100 million metric tons (from 720 to 820 million metric tons). Developing Asia will account for more than half the increase. The regional shares of increased cereal demand during the period 1997-2020 are estimated as follows[2] : developed countries 15 %, China 27 %, India 12 %, other Asian developing countries 14 %, sub-Saharan Africa 11 %, Latin America 11 %, and West Asia/North Africa 10 %.

With accelerating urbanisation and increasing household incomes in both rural and urban areas, not only will the *per capita* consumption of food increase, but also its content is expected to shift substantially towards more dairy products, poultry products and meat, implying increased cereal consumption (most of it maize and soya beans) by livestock [3] Therefore a corresponding increase in the animal feed share, and a decrease in human food share, of the developing world 's total cereal demand is expected [4]

Assuming that domestic production within developing countries rather than imports from the OECD region will have to be the principal means of meeting this demand, the productivity of agriculture in the developing world has to keep pace with the growing demand. The views on how to meet this challenge vary greatly. Some argue for fundamental reforms to agricultural and food systems, while others believe that significant growth in food and feed production can occur only if either new land is brought under cultivation or if agriculture becomes more intensive in its inputs, or both. Still others are convinced that appropriate location-specific combinations of economic, social and technical solutions are the answer.

With the Green Revolution (1970-1990) growth rates in the yields of global staple cereals (maize, rice and wheat) levelling off in the late 1980s, and starting to decline in the 1990s, some GM protagonists argue that the next cycle of significant rises in crop productivity can only be ensured by resorting to agro-biotechnology. Some leading international organisations [5] and United Nations institutions [6] believe that one of the major constraints on increasing the crop yields in smallholder and subsistence cultivation is the non-availability of improved seeds, and that agro-biotechnology, including GM-technology, can redress this disadvantage. This claim is strongly contested by GM-antagonists, who point to the success of several currently employed non- GM techniques in delivering productivity increases.

Needless to say, farmers in developing countries face many problems that technology cannot solve on its own, such as political and socio-economic constraints on equity, lack of infrastructure, management and husbandry, and degradation of the natural resource base. Achieving sustainable growth in farm production is a very complex challenge, and needs an integrated holistic approach, where technology is only one component. In this context, it is clear that agro-biotechnology is not a panacea, but an additional tool to address agricultural problems and challenges. It is important to point out that agro-biotechnology, including GM-technology, can never replace conventional plant-breeding, but it can be an important and successful tool in improving plant-breeding programmes.

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[2] Rosegrant, M. W., Paisner, M. S., Meijer, S. and Witcover, J., *2020 Global Food Outlook: Trends, Alternatives and Choices,* International Food Policy Research Institute (IFPRI), Washington D C, August 2001.
[3] The shift to meat and poultry products will be pronounced in developing Asia, in particular in China, which partly explains why China is expected to account for more than a quarter of the cereal demand in the developing world, while India with a comparable population will be generating less than half the Chinese demand.
[4] The estimated breakdowns are: In 1997: food 67%, livestock feed 21% and other use 12%; In 2020: food 62%, feed 26% and other use 12%; see Rosegrant *et al, op cit.*
[5] Rockefeller Foundation, World Bank, Asian Development Bank, Nuffield Council on Bioethics and the International Agricultural Research Centers (IARCs) of the CGIAR system.
[6] IFPRI, IFAD, FAO, UNDP.

1.3 India's food production and demand: Will there be a shortfall in the future and what factors are in play?

The population of India rose from 687 million in 1980 to 1,048 million in 2002 at the average annual rate of 1.9 percent. It is expected to reach 1,231 million in 2015, with the average annual rate of growth falling to 1.2 percent over the period 2002-15. At present, about 72 percent of the population is rural, 28 percent live below the national poverty line, and 34 and 80 percent live, respectively, below the international poverty lines of 1 and 2 US dollars per day[7].

Although the proportion of the total population that is chronically undernourished (chronically hungry) fell from 25 percent in 1990-92 (216 million) to 21 percent in 1995-1997 (203 million), it remained unchanged at 21 percent in 2000-2002 (221 million). In other words, while the absolute number of the chronically undernourished <u>fell</u> by 13 million during the period 1990/92- 1995/97, it <u>rose</u> by 18 million during 1995/97- 2000/02 [8].

Between the two ten-year periods, 1983-1992 and 1993-2002, the average annual growth rates in crop and livestock production <u>declined</u> from 3.9 to 2.1 percent, and in *per capita* food production <u>fell</u> from 1.9 percent to 0.6 percent[9]. *These figures indicate that the 'Green Revolution' growth rates in the production of the staple cereals, rice and wheat, are levelling off and the comfortable lead that food production growth maintained over population growth is being eroded. Were these trends to continue, the growth in per capita food production could cease in a decade or two, even if the population grows at only one percent per year or less.*

In view of the fact that nearly 20 percent of the population (about 220 million) is at present chronically undernourished, and their number rose by 18 million over the period 1995-2002, the question arises as to whether this is due to shortfall in food production. The answer is a clear 'no'. For many years now, India has produced more food than can be sold on the domestic market, in particular the staple cereals rice and wheat,. The central government owned Food Corporation of India (FCI), the state governments and their agencies, have together a long and successful history of building up large reserve stocks of rice and wheat in a central pool. Each year, the FCI buys up roughly 12 to 15 percent of the rice production and 15 to 20 percent of the wheat production from the farmers at a reasonable 'floor price', while releasing similar volumes of the two staple cereals on to its public distribution system for sale in retail outlets at subsidised prices. Two strategies lie behind the reserve stocks: First, to guard against severe shortfalls in food supply due to climatic disasters (droughts and floods) and biotic epidemics (plant pests and diseases). Second, to act as a reliable and attractive incentive to farmers to grow more food. Experience has demonstrated the success of these two strategies. From the mid-1970s onwards, large-scale famines have been averted. And the growth in the production of staple cereals has kept ahead of the growth in population. In recent years, a third strategy has come into operation: to make food an increasingly important export commodity. The following table of some of the latest available figures provides a 'snapshot' of the recent situation[10].

Table: Production, stocks and export of rice and wheat *(in million metric tonnes)*

	Production in 2002	Production in 2003	Stocks in Central Pool as of October 2004	Export in 2002
Rice	107.6	130.4	6.092	4.97
Wheat	72.7	65.1	14.223	3.67

The above figures strongly suggest that it is not any shortfall in food supply that lies behind the disconcertingly large number of the chronically undernourished. In all probability, the mass

[7] World Development Indicators 2004, The World Bank, www.worldbank.org
[8] The State of Food Insecurity in the World 2004, FAO, www.fao.org
[9] The State of Food and Agriculture 2004, FAO, www.fao.org; World Development Indicators 2004, The World Bank, www.worldbank.org
[10] Sources: FAO, www.fao.org/es/ess/compendium_2004 and FCI, www.fciweb.nic.in/stocks

undernourishment is due to the extreme poverty of nearly 30 percent of the population. A poverty that prevents them from buying adequate quantities of food on the local market at prevailing prices, when they cannot grow the required quantities for self-consumption[11].

The Indian authorities have tried to reduce the large stocks of rice and wheat, which are very expensive to maintain, by trying to export more, but have made little headway, due mainly to excess supply and fierce competition on the global markets.

1.4 The driving force behind Indian agricultural biotechnology development

Since the late 1980s, the Government of India has given high priority and strong support to the development of agro-biotechnology. It is our belief that several interconnected ambitions are motivating the Indian authorities to provide this energetic backing: They want to
- make India one of the world's leading nations in agro-biotechnology
- gear this indigenous technological development to Indian needs
- see Indian crop yields regain the heights reached in the heyday of the 'Green Revolution'
- ensure that India remains self-sufficient in food, far into the future [12], and
- make India a major global exporter of food[13].

In their comments on the final draft version of the present study, DBT advance the following argument (*we quote from DBT's text, subject to our slight editing)*:
"Although the overall contribution of agriculture to India's GDP is gradually declining, it is still the leading and most significant sector of the economy. Indian agriculture faces the challenge of having to produce more farm commodities for an increasing population of humans and livestock under conditions of diminishing per capita arable land and irrigation water resources, and persistent biotic and abiotic stresses."

1.5 The different categories of agricultural biotechnology

Agro-biotechnology, broadly defined, refers to any technique that uses living organisms, or substances from these organisms, to analyse and modify plants, animals and organic products, and to make new organic products. It is not a separate science, but rather a mix of disciplines comprising molecular biology, cell biology, microbiology, biochemistry, genetics and genomics. It consists of a gradient of technologies, ranging from the long-established and widely used techniques of traditional biotechnology (e.g. fermentation of foods and brewing of beverages), through to novel and continuously evolving techniques, such as genetic engineering. The present range of modern techniques in agro-biotechnology is summarised below. All of these techniques are currently in use in the breeding of crops and livestock.

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[11] This is a forceful illustration of Amartya Sen's renowned finding that widespread hunger and famine are, in general, the outcome of the poor's lack of 'entitlements' that prevents them from accessing the food available on the market.
[12] In contrast, say, to China, which with its comparable size in population became a net importer of rice in 2004, the first time in the last fifty years. Current projections foresee China becoming more and more dependent on imported food. Several reasons account for this: Loss of arable land to urbanisation and transport infrastructure; growing demand for livestock feed as food consumption patterns shift towards more dairy, poultry and meat products, in step with rising incomes; and land erosion and degradation due to logging, floods and droughts. The same factors and forces are at work in India too, but somewhat less intensely. In 2002, the arable land available in China was 1.4 million square kilometres (15.4 % of the total land area of 9.3 million square kilometres) for a population of 1280 million; the figures for India for the same year were, respectively, 1.6 million square kilometres (54.4 % of 2.97 million square kilometres) for 1049 million. Sources: World Development Indicators 2004, The World Bank, www.worldbank.org; and FAO, www.fao.org
[13] Over the last decade, ministers and top officials in the ministries of agriculture and science and technology have repeatedly expressed such hopes. For one of the latest statements, see the views of the Union Minister of Science and Technology, Mr Kapil Sibal, quoted in the news report: *India to Promote GMO Crops in New Policy*, Reuters, Atul Prakash, 1Sept 2004, http://www.agbios.com/main.php?action=ShowNewsItem&id=5811

Molecular diagnostics and serology

These consist of nucleic acid based approaches (e.g. Polymerase Chain Reaction/PCR based techniques and DNA probes), and/or of antibodies, to provide rapid and more accurate identification of pathogens and diseases that affect plants and animals. The use of antibodies is a mature and robust technology dating back to the 1960s. No genetic modification is involved.

Tissue culture

This is based on the culture of cell tissues in a nutrient medium under sterile conditions. It is a well-proven and robust technology for rapid mass propagation of improved and disease free planting material for a variety of crops and trees. It is now widely practiced in several developing countries, including India, in the commercial agriculture of a number of crops (vegetables, fruits, spices and some industrial crops). Although almost all of the tissue cultures currently in use are *non-GM*, research work is going on in several developing countries, including India, to incorporate GM-techniques.

Marker aided selection (MAS)

The technique of marker-assisted selection uses DNA-markers to select and identify crop varieties with particular traits (e.g. increased drought and salt tolerance). It makes the traditional breeding of crops and livestock more precise and rapid. No genetic modification is involved.

Genetic modification / Genetic engineering

This involves the transfer and introduction of genes within and across species barriers, conferring potentially desirable traits on crop, livestock, fish and tree species. It results in genetically modified organisms (GMO) with genetic structures incorporating the new traits.

Livestock and fish vaccines

Biotechnology-based advances in immunology have made it possible to develop thermo-stable recombinant-DNA vaccines for preventing certain diseases in livestock and fish. These techniques are closely related to those used in the development of edible vaccines for human beings.

Functional Genomics and Bioinformatics

Functional genomics is the science of the molecular characterisation of genes and the functioning and regulation of genes in a species. Bioinformatics consists in the assembly of data from genomic analysis into accessible and applicable forms. Together, they pave the way towards a more precise engineering of desired physiological and structural properties in living organisms.

1.6 Potential benefits and risks associated with GM-crops

The potential benefits comprise increases in crop yields, decreases in the use of pesticides and herbicides, and improvement in nutritional content and storage characteristics. In contrast to 'Green Revolution ' technology, GM-technology will not directly lead to increases in the seed output of plants. The increases in crop yields are attained *indirectly* through genetically engineered *resistance* in plants to certain pests and diseases ('biotic stresses '), and greater *tolerance* to drought, salinity, frost, etc. ('abiotic stresses'). As these stresses are indeed the major constraints on the growth of crop yields in many developing countries, GM-varieties designed to overcome them are potentially valuable to the developing world.

The potential risks to human and animal (livestock) health would arise from unexpected consequences of introducing new genes, such as the appearance of allergens, toxins and carcinogens in GM-food and GM- livestock feed. Ecological and other environmental risks could arise from cross-pollination between GM-crops and their indigenous wild relatives, potentially leading to loss of biodiversity, and the emergence and spread of pests, diseases and weeds that could acquire the same resistances as are engineered into the GM-crops. The socio-economic safety of small farmers may be put at risk by the potentially negative impact on them of the agronomic and trade consequences of GM-crops.

In their comments on the final draft version of the present study, DBT add the following to the list of potential benefits (*we quote from DBT's text, subject to our slight editing)*:
The application of GM- technology permits "a range of gene-inactivating techniques to reduce, or switch off, the activity of specific unwanted genes. These might be fruit softening, toxin or allergen genes." It also permits "the introduction of new plant genes, or enhancement of existing genes, to improve protein content, increase vitamins and nutrients, starch or oil yield, modify oils or starches, enhance fruit flavour, colour or nutrition." It enables the "development of rapid genetic typing methods to speed conventional plant breeding, leading to identification of genes responsible for desirable traits, and their transfer to other species."

1.7 Biosafety concerns: Differences among countries in their attitudes and approaches to GM-crops

The potential risks associated with genetically modified organisms (GMOs) have made it imperative for governments and civil societies to address the issue of 'biosafety' in all the four major sectors of biotechnology: medical/pharmaceutical, agricultural, industrial and environmental. In the context of GM-crops, the concept of 'biosafety' is, in principle, a broad one, covering three areas: the health safety of humans and livestock, the safety of the environment (i.e. ecology and biodiversity) and socio-economic safety (i.e. the economic and social impact on farmers, consumers and different social classes, as well as on trade and economy in general). While the biosafety regulations in force in industrialised countries (e.g. the USA, the European Union, Canada, Australia, Japan, etc.) address only the health and environmental risks and exclude socio-economic considerations, the regulations in some developing countries tend to include all the three areas.

Countries have responded differently to the opportunities presented by GM-crops and the risks associated with them. The composition of the 'trade off' between potential benefits and risks in each case depends upon whether a government adopts a permissive, precautionary or prohibitive policy approach to GM- crops. For instance, the leading global exporters of grain, the USA, Canada, Argentina and Australia, adopted a permissive attitude very early on, with lower production costs and greater export profits presumably outweighing other considerations. But the European Union (EU), India, Japan, the Philippines and others have taken a precautionary approach to the introduction, cultivation and development of GM-crops, while others like Ethiopia have, for the time being, decided against the introduction of GM-crops altogether. (USA, Canada and Australia would, however, argue that they too have very strict biosafety regulations, but they have other criteria than the 'precautionary-countries' that govern the balancing of benefits against risks which results in their relatively permissive approach.)

The intense public debate in both the developing and industrialised parts of the world on the introduction and commercialisation of GM-crops and GM-products underlines the importance of mechanisms for the representation and participation of the public, in particular the civil society, in biosafety assessments and decision-making. There ought to be active and effective channels of communication between the technology-developers, the policy-makers and the wider public. Public confidence and trust are contingent on governments creating transparent and credible systems for the assessment risks and the enforcement of biosafety regulations that accord to international standards.

1.8 The present study on India: Purpose, scope, structure and methodology

India has emerged as one of the leading countries in the world in promoting local R&D in agricultural biotechnology in general and GM-crops in particular. Further, it has by now a fairly long experience in the functioning of comprehensive biotechnology and biosafety regimes that regulate the introduction and commercialisation of GM-crops and GM-products. Both on its on account (the second most populous country in the world with a broad industrial and technological base and a rapidly growing diversified economy) and as an important example to others, a critical analysis of the Indian effort and its outcome would be of considerable value.

R&D activities in the non-GM categories of agricultural biotechnology and the commercialisation of non-GM innovations (in particular, in the field of tissue culture) in India date back to the early 1980s.

Work on the GM-categories began in the late 1980s. Although, over the last fifteen years (1990-2004), many public sector R&D institutions have been actively involved in developing a score of GM-crops, with huge government support, none of these crops have yet reached the market. We analyse this paradox and offer an explanation in Sections 2, 3 and 4 below.

Private sector involvement, spearheaded by TNC joint ventures and subsidiaries, began in the mid 1990s. So far, the Indian regulatory authorities have authorised the general release and marketing of only one GM-crop, *viz.* GM-cotton varieties resistant to bollworm attack developed by the private sector.

At one level, the Government of India is pushing hard to promote R&D in GM-crops, but at another level, it is holding back tightly from integrating the GM-crop innovations into agricultural production. This 'only thus far and no further' or 'go-stop' policy is not unique to the Indian government, but is shared by other governments. It is therefore of wide interest to explore the causes and consequences of this apparent contradiction as it manifests in India, as we have attempted to do in the present study.

Our study deals only with GM-crops. We have explored the following five sets of issues, combining empirical research with theoretical analyses:

1. The scope and current status of the R&D activities in public sector institutions and private sector companies, measured against the support and opportunities made available and the constraints faced (Section 2);

2. The crucial and decisive roles played by two Government of India agencies in promoting GM-crops (Section 3);

3. The agricultural biotechnology and biosafety policies of the Government of India, the outcome of the implementation of the policies, the thinking and the priorities of certain policy-making authorities and certain sections of the public sector R&D establishment, which shaped the policies, and the policies that have a direct bearing on the transition of GM-crops 'from the lab to the market' (Section 4);

4. The structure and functioning of the biosafety regulatory authorities, the shortcomings in the implementation of the biosafety regulations, the exclusion of civil society organisations (including non-governmental organisations) and the private sector from the policy and regulatory organs and the consequences thereof (Section 5);

5. The influential role of civil society organisations (including non-governmental organisations) in obliging the authorities to heed public concerns, and their campaigns for public participation in the biotechnology and biosafety policy and regulatory regimes and for transparency and accountability by the authorities (Section 6).

The interplay of all these issues in actual practice is illustrated in Section 7, which deals in depth with two cases, GM-cotton and GM-rice. Among other things, this Section reveals the shortcomings in the implementation of the policy and regulatory regimes, and attempts to uncover the underlying reasons. Section 8 summarises the major findings and draws a number of conclusions.

The research methodology comprised the following components:

- collecting documentation from the major 'stakeholders', *i.e.* government entities (ministries, departments, agencies and research councils), public sector R&D institutions, private sector companies, and civil society organisations (including non-governmental organisations);

- gathering information from news reports and feature articles in leading English language national newspapers in India;

- accessing information and documentation on the Internet;

- conducting surveys on the basis of comprehensive stakeholder-specific questionnaires;

- conducting in-depth interviews with selected senior personnel in selected stakeholder organisations mentioned above.

2. R&D ON GM-CROPS IN INDIA

2.1 R&D in GM-crops in India Public Sector Institutions

2.1.1 Introduction

Most R&D work in India has been, and is being, conducted in the public sector, in a large number of specialist national laboratories, and research institutes and centres, and in a *limited* number of 'elite' universities (including agricultural universities) and institutes of technology. This applies to both basic (fundamental) and applied research, and covers natural and engineering sciences and technologies (including the sectors of agriculture, forestry, fishery, livestock, manufacturing and mining industry, transport, energy, etc.), medical and veterinary science and technology, social sciences, and the humanities. These institutions have been, and are being, generously funded by the central government, through several large and centralised national research councils, which also have formal authority over the individual institutions of which they are the principal funders. Besides central government funding, agricultural universities (which play a key role in the R&D of agricultural biotechnology) also receive substantial financial and infrastructural support from the governments of the states in which they are located. For further discussion of the role of the national research councils and of government policy in promoting R&D, in particular in biotechnology, the reader is referred to Sections 3 and 4 below.

2.1.2 Initiation and fostering of public sector R&D in biotechnology

By 1980, several national research councils in India had become aware of the potential importance to India of the advances being made in North America and Western Europe in modern biotechnology in the areas of medicine/pharmaceutics, agriculture and industry. At the initiative of the Council for Scientific and Industrial Research (CSIR) and the Department of Science and Technology (DST), two meetings were held in 1981 (April and July) to discuss the strategy for the development of biotechnology in India. The meetings were attended by a select group of senior scientists, the leadership of CSIR and DST and some top government officials. Within days of the July meeting, the Scientific Advisory Committee to the Cabinet met and recommended to the government the creation of a National Biotechnology Board (NBTB). The NBTB was set up in 1982, with the initial objective of creating awareness among leading circles in the medical/pharmaceutical, manufacturing and agricultural industries, as well as in relevant government departments, of the possibilities offered by biotechnology[14]. At first, the NBTB concentrated on vaccines, plant tissue culture, afforestation of dry lands, and subjects related to these areas. This limited mandate was soon widened and NBTB was transformed in 1986 into the Department of Biotechnology (DBT) under the Ministry of Science and Technology. Since then, DBT has been the principal research council for planning, funding, promoting and coordinating biotechnology R&D programmes in all the four sectors of modern biotechnology, medical/pharmaceutical, agricultural, industrial and environmental.

DBT has established five specialist R&D institutions under its own financing umbrella, one each in immunology, cell research, DNA fingerprinting, brain research and plant genome research. DBT's work is guided by two expert committees, the Scientific Advisory Committee and the Standing Advisory Committee (Overseas), as well as by a number of taskforces. While the two committees provide advice on policy matters, priority setting and monitoring of special projects, it falls to the task forces to provide advise on how to promote R&D in specific areas and to assist in reviewing and assessing research proposals submitted by institutions from all over the country for funding by DBT.

The first consolidated move to promote R&D work in GM-crops in India was made in 1990 by DBT, when it provided generous funding for the creation of six Centres of Plant Molecular Biology

[14] See "Status of Plant Biotechnology in India – An assessment from the small farmer perspective" by Naresh Sharma and P.S.Janaki Krishna, Institute of Public Enterprise, Hyderabad, 1999

(CPMB), one each at the Bose Institute (in Kolkata/Calcutta, West Bengal), Jawaharlal Nehru University (New Delhi), Madurai Kamaraj University (in Madurai, Tamil Nadu), National Botanical Research Institute (in Lucknow, Uttar Pradesh), Osmania University (in Hyderabad, Andhra Pradesh) and Tamil Nadu Agricultural University (in Coimbatore, Tamil Nadu). A seventh CPMB was established in 1997 in the University of Delhi South Campus[15].

In addition to the work at the CPMBs, DBT supports a number of GM-crop projects in several national laboratories, specialist research institutes and centres, and 'elite' institutes of technology and universities (agricultural and general) that come under the aegis (financing umbrellas) of other large central national research councils, such as the ICAR, CSIR, DST and UGC (see Section 3 below).

The other main supporter of agricultural biotechnology R&D is the Indian Council for Agricultural Research (ICAR), which falls under the Ministry of Agriculture. Up until 2002, ICAR rendered its assistance indirectly by making the R&D and field cultivation infrastructure, which it funds in a number of agricultural universities and specialist research institutes, available to DBT-funded projects. Since 2003, ICAR has committed itself to substantial direct funding of GM-crops research in the agricultural universities and institutes that come under its aegis.

For further details and discussion on DBT's and ICAR' policies, priorities and modes of operation, the reader is referred to Sections 3 and 4 below.

2.1.3 Status of public sector R&D in GM-crops

Research into GM-crops in India began in earnest in the early 1990s. As the table below shows, by 2004, twenty-two Indian institutions and two international centres, spread over sixteen cities, were actively involved in R&D work. Of these twenty-four institutions, five are in the union capital New Delhi, which between them account for a large share of the total resources committed so far by the central government to GM-crops research. The nineteen crops being researched are rice, wheat, cotton, potato, banana, tomato, oilseed rape, mustard, coffee, tobacco, aubergine (called 'brinjal' or 'eggplant' in India), cabbage, cauliflower, melon, citrus fruit, mung bean ('blackgram'), peanut ('groundnut'), chickpea and pigeon pea. While eight institutions are tackling two or more crops each, the others are concentrating on one each.

Four kind of traits are being aimed at: (i) Resistance to attacks by insect pests and viral and fungal diseases (called "biotic" stresses in the technical literature), (ii) tolerance of the "abiotic" stresses of drought, water-logging and salinity, (iii) delayed ripening, increase in shelf-life and improved storage properties, and (iv) increase in protein and micronutrient (vitamins and minerals) content.

Table. R&D in GM-crops in public sector institutions in India in 2004

Institution	Crop and variety	Traits aimed at and transgenes (gene constructs) inserted	Stages completed and ongoing
Indian Agricultural Research Institute (IARI) at Pusa in New Delhi	**Rice;** *IRRI's IR-64 and Pusa Basmati 1*	Insect resistance (yellow stem borer, a lepidopteron); Bt-genes Cry1Ab and Cry1Ac.	Greenhouse (glasshouse) tests and contained field tests
	Aubergine (Brinjal in Indian terminology**);** *Pusa purple long*	Insect resistance (shoot and fruit borers); Cry1Ab	-ditto-
	Tomato; *Pusa Ruby*	Insect resistance (fruit borer); Cry1Ac	-ditto-

[15] See Manju Sharma, K.S.Charak and T.V.Ramanaiah, *"Agricultural Biotechnology Research in India: Status and Policies"*, Current Science, Bangalore, Vol. 84, No.3, 10 February 2003

	Cabbage; *Tropical breeding line*	Insect resistance (lepidoptera); Cry1B and Cry1Ab	Greenhouse
	Cauliflower	-ditto-	Greenhouse
	Mustard and **Oilseed Rape**	Tolerance of water-logging and other abiotic stresses; Arabidopsis annexin and choline dehydrogenase	-ditto-
	Banana and Tomato	Delayed ripening; ACC synthase	-ditto-
	Tobacco and Mustard (Brassica)	Resistance to fungal disease; Chitinase, glucanase and RIP	-ditto-
	Pigeon pea	Insect resistance (bollworm and aphids); Protease inhibitor and lectin	-ditto-
IARI Sub-station in Shillong, Meghalaya State, Eastern India	**Rice**	Insect resistance (stem borers); Bt-genes	-ditto-
CPMB, University of Delhi, South Campus, New Delhi	**Rice;** *Pusa Basmati1*	Resistance to abiotic stresses; Cod A, COR 47	Greenhouse
	-ditto-	Drought tolerance; Heat shock protein gene (hsp) 100	-ditto-
	-ditto-	Tolerance of water-logging; Pyruvate decarboxylase and alcohol dehydrogenase	-ditto-
	Wheat; *T. aestium and T. durum*	Herbicide resistance; Bar. Drought tolerance; HVA1. Insect resistance, Pin2	-ditto-
	Tomato; *Pusa Ruby*	Edible vaccine; Ctx-B and antigens of Vibrio cholerae	-ditto-
	Cotton; *Coker*	Insect resistance (bollworms); Cry 1Ac	-ditto-
	Mustard; *B. juncea, Varuna,* and **Oilseed Rape**	Induce and restore male sterility for generating hybrid plants; Barnase and Barstar.	Greenhouse and contained field tests. Transformed lines have been evaluated for phenotypes over three generations.
	Mustard; *RLM 198*	Herbicide resistance; Bar.	Greenhouse and contained field tests
	Aubergine (Brinjal) ; Chitinase, glucanase and thaumatin	Disease resistance	Greenhouse
CPMB and National Centre for Plant Genome Research (NCPGR), Jawaharlal Nehru University (JNU), New Delhi	**Rice**	Protein enrichment; Gene from the amaranthus plant.	Greenhouse
	Potato	Protein enrichment; Amaranthus gene Ama 1	-ditto-
	Tomato	Resistance to fungal disease; OXDC	-ditto-

CPMB, Madurai Kamaraj University, Madurai, Tamil Nadu	**Rice;** *Pusa Basmati1*	Resistance to sheath blight (r*hizoctonia solani) and fungal disease;* Chitinase, glucanase and osmotin genes.	Greenhouse. Transgene plants available in *T2* generation.
	Rice; *IRRI's IR-50*	Salinity and drought tolerance; Pyrroline-5-carboxylate synthase.	Greenhouse. Transgene plants available in *T3* generation.
	Potato; *Darjeeling Red Round*	Insect resistance *(phytophthora);* Tobacco osmotin gene	Greenhouse
	Coffee	Resistance to fungal disease; Chitinase, glucanase and osmotin genes.	-ditto-
	Mung bean ("Blackgram" in Indian terminology)	Resistance to viral disease; Coat protein and replicase genes of *vigna mungo* yellow mosaic virus. Insect resistance and herbicide tolerance; Dianthin, barnase and bar genes.	-ditto-
CPMB, Tamil Nadu Agricultural University, Coimbatore, Tamil Nadu	**Rice;** *Indica*	Disease resistance (leaf and sheath blight); Chitinase gene X21 and TLP. Insect resistance (stem borer, brown plant hopper and leaf roller); Cry1Ab,1Ac and 2A. Virus resistance and drought tolerance; Reporter genes hph and gus A. Insect resistance (gall midge); Insect resistance (brown plant hopper) Snowdrop lectin (galanthus nivalis/GNA) gene	Greenhouse. *T4* generation has been reached in the chitinase work.
CPMB, Osmania University, Hyderabad, Andhra Pradesh	**Rice**	Insect resistance (brown plant hopper); Snowdrop lectin (galanthus nivalis/GNA) gene	Greenhouse
CPMB, Bose Institute, Kolkata (Calcutta), West Bengal	**Rice**	S-adenosylmethionine decarboxylase	-ditto-
CPMB, National Botanical Research Institute (NBRI), Lucknow, Uttar Pradesh	**Cotton;** *Coker*	Insect resistance (*spodoptera litura* and *heliothisis armigera*); Cry1C and Cry1E	-ditto-
Directorate of Rice Research (DRR), Hyderabad, Andhra Pradesh	**Rice**	Insect resistance (stemborer and brown plant hopper); Cry1Ab. Disease resistance (leaf and sheath blight); Chitinase X21 and TLP	-ditto-
Indian Horticultural Research Institute, Hesarghatta, Karnataka	**Tomato**	Resistance to leaf curl virus and fungal disease; Chitinase and glucanase	-ditto-

-ditto-	**Citrus fruits**	Resistance to triesteza viral disease; Coat protein gene from citrus triesteza virus	-ditto-
-ditto-	**Melon;** *musk*	Edible vaccine; Rabies glycoprotein gene	-ditto-
University of Agricultural Sciences, Bangalore, Karnataka	**-ditto-**	-ditto-	-ditto-
Punjab Agricultural University, Ludhiana, Punjab	**Rice;** *Pusa Basmati1*	Sheath blight resistance; Chitinase X21. Resistance to yellow stem borer; Cry1Ab and Cry1Ac	T4 generation plants have been developed. Greenhouse.
M. S. Swaminathan Research Foundation (MSSRF), Chennai (Madras), Tamil Nadu	**Rice**	Salt tolerance; Genes from mangroves (?)	Greenhouse
Central Potato Research Institute (CPRI), Shimla, Himachal Pradesh	**Potato**	Insect resistance (lepidoptera); Cry1Ab	Greenhouse and contained field tests.
Central Tobacco Research Institute, Rajahmundry, Andhra Pradesh	**Tobacco**	Insect resistance (*spodoptera litura and helicoverpa.armigera)* Cry1C and Cry1Ab	Greenhouse and contained field tests
Assam Agricultural University, Jorhat, Assam	**Chickpea**	Insect resistance (bruchids); Bean aplha A1	Greenhouse
Central Institute for Cotton Research (CICR), Nagpur, Maharashtra	**Cotton**	Insect resistance (lepidoptera);Bt-Cry genes	-ditto-
Centre for Cellular and Molecular Biology, Hyderabad, Andhra Pradesh	**Rice**	Herbicide resistance; Bar	-ditto-
Centre for Rice Research, Cuttack, Orissa	**Rice**	Insect resistance (lepidoptera); Cry 1Ab	-ditto-
Narendra Dev University of Agriculture, Faizabad, Uttar Pradesh	**Rice**	Resistance to insects (lepidoptera) and bacterial and viral diseases; Cry1A(b)	-ditto-
Tata Energy Research Institute[16], New Delhi	**Mustard**	Beta carotene (precursor to vitamin A) enrichment; Ssu-maize psy and ssu-tp ctrl genes	-ditto-

[16] The Tata Energy Research Institute (TERI) is not a public-sector institution. It is a non-governmental organisation (NGO) that was established with funding provided by the private sector Tata industrial group, an Indian transnational corporation (TNC). Its inclusion here rather than under Section 2.2, which deals with private sector R&D, seems more appropriate because a large part of its funding comes from international donor agencies and the Indian government. The work on GM-mustard is funded by the DBT. Most of TERI's work is in policy-oriented energy research.

International Centre for Genetic Engineering and Biotechnology (ICGEBT), New Delhi	**Rice**	Resistance to gall midge; Gm2	-ditto-
	Tobacco	Insect resistance (Spodoptera litura); Cry2a5	-ditto-
International Crop Research Institute for the Semi-Arid Tropics (ICRISAT)[17], Patancheri, Andhra Pradesh	**Peanut (‘Groundnut’ in Indian terminology)**	1. Resistance to Indian peanut clump virus (PCV); coat protein/replicase genes 2. Resistance to Fungal disease 3. Drought tolerance	1. Greenhouse and contained field trials 2. Greenhouse 3. Laboratory
	Pigeon pea	1. Insect resistance, legume pod borer; Bt-gene Cry 1ab and SBTI genes 2. Resistance to fungal disease 3. Biofortification (nutritional enrichment) with sulphur, amino acids and vitamin	1.Greenhouse and contained field trials 2. Greenhouse 3. Laboratory
	Chickpea	1. Insect resistance; Bt-genes Cry 1ab, 1ac and 2a and STBI genes 2.Resistance to fungal disease; PGIP 3. Drought tolerance	1. Greenhouse and contained field trials 2. Greenhouse 3. –ditto-

Sources:
- Our questionnaire survey and interviews
- P.K.Ghosh and T.V.Ramanaiah, *“Indian Rules, Regulations and Procedures for Handling Transgenic Plants”*, Journal of Scientific and Industrial Research, Vol 59, February 2000, pp 114-120
- Manju Sharma, K.S.Charak and T.V.Ramanaiah, *“Agricultural Biotechnology Research in India: Status and Policies”*, Current Science, Bangalore, Vol. 84, No.3, 10 February 2003

With the single exception of the Amaranthus gene isolated and used by the research team at JNU (for protein enrichment of potato and rice), all the other transgenes (gene constructs) listed in the table above originate from a few advanced public sector research institutions in some leading OECD countries, a couple of IARCs in the CGIAR-system and a few TNCs. Their transfer to India is subject to the intellectual property rights (IPR) of the transferring institutions and companies. We discuss the

[17] ICGBT and ICRISAT are **not** Indian institutions (in the strict sense of the term) but public international institutions funded by some donor governments and agencies. The ICGBT in New Delhi, which is an offspring of the Trieste (Italy)-based parent ICGBT, was set up with the financial assistance of DBT and continues to enjoy DBT support. Its main work is in medical biotechnology (bio-medicine) and its involvement in GM-crop research is minor. ICRISAT is one of the 16 international agricultural research centres of the World Bank administered Consultative Group on International Agricultural Research (CGIAR). ICRISAT’s work is almost entirely on conventional, **non**-GM, crops.

implications of the IPR of the technology-owners for the potential commercialisation of public sector GM-crops in Section 8 (Summary and Conclusions) of the present study.

The following pattern emerges from the table: Rice is the most intensively researched crop, with fifteen institutions involved. There is a concentration on four varieties: IRRI's 50 and 64, IARI's Pusa Basmati 1 and Indica. Resistance to a number of both biotic and abiotic stresses are being tackled, as well as protein enrichment. This extensive effort in rice is the result of the participation of Indian institutions in the International Program on Rice Biotechnology (IPRB) launched and supported by the Rockefeller Foundation. We explore the evolution of transgenic rice R&D in India (including the controversy generated by the transfer to India of the so called 'Golden Rice'-technology from a Swiss institution) in detail in Section 7.2 below. With the exception of one institution, none of the others is working on transgenic wheat, although wheat is as predominant a staple cereal in India as rice is. Two main reasons may account for this: Wheat is a much more difficult crop to modify genetically than rice is, with the result that few gene constructs are on offer for transfer to India from the leading public sector research institutions abroad. Secondly, the two TNCs that are developing transgenic wheat, Monsanto and Syngenta, are not yet ready to transfer their transgenes. (In May 2004, Monsanto announced that it was halting its effort to market its herbicide resistant 'Roundup Ready' GM–wheat, citing the lack of demand by wheat farmers in the US and the resistance of European and Japanese importers to GM-wheat. Notwithstanding Monsanto's retreat, Syngenta says it is persisting with its development of GM-wheat.)

After rice, the number of institutions dealing with the <u>*same crop*</u> drops sharply. Four institutions are involved in tomato, three each in cotton, mustard, potato and tobacco, and two each in aubergine (brinjal), chickpea, pigeon pea, melon and oilseed rape. The remaining eight (banana, cabbage, cauliflower, citrus fruit, coffee, mung bean (blackgram), peanut/groundnut and wheat), are being addressed by just one institution each. Another proxy indicator of concentration of R&D effort is the number of research groups tackling the <u>*same type of trait*</u> (e.g. insect resistance, viral disease resistance, etc.). Here again insect and disease resistant rice leads, as the table below shows.

Table: Crop-wise proxy indicators of magnitude of R&D resources committed and concentration on same traits

Crop	No. of institutions	Same trait research groups, ***if*** *more than one*
Rice	15	Insect 8, Fungal 6, Viral 2, Drought 3, Salinity 2
Tomato	4	Fungal 3
Cotton	3	Insect 3
Mustard	3	
Potato	3	Insect 2
Tobacco	3	Insect 2
Aubergine (Brinjal)	2	
Chickpea	2	
Pigeon Pea	2	
Melon	2	Edible vaccine 2
Oilseed Rape	2	
Other eight crops	1	

If one assumes that the proxy indicators shown in the table above are, to some degree, indicative of the speed with which an innovation (i.e. a given crop with a given trait) is approaching the stage of large scale field trials, then the innovations that are likely to be "leading the pack" are:
- **rice** resistant to insects and fungal and viral diseases, and tolerant of drought and salinity;
- **tomato** resistant to fungal diseases;
- **cotton, potato and tobacco** resistant to insects; and
- **melon** engineered to produce edible vaccine.

These six groups of innovations may by now (mid 2004) have completed the stage of contained field tests.

However, it is important to bear in mind that the ‘proxy indicator analysis’ is no more than a ‘guesstimate’. It is of course impossible to predict which of the 18 GM-crops currently being developed in the public sector institutions will be the first to complete the multi-location, large scale field trials stipulated by the biosafety regulatory regime and to obtain the approval of the regulatory authorities for general release and commercialisation. Since none of them has yet (as of late 2004) begun the process of multi-location large scale field trials, and which could take several years to complete (*assuming that the authorities will be at least as stringent with the public sector institutions as they have been with the private companies and not let them cut corners because they belong to the ‘public sector family’)*, the earliest that a public sector GM-crop innovation is likely to be approved for marketing *(if at all)* is unlikely to be before 2007. Thus, it will have taken at least fifteen years (but in all probability more) for a public sector GM-crop innovation to reach the market (if at all). This raises several decisive questions about the efficiency of the innovation process in the public sector, which need to be addressed but are outside the scope of the present study.

It is significant that the first GM-crop to have been approved by the biosafety regulatory authority GEAC for general release in India is the bollworm resistant Bt-cotton developed by the private sector India-USA joint venture Mahyco-Monsanto. It was approved in April 2002 and the first harvests reached the market in late 2002. Under license from Mahyco-Monsanto, an Indian private sector company, RASI seeds, has bred further varieties of this Bt-cotton, which were approved by GEAC for general release in March 2004.

Meanwhile, as indicated in the table above, three public-sector institutions (NBRI in Lucknow, CICR in Nagpur and CPMB in the south campus of Delhi university) are continuing their work on their versions of Bt-cotton. It has been reported[18] that an Indian private sector company, Swarna Bharat Biotechnics Private (SBBPL) in Hyderabad, has obtained NBRI’s Bt-cotton technology on license with the intention of developing and commercialising lepidoptera insect resistant cotton seeds and that the company is negotiating with the CPMB in Osmania University in Hyderabad the licensing of Osmania’s lectin-gene technology (that Osmania has developed in connection with its GM-rice research) to produce sucking pest (aphid) resistant cotton seeds.

We refer the reader to Section 7.1 below for a detailed examination and analysis of the processes and the stakeholders’ roles involved in the introduction and commercialisation of Bt-cotton in India, and the ensuing fierce controversies.

The post-regulatory approval transition “from the lab to the market” depends upon several crucial factors: technology demonstration and dissemination, “entrepreneurial bridges” between the lab, the seed producers and marketers, economic viability at the small farm level, consumer acceptance and market competitiveness. The precondition for entering the transition process is the embarking on, and satisfactory completion of, multi-location large-scale field trials that conform to the biosafety regulatory regime. None of the public sector R&D institutions involved in GM-crops has the resources (financial, infrastructural and field staff) to undertake these trials on its own. Only ICAR has the required resources and thus its commitment is indispensable. We will address the transition and the pre-transition issues in Section 8 (Summary and Conclusions) of the present study.

[18] 'India is now developing its own GM technology to protect cotton from pests', K. S. Jayaraman, Nature Biotechnology, March 2004 Vol. 22, N0.3, pp255-256 www.nature.com

2.1.4 Biosafety responsibilities of the R&D institutions: Role of the Institutional Biosafety Committees

The national biosafety regulations stipulate that every institution (whether in the public or private or NGO sector) that carries out laboratory and post-laboratory (i.e. greenhouse and field trial) work involving GMOs, sets up its own internal Institutional Biosafety Committee (IBC) and have it approved by DBT. In addition to the head of the institution or his/her representative and appropriate subject-specialist staff of the institution, each IBC includes an external specialist who sits on the committee as the nominee of the DBT.

All project proposals involving GMOs have to be scrutinised and approved by the IBC before being submitted to the RCGM/DBT for biosafety clearance, which is mandatory for conducting the proposed work. The IBC is expected to assess the scientific and technical feasibility of the proposed projects, to estimate the funding required and to ensure that the data required by the RCGM for assessing the proposals are forwarded to the RCGM together with the project proposals. Funding by DBT or any other research council is contingent on the project proposal being approved by the RCGM. Once a project is approved and launched, it is the formal responsibility of the IBC to ensure that the R&D project adheres to the biosafety regulations and procedures laid out in the national biosafety regulations and the approval document issued by the RCGM. In all this, the DBT nominee has a decisive role to play.

In an *ongoing* project, experiments involving risk categories I and II, and conducted under laboratory and contained greenhouse conditions, can be approved by the IBC. According to the Indian classification of risks, category-I risks pertain to '*routine*' rDNA experiments in the lab and work involving 'well defined' genes and DNA of microbial, plant or animal origin 'that are generally considered to be safe'. Category-II applies to laboratory and contained greenhouse work involving genes and DNA that are '*non-pathogenic to humans*', but could have risk implications for plants and insects. Category-III involves genes and DNA 'that could potentially cause alterations in the biosphere', e.g. *open* field tests and field trials. Category III work falls outside the remit of the IBC and can only be approved by the RCGM. Ongoing projects have to report to the RCGM/DBT, on prescribed formats, at least once in six months on the work-in-progress.

It is part of an IBC's responsibility to ensure that the research and related infrastructure in the institution is adequate for effectively containing GMOs and that the GMOs do not 'infect' or 'contaminate' areas outside the contained spaces of the laboratory and the greenhouse.

The RCGM, the DBT and the MEC have thus, in effect, shifted the onus of ensuring the biosafety of ongoing R&D projects on to the institutions themselves and their IBCs. The general public and the GM-active civil society organisations (CSOs) do not seem to be aware of this decentralised delegation of biosafety responsibility for ongoing projects and its implications. Under these circumstances, therefore, one would expect the IBCs to be subject to at least occasional evaluations by independent external experts. As no such external independent evaluations have been carried out so far, it is not possible to say how conscientiously and effectively the IBCs have discharged their biosafety responsibilities.

Our interviews with some senior staff at selected R&D institutions have elicited fairly critical views on the performance of IBCs, as well as on the role of DBT vis à vis the IBCs. They are concerned about the low priority accorded by senior scientists to IBC work and the tendency to draft junior scientists, with limited experience, on to the committees. The total absence of social scientists and finance officers in the IBCs means that the projects are not vetted for their economic and social relevance to small farmers and the community at large, for potential demand by consumers and for the realism in the proposed project budgets. The DBT nominees on the IBCs (who are, as a rule, senior scientists from sister public sector institutions working in the biotechnology area), often do not have the time to immerse themselves in project details and the documentation provided, putting at risk the quality of their assessment. There is no institutionalised mechanism for appealing against the decisions of the RCGM. DBT is felt to be too remote and un-approachable by the institutions' and the projects' leaders not located in Delhi.

2.2 R&D in GM-crops in Private Sector Companies

2.2.1 Introduction

As pointed out in Section 2.1, in most areas of knowledge in India, the research work being carried out in the Indian private sector is very limited in terms of scope, content and resources, compared to the public sector. This is true of the biotechnology sector in general (medical/pharmaceutical, agricultural, industrial and environmental) and of GM-crops in particular. Conventionally, the term "R&D" signifies the combination of some "discovery" in basic (fundamental) or applied knowledge and "innovation" or "improvement" based on that discovery (however incremental). The R&D in GM-crops conducted so far by the private sector in India can be classed under the label "improvements" based on the GM-innovations imported from agro-chemical TNCs in the West. Specifically, this "R&D" consists in "backcrossing" the genetically engineered traits from the imported GM-crop seeds into selected local varieties of the crop through standard breeding techniques. In sub-section 2.2.2 below, we list the private sector companies involved in the R&D of GM-crops and the associated "backcrossed" traits and transgenes.

We turn now to the question of biotechnological *production*. Reliable information on the true extent of private sector activity in biotechnological production in India is very hard to come by. The reported activities do not differentiate between "traditional (i.e. non-GM) " and "modern (i.e. GM)" biotechnology. There are apparently hundreds of small and medium enterprises in the area of traditional biotechnology in the industrial and agricultural sectors (e.g. fermentation products, breweries and distilleries, processing of naturally occurring biological pesticides, herbicides and fertilisers, horticulture, tissue culture, etc.), which do not bother to report adequately to the authorities on their activities. Even the large-scale companies (including the local subsidiaries of, or joint-ventures with, transnational companies) are unwilling to part with anything but bland and innocuous information. There appears to be no regular, systematic and comprehensive collection and processing of biotechnological data (whether on R&D or on production) by government agencies (including research funding councils). There is manifest inability, or/and unwillingness, on the part of government agencies and research funding councils to put even the limited data at their disposal into the public domain in readily accessible form (e.g. regular and updated statistical publications and online databases).

A reading of the published papers and reports (including several by government officials) leaves a chaotic impression. Further, one is struck by the tendency in government publications, in the papers published by government officials under their own names, and in the English language national newspapers and periodicals to "hype up" the biotechnological sector in the country with no reliable evidence to back up the claims[19].

One needs to bear this in mind in reading and interpreting the data presented in the following table and in the other tables further below in this section.

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[19] The following remarks by a senior official of DBT are illustrative. "There are no authentic statistics on the investment in the private sectors. This because the definition of biotechnology and its indicators vary for different estimations. An Indian directory prepared by Biotechnology Consortium India Ltd. (BCIL) in January 2001 includes biotechnology activities of about 176 companies in private sector whose products range from those in agriculture, environment and healthcare. On the other hand, estimates have also been made that about 800 companies are operating in various sectors of biotechnology, based on the definition that biotechnology includes basic industry such as food processing and highly sophisticated recombinant products. Employing the same definition one estimate says that 10% (80) of these companies are operating in modern biotechnology sectors while according to another conservative estimate there are only 20 companies engaged in sophisticated biotechnology business. Similarly, it is also estimated that the industry employees 10 to 20,000 people and generates roughly a revenue of US$500 million annually. The Indian share of the biotechnology market was estimated at US$800 million in 1999 and has risen approximately to US$2.5 billion this year. Consumption of biotechnology products is expected to touch the figure of Rs.14.6 billion." S.R.Rao, *"Indian Biotechnology Developments in Public and Private Sectors - Status and Opportunities", Asian Biotechnology and Development Review*, Vol.5. No.1 November 2002.

Table Private Sector Biotechnology Industry in India, 2000/2001

Sector/sub-sector	**Number of Companies**	**Investment in Rs. million**	**Turnover in Rs million**
Medical and Pharmaceutical			
Vaccines	31	2850	2650
Diagnostics	10	1000	3600
Antibiotics	13	14000	14000
rDNA products	8	360	2370
Sub-total	**62**	**18210**	**22620**
Agriculture			
Tissue culture	30	1000	200
Bio-fertilisers	70	150	230
Bio-pesticides	50	500	400
Floriculture	135	1850	820
Mushrooms	23	3500	1800
GM-crops (transgenic crops)	3	1120	0
Sub-total	**311**	**8120**	**3450**
Manufacturing Industry			
Alcohol	280	28000	19800
Enzymes	17	250	595
Organic industries and other products	15	400	750
Sub-total	**312**	**28650**	**20845**
Environment	**15**	Not available	Not available
Grand total	**700**	**54980**	**46915**

Source: S.R.Nair, "Biotechnology" in *Technology for Small Scale Industries: Current Status and Emerging Need*, SIDBI, Tata McGraw Hill Publishing Ltd, New Delhi, 2001

Thus, in *2000/2001*, only 11 companies (out of a total of 700) were *explicitly* listed as undertaking activity involving *GMOs* (pharmaceutical rDNA products 8 and GM-crops 3) [20]. One should note, however, that the three companies listed under GM-crops had no turnover in 2000/2001, as they were then still at the stage of developing their "backcrossed" varieties and conducting field trials[21]. The rest were all in *traditional (i.e. non-GM)* biotechnology, with the leading branches being alcohol (280 companies), floriculture (135), bio-fertilisers (70), bio-pesticides (50) and tissue culture (30). Here it would be appropriate to point out that, unlike in India, in the OECD region the term "biotechnology" does not cover breweries and distilleries producing alcoholic beverages, nurseries (floriculture), organic fertilisers (bio-fertilisers), etc.

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[20] It is probable that some of the companies in the vaccine and medical diagnostic sub-sectors would be working with GMOs and GM-technologies.

[21] Mahyco-Monsanto, Proagro-PGS and Rallis

2.2.2 Status of private sector R&D in GM-crops

Private sector efforts at introducing GM-crops into India began, in effect, in 1995, when Maharashtra Hybrid Seed Company (MAHYCO) obtained the approval of RCGM/DBT to import Bt-cotton seeds from the USA based TNC Monsanto for backcrossing into selected Indian cultivars and to test the performance of the Bt-hybrids so developed. So began the practice by companies of importing "readymade GM-crop technology" from North America and Western Europe for backcrossing into Indian cultivars and breeding hybrids resistant to biotic stresses. A new practice was added in 2004, when Indian companies began the backcrossing work with GM-technologies obtained on license from Indian public sector R&D institutions, which in turn had imported the original transgenes (gene constructs) from the West.

Of the total of ten private sector companies that were actively working on GM-crops in 2004, one is Mahyco-Monsanto, a joint venture with the transnational corporation (TNC) Monsanto (USA), four are subsidiaries of the TNCs Syngenta (Switzerland), Bayer /Proagro -PGS (Germany)[22], the Tata Group/Rallis (India) and Indo-American Hybrid Seeds (USA), while the other five are the wholly Indian owned smaller firms, Rasi Seeds, Navbharat Seeds, Hybrid Rice International, Ankur and Swarna Bharat Biotechnics.

Table. R&D in GM-crops in private sector companies in India in 2004

Company	**Crop**	**Traits aimed at and transgenes backcrossed**	**Stages completed and ongoing**
Mahyco Monsanto Biotech, Mumbai (Bombay)	**Cotton**	Insect resistance (bollworm, lepidoptera); Bt-genes Cry1Ac, Cry X	GEAC approved the general release and commercialisation of three hybrid varieties of Bt-cotton in March/April 2002. Work on other hybrid varieties ongoing. See Section 7.1 below
	Cotton	Resistance to the broad spectrum herbicide glyphosate (Monsanto's 'Roundup'); CP4 EPSPS	Greenhouse and contained field tests
	Maize	Insect resistance (lepidoptera); Bt-gene Cry1Ab	-ditto-
	Pigeon pea	Virus resistance; Gus	-ditto-
	Rice	Insect resistance (lepidoptera); Cry1Ac. Resistance to bacterial leaf and sheath blight; Chitinase Xa 21. Insect resistance (gall midge, sucking pests); Insect resistance (brown plant hopper); Snowdrop lectin (galanthus nivalis/GNA) gene	-ditto-
	Mustard	Resistance to the broad spectrum herbicide glyphosate (Monsanto's 'Roundup'); CP4 EPSPS	-ditto-
Mahyco Research Foundation, Hyderabad	**Rice**	Resistance to bacterial leaf and sheath blight; Chitinase Xa 21.	-ditto-
RASI Seeds,	**Cotton**	**Under license from Mahyco-**	GEAC approved the general

[22] Proagro-PGS belonged to the Dutch holding company Biogenetic Technologies B.V. (BGT), which was acquired 100% in 1999 by the German TNC Hoechst Schering AgrEvo Gmbh, which merged with the French Rhône Poulenc SA to form Aventis CropScience, which in turn was taken over by the German TNC Bayer.

Hyderabad		**Monsanto.** Insect resistance (bollworm, lepidoptera); Cry1Ac	release and commercialisation of one hybrid variety of Bt-cotton in March 2004, developed **under license from Mahyco-Monsanto**. Work on other hybrid varieties ongoing. See Section 7.1 below.
Navbharat Seeds, Ahmedabad and Hyderabad	**Cotton**	Insect resistance (bollworm, lepidoptera); Cry1Ac	A hybrid variety of Bt-cotton was marketed in 2001, **without approval by GEAC (i.e. illegally)** [23].
Proagro-PGS (India), Gurgaon, Delhi. A subsidiary of the German TNC Bayer.	**Mustard /Brassica**	Male sterility for generating hybrid plants; Barnase and Barstar. Herbicide resistance; Bar.	Multi-location and large-scale field trials completed, and results submitted to GEAC. Decision by GEAC pending, even after two 'final deliberations' about general release and commercialisation.
	Tomato	Insect resistance (lepidoptera); Cry 1Ab	Greenhouse and contained field tests
	Aubergine (Brinjal)	-ditto-	-ditto-
	Cauliflower	Male sterility for generating hybrid plants; Barnase and Barstar. Herbicide resistance; Bar.	-ditto-
	Cauliflower	Insect resistance (lepidoptera); Cry1H and Cry9C	-ditto-
	Cabbage	-ditto-	-ditto-
Syngenta (India) , Pune	**Cotton**	Insect resistance (lepidoptera); Vip-3	Greenhouse and contained field tests
	Maize	Insect resistance (lepidoptera); Cry 1Ab	-ditto-
Rallis (India), Bangalore. Part of the Indian TNC, the Tata Group	**Chilli**	Insect resistance (lepidoptera, coleoptera and homoptera); Insect resistance (brown plant hopper); Snowdrop lectin (galanthus nivalis /GNA)	Greenhouse and contained field tests
	Bell pepper (Paprika)	-ditto-	-ditto-
	Tomato	-ditto-	-ditto-
Indo-American Hybrid Seeds, Bangalore	**Tomato**	Resistance to viral and fungal disease; Alfalfa glucanase and tomato leaf curl virus gene	-ditto-
Hybrid Rice International, Gurgaon, Delhi	**Rice**	Insect resistance (lepidoptera); Cry 1Ab and Cry 9C. Herbicide resistance; Bar.	-ditto-
Ankur Seeds,	**Cotton**	Insect resistance (lepidoptera);	-ditto-

[23] It is alleged that this variety is based on Mahyco-Monsanto's Bt-cotton and was developed without obtaining a license from Mahyco-Monsanto. The central government authorities conducted an investigation, forbade Navbharat from further marketing this variety and are prosecuting the company in a high court. Meanwhile, according to the Indian press, the sale of illegal Bt-cotton seeds (of unknown and unproven provenance) by a host of seed retailers in various parts of the country has continued. See Section 7.1 below for a detailed exposition of this case and its implications.

Nagpur		Cry 1Ac	
Swarna Bharat Biotechnics, Hyderabad	**Cotton**	Insect resistance (lepidoptera and aphids/sucking pests); Cry 1Ac[24]. Insect resistance (brown plant hopper); Snowdrop lectin (galanthus nivalis/GNA) gene[25]	Greenhouse

Sources:
- Our questionnaire survey and interviews
- P.K.Ghosh and T.V.Ramanaiah, 2000,
- Manju Sharma, K.S.Charak and T.V.Ramanaiah, *"Agricultural Biotechnology Research in India: Status and Policies"*, Current Science, Bangalore, Vol. 84, No.3, 10 February 2003

In the private sector in India, Mahyco was the first company to enter the field of GM-crops with its technology transfer agreement with Monsanto in 1995. By 2000, Proagro-PGS and Rallis were also well into the backcrossing of a number of crops. The pace of entry seems to have quickened since then, with seven companies joining in between 2001 and 2004.

From the Table above one notes that, by 2004, the private sector was involved in eleven crops: cotton, rice, mustard, maize, tomato, pigeon pea, aubergine (brinjal), cauliflower, cabbage, chilli and paprika (bell pepper). With the exception of maize, chilli and paprika (bell pepper), the other eight crops and the corresponding traits are also being tackled by public sector R&D institutions. Of the eleven crops, cotton is attracting the most attention with six companies working on it, followed by tomato (3 companies), mustard (2), rice (2) and maize (2). In terms of the intensity of attention accorded, there is an overlap between the public and private sector R&D work in cotton, tomato, mustard and rice.

Although public sector R&D into GM-crops in India was under way by 1990, and private sector activity began five years later (with the technology transfer agreement between Mahyco and Monsanto in 1995), it was the private sector that was first off the mark in putting a GM-crop on the Indian market (i.e. Mahyco-Monsanto's Bt-cotton in 2002; Proagro-PGS was poised to follow with its GM-mustard in 2003, but has been held up by postponements of the final decision by GEAC for reasons that are not transparent).

We think that one of the several reasons for the inability of the public sector R&D institutions to emulate the momentum of the private sector companies lies in their lack of resources (financial, infrastructural and staffing) to conduct large- scale, multi-location field trials (which are obligatory under the biosafety regulatory regime), including the breeding of sufficient magnitudes of GM-seeds to that end. In terms of access to such resources, the private sector companies are much better placed than the public sector institutions. As we suggest in Section 8 (Summary and Conclusions), and have indicated in Section 2.1 above, the "resource barrier" cannot be overcome without a serious commitment by ICAR to put its well- established, well-functioning, nation-wide system of "All India Crop Trials" at the disposal of the GM-active public sector R&D institutions, irrespective of whether or not they come under the "ICAR aegis".

The situation as of 2004 is that several of the private sector companies, *if given the go ahead by GEAC*, can launch large-scale, multi-location field trials straightaway with the GM-hybrids that they have already developed and are holding "in the pipeline". *It is a moot question as to whether, when and by what stages GEAC will act on the applications for approval such trials submitted by the companies.* Given the disarray caused by the "fall out" from the Bt-cotton case, it will take a while for some clarity to emerge on this question.

An alternative or a complement to a tie up with ICAR's "All India Crop Trials" would be partnerships with private sector seed companies. Public sector institutions could license

[24] On license from the public sector R&D institution NBRI, Lucknow (see Section 2.1 above)
[25] On license from the public sector R&D institution, CPMB at Osmania University, Hyderabad (see Section 2.1 above)

their innovations to private sector companies with the resources and infrastructure to carry out the large-scale, multi-location field trials and to embark on the process of acquiring GEAC's approval for commercialisation. Such public-private partnerships may be attractive to the private sector companies if they sense a potentially profitable market for GM-crops. One example of such an arrangement (mentioned above) is the NBRI's (Lucknow) licensing of its Bt-cotton technology (based on transgenes obtained from a foreign institution) to Swarna Bharat Biotechnics in Hyderabad.

2.2.3 Ensuring biosafety and interacting with the biosafety regulatory authorities

The private companies are subject to the same regulations about institutional biosafety committees (IBC) as the public sector institutions. Our interviews indicate that the larger companies have, in principle, the scientific staff to constitute competent IBCs and the infrastructure and resources to comply with the legally obligatory biosafety procedures and measures at all stages of the development of GM-crops. But it is debatable whether the same is true of the small companies, whose main concern would be to get the backcrossing and testing work done as inexpensively as possible, which means, among other things, keeping investment in in-house scientific expertise and infrastructure to a bare minimum. We found examples of small companies seeking the assistance of some public sector state agricultural universities to get their biosafety testing done.

It is all too likely that the composition and mode of operation of the IBCs of the larger companies are not exempt from the constraints and shortcomings that affect the IBCs of public sector institutions.

The companies have neither a policy nor a practice of consultations with GM-concerned non-governmental and civil society organisations and publicists, whether in planning, deciding, designing and conducting their GM-activities. The same is true of the public sector institutions. Both groups tend to regard the GM-concerned NGOs, CSOs and publicists with hostility. They are angry about the campaigns and activism of these organisations.

Our interviews with a selected number of companies elicited the following remarks, views and attitudes about the current biosafety regulatory regime in India. Similar concerns also emerged in our interviews with selected public sector R&D institutions:

- The biosafety guidelines and regulations are very cumbersome, stringent and time consuming. A literal compliance would be too difficult to achieve.

- Of particular concern are the problems posed by the requirement to test for potential toxic effects on livestock of feed and forage derived from GM-crops (e.g. seeds from ginning GM-cotton, post-harvest residues, GM-forage maize, etc.), not least due to the difficulties in obtaining permission by the relevant authorities to conduct the tests and the impact of the campaigns by animal rights activists [26].

- The activism of the anti-GM non-governmental and civil society organisations is a "nuisance".

- The transgenes that have been cleared by the regulatory authorities as being safe in the context of a given crop (e.g. the Bt-genes in Bt-cotton) should be "deregulated" and be exempt henceforth from the regulations, when used in other crops, i.e. the case-by-case approach should be interpreted as applying to transgenes and "transgenic events" and not to individual crops.

- The regulations should be made less stringent for GM-crops whose transgenes are derived from "closely related plant species".

[26] There is considerable debate in India about the rules and regulations in force governing the use of animals in scientific, medical and other experimentation. See, "Animal experiments and bio-medical advance" by V.Ramalingaswami, http://www.iisc.ernet.in/~currsci/august/articles9.htm and "Biotechnology: an answer to alternatives for animal model testings", by S. Indu Kumari and Kaiser Jamil, http://www.iisc.ernet.in/~currsci/apr25/articles15.htm

- The smaller and less well-endowed companies want access to an increased number of public sector risk assessment facilities (e.g. national laboratories and agricultural universities) spread over country.
- The replacement of the present regulatory system (with its dispersed, unclear and confusing mandates, responsibilities and powers) by a new, single, integrated authority with a comprehensive mandate and a wide range of responsibilities, with the power to implement the regulatory regime with speed and efficiency.

- A historically and traditionally conditioned atmosphere of mutual distrust still bedevils relations between government authorities and the private sector.

The last bullet point above on “mutual distrust” is rather disingenuous, in view of the fact that some of the top personnel (both managerial and scientific) in the large companies have been recruited from the top ranks of government departments and public sector R&D institutions. The “corridors of power” are open to them and they enjoy good relations with top government officials. As such, they would have little difficulty in “cutting corners” when faced with “problems” in complying with the provisions of the current biosafety regulatory regime. This privilege dents somewhat the seriousness of the demand by the companies for the changes listed above and the credibility of any effort they may be making to achieve the changes.

3. ROLE OF NATIONAL RESEARCH FUNDING COUNCILS

3.1 Introduction

Almost all research in India is publicly funded, whatever the field: Science and technology, agriculture, forestry and fisheries, medicine and pharmaceuticals, manufacturing and mining industry, energy and transport, the social sciences and the humanities and arts. In comparison with the huge resources (financial, personnel and infrastructural) committed to research by the central and state governments, and the public sector bodies, over the last half century, the contributions by the Indian private sector and by foreign donors seem marginal.

Although India has nearly two hundred universities, university-equivalent institutions and other higher education bodies, spread all over the country, most of them concentrate almost exclusively on producing graduates and postgraduates, while a sizeable fraction also generate doctorates. It is, however, in the fairly large number of public sector specialist national laboratories and research institutes/centres, and in a small number of public sector 'elite' universities and university- equivalent institutions (e.g. institutes of technology), that most of the research takes place. In all they add up to about fifty. Of these, the following five 'belong' to DBT, i.e. come directly under the 'financing umbrella' of DBT:

1. National Institute of Immunology, New Delhi
2. National Cell Science Centre, Nagpur
3. Centre for DNA Finger Printing, Hyderabad
4. National Brain Research Centre, Gurgaon
5. National Centre for Plant Genome Research, Jawaharlal Nehru University, New Delhi

The central government channels public funds into public sector R&D through half a dozen large central national research councils located in New Delhi. They are the Department of Science and Technology (DST), the Council for Scientific and Industrial Research (CSIR), the Department of Biotechnology (DBT), the Indian Council for Agricultural Research (ICAR), the Indian Council for Medical Research (ICMR), the Indian Council for Social Science Research (ICSSR) and the University Grants Commission (UGC).

Support to R&D activity in biotechnology in India covers all the four biotechnological sectors: medical/pharmaceutical, agricultural, industrial and environmental, in that order in terms of the magnitude of resources allocated. In terms of *direct financial support* to projects, programmes and infrastructure, DBT accounts for nearly all the resources made available to these four biotechnological sectors, with the other councils making a comparatively marginal contribution. However, if one considers the *indirect* support provided, by making the research infrastructure and the services of the research and ancillary personnel available to the DBT-sponsored biotechnology projects, then ICMR, ICAR, CSIR, DST and UGC also emerge as important players in the total national effort to promote biotechnology [27]. This is because different public sector national laboratories and research institutions (including the 'elite' universities and Institutes of Technology) come under the 'financing umbrellas' of different funding bodies, depending on the research areas involved, e.g. medical/pharmaceutical 'under ICMR', agricultural 'under ICAR', fundamental and parts of applied science 'under DST and CSIR', and so on [28].

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[27] See S.R.Rao, 2002, "Indian Biotechnology Developments in Public and Private Sectors - Status and Opportunities", *Asian Biotechnology and Development Review*, Vol.5 No.1, pp.9. According to the author (a high-ranking official of the DBT), "Since in all these organisations there is no separate data pertaining to biotechnology, it is difficult to provide the actual figures of investments made by these agencies. However, normally the contribution or sharing of cost in most of the projects is about 30%, and therefore, it can be presumed that the distribution by all these organisations would be around Rs.4 billion since 1985 till date (i.e. 2002)."

[28] There is considerable overlap in the research areas, disciplines and sub-disciplines supported by the research councils. For example, the National Chemical Laboratory in Pune 'belongs' to the CSIR, but a number of its projects receive substantial funding also from DST and DBT.

As explained in the 'Introduction' Section 1 above, the concept of 'agricultural biotechnology' covers the following six main categories of activities, three of which are characterised by genetic modification using recombinant DNA techniques (hereinafter 'GM-technology') and three which do not (non-GM), the latter group usually preceding the former as countries have embarked on R&D work in these areas:

Non-GM categories:
- Tissue culture
- Molecular diagnostics
- DNA-Marker aided selection

GM categories
- Genetic modification/Genetic Engineering
- Genomics
- Bioinformatics

Since the focus of our study is on the integration of biosafety into agricultural biotechnology development, *we restrict ourselves to the GM categories, as it is in the context of genetic modification that the issue of biosafety arises*. We would therefore have liked to trace the growth of R&D funding to the GM categories in agricultural biotechnology and to individual GM-crops. However, such disaggregated data are not yet available in any publicly accessible database or other types of information sources in India. We had hoped to be able to obtain disaggregated information directly from DBT, ICAR and other sources, but were told during our interviews that it was not readily accessible. The same is true even at the aggregated level of 'agricultural biotechnology', except for a few recent years. The non-availability of disaggregated data makes it impossible to embark on a time-series and comparative analysis of the links between funding levels and achievement of results, by category (GM and non-GM), crop and institution.

To recollect from Section 2 above, almost all R&D in GM-crops technology in India has occurred, and continues to be conducted, in public sector institutions. Most of the work done in the private sector is limited to backcrossing imported GM-seeds with local cultivars. Almost all of the public sector work has been, and is being, funded by DBT, with ICAR and state governments making significant contributions indirectly through their support to the research and extension infrastructure (including personnel salaries) in the agricultural universities and research institutions that are actively involved in GM-R&D (see the Table of R&D institutions in Section 2). The Rockefeller Foundation has made outstanding and decisive contributions to GM-rice R&D in India, as elsewhere in Asia (see Section 7.2 on 'Transgenic Rice in India'). A few other international donor agencies have funded individual projects, with the Swiss heading the list in terms of the magnitude of support.

3.2 The Role of DBT

Research in India into some areas of *non-GM* agricultural biotechnology (e.g. tissue culture) goes back to the 1970s, conducted principally under the umbrella of ICAR. But research into *GM-categories* was initiated by DBT in the late 1980s. Since then, DBT has been the predominant funder and promoter of GM-crops R&D in India.

DBT acts as the focal point in the administrative structure of the Government of India (GoI) for the planning, execution, promotion and coordination of biotechnological activities and programmes. Its inputs into the government's successive Five Year Plans have strongly influenced not only the biotechnology policy of the government over the last two decades, but also the levels of funding made available by the government for the promotion of biotechnology.

The broad categories of programmes and activities supported by DBT are: Human Resource Development (postgraduate, doctorate and post-doctoral work, specialist training of research personnel and ancillary technical staff, etc.), Basic (i.e. fundamental science) and Product-oriented R&D, Establishment of Centres of Excellence and Biotech facilities, Biotech product and process development and Bioinformatics [29].

DBT has identified a number of priority areas for research and development in all the four sectors of biotechnology: medical/pharmaceutical, agricultural, industrial and environmental. It has set up task forces and expert committees, comprising eminent scientists from across the country, to advise on the identification of so called 'thrust areas' that deserve to be specially promoted.

The DBT grants cover all sectors of biotechnology (medical/pharmaceutical, agricultural, industrial and environmental), with the lion's share going to the medical/pharmaceutical sector, the agricultural coming next but far behind, and industrial and environmental shares being marginal.

Starting with a budget of Rs. 235 million in 1986-87, the annual allocations to DBT by GoI have grown rapidly to reach Rs 2356 million by 2002-03, in current prices. Even allowing for a rule-of-thumb average annual rate of inflation of 10 percent, the tenfold increase in DBT's budget in current prices over a period of 16 years, testifies to the great importance that GoI attaches to biotechnology [30]. DBT has projected its requirement of funds during the Tenth Five Year Plan Period (2003-2008) to 20,750 million Rupees [31], a trebling over the 6750 million approved by GoI for the Ninth Five Year Plan period (1997-2002).

The annual increases and rates of growth in DBT's budget over the past twelve years can be read off the following table.

Table DBT's budget

Fiscal Year	**In million Rupees**	**Annual growth in percentage**
1990-1	655	
1991-2	740	13.0
1992-3	780	5.4
1993/94-1997/98	Figures for these years are not readily available	
1998-9	1142	
1999-2000	1282	12.2
2000-1	1361	6.2
2001-2	1860	36.6
2002-3	2 356	26.6

Source: Compiled from DBT's Annual Reports

From our interviews with selected senior officials in DBT and senior scientists in GM-active institutions, we surmise that the support by DBT to the *GM-categories of agricultural biotechnology* has over the years amounted to only a very small fraction of DBT's total budget (less than five percent), although the absolute magnitude of the grants to individual GM-active institutions may be impressively large [32]. The validity of this working hypothesis can only be tested if and when DBT releases detailed figures *disaggregated* at the GM-categories and GM-crops levels.

Our interviews reveal markedly different experiences and perceptions among public sector institutions on the levels of funding made available for agro-biotechnology R&D. The centrally funded national

[29] *ibid*
[30] Annual Reports of DBT. See also www.cagindia.org/reports/scientific/2001_book1/index.htm
[31] See the reply to Starred Question No.515 on 28.08.01 in the *Lok Sabha* (lower house of parliament), on the Demand of Funds by DBT, raised by Shri.Iqbal Ahmedsaradgi and answered by Minister of Science and Technology, Prof. Murli Manohar Joshi.
[32] In an interview at DBT, a senior official indicated that in 2001-2, about 3 percent of DBT's total budget was spent on agriculture-related GM-work and 2.7 percent on tissue culture.

laboratories (belonging to the DST, CSIR, DBT and other research council systems) say they have adequate funds. This is in sharp contrast to the state agricultural universities, whose GM-active scientists complain of funding shortages. They say that the grants made just about cover the salaries of the research personnel, with little left over for investment in research equipment and supplies and other components of the research infrastructure. They point out that they have to resort to much lobbying in New Delhi to counteract the pervasive Delhi-centric culture of the central authorities and extract enough funds. At a wider level, scientists who are involved in conventional (non-GM) crop research, complain that, in contrast to the recent decades, their work is now less favoured, leading to a skewing of new research proposals to include biotechnology components, to make them more attractive to the central funding bodies. The charge of Delhi-centrism is strongly rejected by DBT officials, who underline their sincerity and efforts to encourage biotechnology research in universities and research institutions in various parts of the country far from Delhi.

However, some of our interviewees advocated restructuring and reforming the various agricultural research funding systems in the country to one integrated hybrid centralised-decentralised system, under which crop research proposals from all over the country would be submitted to one central authority, whose mandate would be limited to arranging the peer-reviewing and assessment of the proposals by nationally constituted panels of subject-experts, but all government allocations to agricultural research would be decentralised to state-based agencies, whose responsibility it would then be for disbursing grants to the proposals approved by the centrally-empowered expert panels. According to the interviewees, such a centralised-decentralised system would be the appropriate one for harnessing the potential of the different agro-biodiversity areas and agro-climatic zones of the country to the task of sustainable agricultural development.

DBT has formed an expert group to identify and promote product- and technology-oriented R&D projects. R&D institutions (both inside and outside academia) are being urged and helped to interact with industry, in order to specifically promote not only product- and technology oriented research but also the transfer of technology and innovations from the R&D establishments to the industrial sector. These moves have resulted, to date, in the transfer of about fifty technologies and products, most of them in the medical/pharmaceutical biotechnology sectors, *but none so far in the GM-crops sector* (for a discussion of the issue of the transfer of GM-crop innovations, see the sub-section 3.4 below on the role of ICAR).

The Government of India has provided DBT with special funds to facilitate the setting up of so called “biotechnology incubators” and “biotechnology parks” to promote entrepreneurship in the biotechnological sectors.

3.3 DBT's processing of proposals for funding

DBT follows three different approaches in processing research proposals and awarding grants. The first applies to the five national research centres mentioned above that 'belong' to DBT. Proposals from these centres are given particular attention. The second avenue is to invite specific researchers and research teams to apply for grants in the areas identified by DBT as being of high priority with earmarked funds. The third is the 'in-tray' approach under which proposals are processed as and when they arrive at DBT from institutions and researchers from around the country. All proposals are peer-reviewed for scientific merit and feasibility.

In the case of the 'in-tray' proposals, grants are made subject to funds being available in DBT's uncommitted and un-earmarked budget. In case of shortfalls, DBT submits requisitions to GoI for extra funding, in particular in cases where proposals are deemed to be of special importance and merit.

There are three stages in the processing of proposals. The first consists of a review by the applicant institution's internal Institutional Biosafety Committee (IBC). If approved by the IBC, the proposal moves to the second stage to be assessed by a Project Assessment Committee (PAC) set up by DBT. If the grant requested is more than 10 million Rupees, the proposal moves to the third and final stage of review by the DBT's Biotech Research Programme Committee (BRPC). There are a number of PACs, one for each of the main disciplines and subject-areas covered by DBT. Each PAC comprises subject-specialists. The PACs' chairpersons together constitute the BPRC. Any proposal that involves investment in infrastructure and institutional capacity goes straight to the BPRC, with DBT's Finance Committee having the right to raise questions during the review process.

In addition to conducting its own review, a PAC usually sends out the proposals for refereeing by external experts. The second stage can take up to two years, causing much frustration among applicants. Some interviewees expressed great irritation at the situation where the referees express diagonally opposite views, which in some cases compels the applicant 'to go back to the drawing board' and start the process all over again. Also anything to do with infrastructure facility/institution comes straightaway to BRPC.

3.4 Role of ICAR

Indian Council for Agricultural Research (ICAR) is an autonomous body under the Department of Agricultural Research and Education of the Ministry of Agriculture. Since the 1970s, ICAR has played a decisive role in Indian agricultural development through its initiation of, and sustained support to, multifarious components of public sector agricultural R&D throughout the country. In fact, the R&D efforts in crop science and technology that laid the foundations of the 'Green Revolution' (in the 1970s and 1980s) in rice and wheat in India are almost entirely to the credit of ICAR and the agricultural universities and agricultural research institutes and centres that come under its aegis.

Since 1989, ICAR has also devoted substantial resources to the breeding and dissemination of hybrid rice varieties. But in stark contrast to the success of the high-yielding rice varieties of the Green Revolution, the hybrid rice varieties have been almost total failures with consumers, farmers and traders (see Section 7.2 below for a detailed discussion of the hybrid rice programme in India).

Further, ICAR and 'its' institutions have also been involved in the R&D of some millets, tubers, legumes (pulses), oil crops, vegetables, fruits and tree species. *The primary objective* of these R&D efforts was to *increase crop productivity*, through (i) breeding higher-yielding cultivars, (ii) developing 'cultivation regimes' involving the systematic use of irrigation and industrial fertilisers, pesticides and herbicides, (iii) promoting 'integrated pest management' techniques and (iv) dissemination of the outcome of the R&D to the farming communities and plant breeding and trading companies, through extension work.

Another of ICAR's significant moves in raising agricultural productivity was to promote *non-GM tissue culture* for the rapid mass propagation of disease-free elite cultivars of some tubers, vegetables, fruits, spices, flowers and tree species [33]. R&D work in plant tissue culture in India goes back to the early 1980s and the first commercial ventures to the mid 1980s. DBT too has been involved in this. ICAR's and DBT's strategies of investing not only in R&D, but also in the transfer of tissue culture technology and innovations (free of charge) from the public sector research institutions to small and medium scale private sector companies has paid off in the widespread marketing of a number of tissue cultured commodities, e.g. potato, sugarcane, coffee, banana, strawberry, cardamom, ginger, turmeric, vanilla, liquorice and flowers [34]. Anticipating our discussion in Section 8 below (Summary and Conclusions) on the "transition from the laboratory to the market", the question arises as to why the "tissue culture strategy" does not seem to be "on offer" by DBT and other government agencies for disseminating the GM-crops being developed by public sector institutions.

The table below provides ICAR's total expenditure figures over the period 1995-2000. As until the end of 2003, the grants made by ICAR were devoted almost exclusively to conventional (i.e. non-GM) agriculture. The recipients are agricultural universities and specialist agricultural research institutes spread all over the country. They comprise 54 state-government funded agricultural universities, colleges and crop and commodity institutes, and 89 specialist institutes, with over 5000 R&D staff [35]. The ICAR grants cover undergraduate and postgraduate teaching, research training leading to doctorates and agricultural extension work among the farming communities to disseminate the results of research and breeding. Most of the expenditure is on salaries and the infrastructure underpinning teaching, research, extension and the dissemination of innovations. As indicated in an earlier paragraph above, it is important to note that some contribution by ICAR has accrued, *indirectly and in kind,* to GM-R&D, through the services provided to DBT-funded GM-crop projects by the infrastructure and personnel in ICAR affiliated agricultural universities and institutions.

ICAR's total expenditure in million Rupees and its annual growth rate in percentage

Fiscal Year	In million Rupees	Annual growth in percentage
1995-6	5219	
1996-7	5893	12.9
1997-8	6810	15.6
1998-9	9725	48.2
1999-2000	12759	31.2

Source: Compiled from ICAR's Annual Reports
See also www.cagindia.org/reports/scientific/2001_book1/index.htm

Given its history of being the predominant force in agricultural R&D in India, it is surprising that ICAR *did not get directly involved* in GM-crops until 2001, when it was directed by GoI (through GEAC) to conduct the final round of field trials of Monsanto-Mahyco's Bt-cotton to resolve the controversy about credibility of the trials conducted by Mahyco (see Section 7.1 for details).

Be that as it may, the pressure exerted over the years by GM-active research groups in ICAR-supported institutions and by ICAR's parent Ministry of Agriculture resulted in December 2003 to the announcement by GOI that ICAR will henceforth involve itself directly and strongly in the R&D of

[33] The ICAR-funded National Facility for Plant Tissue Culture Repository at the National Bureau of Plant Genetic Resources in Delhi is a repository of tissue cultured tuber and bulbous crops, spices, fruit crops, medicinal and aromatic plants and some species of endangered plants.

[34] Naresh Sharma and P.S.Janaki Krishna, "Status of Plant Biotechnology in India – An assessment from the small farmer perspective", Institute of Public Enterprise, Hyderabad, 1999

[35] See the answers to questions in the *Rajya Sabha* (Upper House of Parliament): Question number 196, answered on 15.3.2002 by Shri Ajit Singh, Minister of Agriculture, "Growth of seeds by Agricultural universities and colleges"; and Q.No.3525, answered on 27.4.2000 by Shri Hukumdeo Narayan Yadav, Minister of State in Ministry of Agriculture, "Institutes under Agricultural Research".

GM-local crops [36]. In a briefing to the Parliamentary Consultative Committee attached to his ministry, the Minister for Agriculture said that ICAR will allocate Rs 400 million to the GM-R&D of the following crops in the agricultural universities and research institutes that fall under the financing umbrella of ICAR: cotton, maize, soya bean, oil seed mustard (brassica), potato, cassava, pigeon pea, chickpea, tomato, aubergine (brinjal/eggplant), banana and papaya. The traits aimed at will be the resistance to attack by insects and fungal and viral diseases (biotic stresses), tolerance of drought and salinity (abiotic stresses) and the prolonging of "shelf-life" (storage quality). As all these crops and traits are already being worked on at several institutions with DBT funding (see Section 2.1 above on "The Public Sector R&D Institutions"), it is unclear whether the proposed ICAR funding will back up ongoing R&D activities, or duplicate them and/or initiate new ones, in exclusively ICAR-affiliated institutions. We will discuss the background to and the reasons for this policy decision in Section 4 below on "The Policy Regime", highlighting the indispensability of ICAR's involvement to enable the transition "from the lab to the market" of the GM-local crops innovated by the public sector institutions in India.

In early October 2004, the Director General of ICAR, Dr Mangla Rai, announced that ICAR will be investing about Rs. 320 million to build up Indian R&D capacity in the *functional genomics of rice*. Its purpose was to develop GM-rice varieties that are resistant to attacks by insects (e.g. the yellow stemborer), tolerant to drought and salinity, more efficient in the uptake of water and fertilisers, and of shorter crop-cycle duration [37]. In this context, it is worth recalling that the DBT-funded effort to incorporate several of these traits into rice (e.g. insect resistance and drought and salinity tolerance) has been going on for many years in more than half a dozen public sector research institutions.

[36] See the 22 Dec 2003 report in The Business Standard, www.business-standard.com/today/story
[37] 'India: ICAR Focusing on Genetic Improvement of Rice', The Hindu Business Line, 5 October 2004

4. AGRICULTURAL BIOTECHNOLOGY POLICY REGIME

We have described in Sections 2 and 3 above, the origin of the Indian Government's policy in the early 1980s for promoting public sector R&D in biotechnology and its evolution since then. To recapitulate briefly, the need for a conscious policy arose from the recognition that biotechnology was advancing rapidly in the West because of the perception by the West's private corporate sector of the technology's very promising economic potential. But a similar initiative by the Indian private sector was not on the cards, given the history of India's then planned economy in which the private sector had got used to, and thus expected, the government to take the plunge in ventures (whatever the sector) involving significant risks. And given the philosophy of 'catching up with the West' that has always determined the Indian government's development policies, it was but logical for GoI to take the policy initiative in introducing and promoting biotechnology.

In retrospect, one can see that the decisive policy move by GoI was the creation in 1986 of the Department of Biotechnology (DBT) under the Ministry of Science and Technology (MoST). Although the ministries and national research councils dealing with health (medicine), agriculture, industry and environment, have been formally involved in biotechnology policy deliberations through representation on several key committees (e.g. RCGM and GEAC), in practice it is DBT that has initiated, shaped and implemented biotechnology R&D policy. The concentration of policy responsibility and policy power in DBT has been underpinned by GoI's massive funding of DBT and its rapid growth in the 1990s. The policy and funding supremacy of DBT in agricultural biotechnology R&D was unchallenged until the end of 2003, when the Indian Council of Agricultural Research (ICAR, under the Ministry of Agriculture/MoA) came off the fence to announce its own specific policy and funding.

4.1 The policy process

Two intermeshing approaches have been used in making R&D policy. One is the identification by DBT of broad areas to promote and the other is the joint identification by DBT and "expert groups" external to the DBT of projects and programmes to initiate and support. With twenty-four broad areas already identified (see below) and their (explicit or implicit) hierarchical placing in the overall budget framework determined, there is unlikely to be significant new additions to and changes in the list of broad areas, for the foreseeable future. One can therefore conclude that the *first* of these two overarching processes has run its course and there is unlikely to be any major move to set it going again unless new overall priorities are dictated by echelons of the GoI much further up the ladder than DBT. However, the second process continues to operate, as it has to deal with new project and programme ideas that are submitted to DBT by researchers in the public sector R&D establishment.

The process of determining which R&D projects and programmes to initiate and support under each broad area takes place within a task force or a steering committee that DBT has set up in that area. In addition to this 'operational set' of task forces and steering committees, there are three other 'operational sets', one that implements the biosafety regime, an other that engages itself in 'broad brush' policy advice and policy advocacy on emerging R&D fields of potential importance to India and a third one to deliberate on the utilisation of biological resources in the economy. We list the four sets below[38]:

<u>The 'biosafety regime' set</u>:
- The Review Committee on Genetic Manipulation (RCGM)
- Monitoring-cum-Evaluation Committee (MEC) of the RCGM

<u>The 'R&D policy advice and advocacy' set</u>:

[38] See DBT's Annual Reports for 2003/2004 and 2002/2003. Available on www.dbtindia.nic.in

- The Scientific Advisory Committee (SAC)
- The Standing Advisory Committee Overseas (SACO)
- The Biotechnology Research and Promotion Committee (BRPC)
- The National Bioethics Committee

The biological resources (bioresources) set:

- The National Bioresources Development Board (NBDR), chaired by the State Minister of Science and Technology and comprising exclusively a small group of top civil servants (Secretaries) who head some selected ministries and research councils
- The Steering Committee of the NBDR

Task Forces and Steering Committees in the broad areas of:

-Medical Biotechnology
-Agriculture Biotechnology
-Plant Biotechnology
-Animal Biotechnology
-Biotechnology Product and Process Development
-Aquaculture and Marine Biotechnology
-Apex Committee of Indo-US Vaccine Action Programme
-Basic Research in Modern Biology
-Biodiversity Conservation and Environment
-Biofertilisers
-Biofuels and Bioenergy
-Bioinformatics
-Biopesticides and Crop Management
-Bioprospecting and Molecular Taxonomy
-Biotechnology-based Programmes for SC/ST Population and Rural Development[39]
-Biotechnology-based Programme for Women
-Biotechnology for Food and Nutrition Security
-Expert Committee on Setting Up Biotechnology Parks
-Human Genetics and Human Genome
-Human Resource Development
-Infrastructure Facilities
-Medicinal and Aromatic Plants
-Sericulture (i.e. silkworm breeding and silk production) Biotechnology
-Stem Cell Biology

To the biotechnology stakeholders in the country at large, the above-mentioned policy processes remain entirely opaque, as only the top officials of the DBT on the one hand, and a select group of senior civil servants and senior scientists on the other, are privy to what goes in the committees and task forces[40]. The proceedings and minutes of these bodies are not put into the public domain. According to the 'stakeholders at large', it is the highly centralised and elitist nature of the processes that renders them non-transparent. In the context of *agricultural* biotechnology, it is surprising that the state governments have not been drafted into the policy processes directly, given the fact that agriculture (according to the Indian Constitution) is a state government responsibility and no new crops can be introduced in any given state without the approval of the government of that state.

The key questions that arise are what perceptions, aims and criteria, and whose, informed the policy process that resulted in the above list of areas and taskforces. We take a stab at these questions further below, in particular in Section 4.2.

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[39] SC and ST denote "Scheduled Castes" and "Scheduled Tribes", who are among the poorest and the most disadvantaged sections of Indian society
[40] Our interviews with a selected cross-section of stakeholders

Speaking schematically, the process of arriving at decisions on projects and programmes proceeds in three stages. Ideas are first mooted and discussed within the expert committees, taskforces and the steering committees (hereinafter referred to collectively as the "expert groups"). The draft proposals that emerge from the "expert groups" are discussed, both formally and informally, within a small circle of Advisers and Directors within DBT, under the overall leadership and guidance of the Secretary of DBT. Amended proposals are then sent back to the "expert groups" for further discussions and revisions. This two-way process is repeated until final drafts are agreed, which are then presented by DBT's Secretary to the Minister of Science and Technology for final approval. By virtue of being represented in the "expert groups" by some of its top officials, DBT is well placed to put across its views to the groups.

The membership of the "expert groups" is drawn predominantly from a select group of senior and eminent scientists. It is therefore to be expected that the proposals emerging from the groups are strongly influenced by the scientific and technological interests, priorities and careers of leading scientists in the country, as well as by overseas scientists of Indian origin of international standing in the biotechnology arena. The heavy science and technology bias of the policy processes tends to be further skewed by the fact that the academic backgrounds of the top echelons of DBT are, in the main, in the natural, engineering and medical/biomedical sciences. However, '*national economic*' interests and priorities, as perceived and projected by GoI, also come into play in the policy processes by the intervention of the representatives of the ministries of agriculture, industry and commerce (trade) sitting in the expert groups [41].

Given the potential importance of biotechnology on the economy and society as a whole, it is surprising that expertise from the social sciences and legal disciplines has not been drafted into the expert groups. And *civil society's* perceptions and concerns about the potential impact of biotechnology on society have been systematically excluded from the policy processes[42]. Nevertheless, GM-concerned civil society and non-governmental organisations (CSOs/NGOs), together with GN-concerned media, have been successful in exerting pressure on the authorities to proceed more slowly and with greater caution in introducing GM-crops than might have been otherwise the case. We believe that it is the strong campaign mounted by GM-concerned civil society and media, in the run up to and the aftermath of the first case of commercialisation of a GM-crop in India, i.e. GM-cotton in 2002, that has made the authorities mark time over the approval of other GM-crops. (The reader is referred to Sections 6 and 7 below for a discussion and analysis of the role played by CSOs /NGOs, in particular in the context of GM-cotton and GM-rice.)

4.2 The R&D policies implemented in agricultural biotechnology

The policy processes sketched above has resulted in DBT's decision to promote public sector R&D on as wide a front as possible. We surmise that the 'wide front' policy is the outcome of the convergence of the convictions of public sector scientists and top government officials that India should establish R&D activity in all the subject-areas that are being pursued in biotechnologically leading countries in the OECD region, in all the four sectors of biotechnology (medical/pharmaceutical, agricultural, industrial and environmental).

This overarching 'wide front' policy is being implemented through three major interconnected 'down-stream' policies, of which the dominant one is to build R&D *capacity* through the creation of subject-specialist R&D institutions under DBT aegis (see Section 3 above) and through providing funds to old established institutions with wide mandates (national laboratories, agricultural universities, etc.) to set up biotechnology research groups. Capacity building encompasses, among other things, the creation and strengthening of R&D infrastructure (e.g. laboratory equipment and supplies), programmes for postgraduate (M. Sc., M. Tech., Diploma, etc.), doctorate (Ph. D.) and post-doctoral training at over

[41] Our interviews at DBT, selected central government and state government ministerial departments, and selected public sector R&D institutions, including agricultural universities.
[42] Our interviews at selected civil society organisations (CSOs, including non-governmental organisations /NGOs).

fifty higher educational institutions (universities, agricultural universities, institutes, etc.), and advanced training at selected institutions abroad[43].

It is assumed that every approved project contributes, either directly or indirectly, to capacity building. Therefore, the top priority given to capacity building in as large a number of institutions as possible spread across the country has meant that any project proposal that survives the scientific scrutiny and refereeing procedures tends to get funded, with considerably less weight attached, in practice if not in principle, to the criterion that a proposed project should have a realistic chance of leading to a commercially viable innovation.

The second 'down-stream' policy is to let the transfer of GM-technology from selected institutions and companies in North America and Western Europe determine the specific GM-routes through which Indian researchers are attempting to combat the biotic and abiotic stresses to which local crops are prone. With the exception so far of one project, all the other ongoing projects are based on transgenes (GM-constructs) obtained from abroad (see Section 2.1).

A parallel track pursued is the promotion of research collaboration between selected Indian and foreign public sector institutions, with DBT and foreign government aid agencies sharing the costs. Of the several bilateral programmes that have *actually been active* over a number of years (as apart from others which are still at the stage of 'letters of intent', 'memoranda of understanding', etc), the following are the largest in terms of the number of projects (completed, ongoing and newly funded). Besides research *per se*, the collaboration usually encompasses capacity building elements, such as the supply of laboratory equipment and specialist training for Indian scientists in the foreign institutions. The predominant area of collaboration is the medical/biomedical sector, with agriculture coming next but far behind and industry and environment being marginal [44].

Collaboration in the medical/biomedical sector, as of 2003/2004:

USA: Five projects have been completed, nine are ongoing and three new ones will be funded. The emphasis is on human contraceptive and reproductive research and on vaccine research in respiratory, diarrhoeal and other enteric diseases, streptococcal infections, HIV/AIDS, malaria, tuberculosis, hepatitis, leishmaniasis, rabies, and typhoid.

Israel: Nine projects ongoing in human genomics and neurodegenerative diseases and disorders (e.g. Alzheimer)

Germany: Three projects completed, one ongoing and three new ones will be funded. The emphasis is on human genomics, medical genetics, proteomics and bioinformatics

Other countries: Considerably smaller bilateral programmes than the above have been completed or are ongoing with France, Sweden and the UK. The Swedish project, completed in 2002, was on biosensors for rapid and inexpensive diagnosis of cholesterol

Collaboration in the agricultural and other sectors, as of 2003/2004:

Switzerland: Ten projects ongoing and 47 new ones will be funded. The ongoing projects are on developing disease resistant wheat and legumes (pulses, e.g. chickpea). The new ones will be in the fields of soil improvement, bioremediation, biofertilisers, biopesticides, marker assisted breeding, biosensors for detecting pesticides in soils and water bodies.

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[43] See the Annexures to DBT's Annual Report for 2002/2003, www.dbtindia.nic.in
See also S.R Rao, 2002, "Indian biotechnology developments in public and private sectors -- Status and Opportunities", *Asian Biotechnology and Development Review*, Vol.5 No.1, November. In this paper by a top official of DBT, it is claimed that in the Indian biotechnology sector as a whole (medical/pharmaceutical, agricultural, industrial and environmental) there are "at least 165 institutions working in rDNA research, which include 55 institutions engaged in transgenic plant research, both in public sector (42) and private (13), ----at least 1500 R&D projects implemented by all S&T agencies, --- a large number of private institutions engaged in rDNA therapeutics"
[44] DBT's Annual Reports for 2002/2003 and 2003/2004, www.dbtindia.nic.in

Belarus: Seven projects ongoing in the genetic modification of potato, barley and wheat, and in the genomic analysis of flax

Russia: Six projects ongoing in potato, sunflower and wheat. Two new ones will be funded in marker assisted breeding of brassica and in the genetic modification of plants to produce edible hepatitis vaccine.

Sweden: A project each on tree tissue culture/forest genetics, biocatalysis for lactic acid production and the bioremediation of soils polluted by the mining industry was completed in 2002.

In the context of collaborative programmes in agricultural biotechnology, Indian public sector institutions have gained greatly by participating in the International Program on Rice Biotechnology (IBRP, 1984-2000) that was launched and supported by the Rockefeller Foundation. The seminal and crucial contributions by the IRBP are described in Section 3 above and Section 7.2 below.

Although there are as yet no ongoing bilateral collaboration projects with the USA in agricultural biotechnology, a substantial programme may be in the offing (perhaps rivalling the Swiss one), if the 'letter of intent' signed in June 2004 by India (through the agency of DBT) and the USA is implemented. The intention is to focus on the development of crops resistant to drought, heat and salinity. The intended activities include technology diffusion and development, biosafety, joint workshops and conferences, and exchange and training of scientists.[45]

The third 'down-stream' policy is to earmark substantial long-term support to certain R&D institutions (for example, the DBT-sponsored Centres for Plant Molecular Biology /CPMBs listed in the Table in Section 2.1 above), in order to expedite the innovation of some selected GM-crops, with certain biotic and abiotic traits, regarded as being of special importance to India.

Besides the creation of R&D capacity in GM-crops technology, as well as in *non-GM* agricultural biotechnology (e. g. *non-GM* tissue culture, biopesticides and biofertilisers), the *actual outcome* of the implementation of DBT's policies *in the specific arena of GM-crops*, over the period 1986- 2004, has been the involvement of 22 public sector R&D institutions in active work on 18 GM-crops (see the Table in Section 2.1 above). One consequence of the policy decision to invest in a wide range crops and activities, rather than on concentrating on a few, is the growing accumulation of projects, *with none as yet reaching the stage of commercialisation.*

4.3 Policies addressing the transition from R&D to commercialisation: 'From the lab to the market'

4.3.1 The Background

We note, to start with, that in the *biomedical/medical/pharmaceutical and the industrial sectors of biotechnology*, several measures have been introduced by GoI to promote the transition from the R&D stage to the innovation and commercialisation stages, A Technology Development Board (TDB) and a Pharmaceutical Research and Development Support Fund (PRDSF) have been set up under the Department of Science and Technology (DST, in the Ministry of Science and Technology/MoST) to provide soft loans to entrepreneurs and companies. Other incentives are exemption from price control on some specified biotechnological products under the Drugs (i.e. pharmaceuticals) Price Control Order of 1995 and total tax exemptions on R&D investment and expenditure. Relatively heavy duties

[45] See The Economic Times, 29 June 2004 http://economictimes.indiatimes.com/articleshow/758651.cms"India, US ink pact on agri research, hope to double farm output by '25" See also http://asia.news.yahoo.com/040629/4/1k6f2.html

have been imposed on the import of biotechnology products in order to protect the still nascent domestic biotechnology industry.

Foreign Direct Investment (FDI) is being encouraged, accompanied by promises of speedy implementation of the biotechnology projects approved by the public sector Foreign Investment Promotion Board (FIPB). Medical/pharmaceutical and industrial biotechnology projects have been included in the ambit of the Fast Track Committee (FTC) of the Foreign Investment Implementation Authority (FIIA).

At some of the 'elite' public sector universities and Indian Institutes of Technology (IITs), specialist training is offered in industrial biotechnology. As further incentives to scientists, institutions and industries, GoI confers annual national "Awards in Biotechnology Product and Process Development and Commercialisation".

By 2003/2004, out of the vast number of R&D projects that DBT has supported (see footnote 44 above) during its 18-years of existence, a total of only 56 technologies had been transferred to commercial companies. Most of the firms acquiring the technologies are small- and medium-scale enterprises in the private sector. Information about the terms and conditions of the transfer is not available. As to how many of the 56 have in all been actually commercialised to date remains undisclosed, except the three listed in one of the Annexures to DBT's Annual Report for 2002/2003. With the exception of the medical/biomedical/pharmaceutical and veterinary sectors, where the transferred technologies contain both GM and non-GM techniques, *the rest are all non-GM.*

Table. Number of Technologies Transferred to Commercial Companies.

Sector	Technologies Transferred	Transferring Institutions	Technology Buying Companies
Medical/Biomedical/ Pharmaceutical	36	15	18
Veterinary	4	5	4
Food, Animal Feed and other industries	5	6	4
Plant Tissue Culture	3	3	2
Biopesticides	4	3	7
Biofertilisers	2	2	3
Aquaculture	1	1	1
Environment	1	1	1
Total	56		

An in-depth analysis of what these figures signify is essential for understanding the relative strengths, shortcomings and prospects of public-private partnerships in the in-country transfer and commercialisation of technologies in the various biotechnological sectors, but it is outside the scope of the present paper. We simply note several points here. The transfer of a technology 'from a lab to a company' does not by itself signify that it will be commercialised; it is but one step out of the many that will have to be taken to arrive at commercialisation. The number of transferred technologies is extremely modest in comparison with the large resources invested by GoI through DBT in public sector R&D. The biomedical/medical/pharmaceutical sector is far ahead of the other sectors, accounting for nearly two-thirds of the total number of technologies transferred and within the sector a few institutions and a few companies account for a greater share of the technologies transferred, i.e. there is a certain degree of concentration that may result in some commercialisation down the road. (In this context, it is worth recalling from Section 3 above, that a lion's share of DBT's R&D allocations has gone to the biomedical/medical/pharmaceutical sector.) In all the other sectors, the development of transferable technologies of potential interest to companies seemingly lacks momentum. (As to why this should be so merits an in-depth policy research investigation on its own, but that is beyond the scope of the present study.)

4.3.2 Transition of GM-crops 'from the lab to the market'

Given, on the one hand, the potential risks posed by GM-crops and the need therefore to ensure their environmental, health and socio-economic safety, and on the other hand, the extremely fragmented and heterogeneous character of small-scale farming that predominates in India, the transition from R&D to innovation and commercialisation in agricultural biotechnology has had to be addressed in an entirely different fashion than has been done in the non- agricultural biotechnology sectors.

Further, under the Constitution of India, it is not the central GoI but the state governments that exercise formal authority over agriculture. Thus, while GoI may take the initiative in the policy arena and formulate policies concerning agricultural biotechnology and GM-crops (in R&D as well as commercialisation), the agreement and active cooperation of state governments are indispensable for implementing the policies. The critical importance of consultation and coordination between the GoI and the state governments to the introduction and promotion of GM-crops was revealed by the controversies between the centre and the states that accompanied the field trials and commercialisation of GM-cotton, the first and only GM-crop so far to have been approved by GoI for general release and marketing. The reader is referred to Section 7.1 for an analysis of the tensions between the centre and the states that surfaced in the GM-cotton case and their significance for the future.

Public sector R&D institutions have to successfully complete *two major stages* in taking their GM-crop innovations "from the lab to the market". First, they have to conduct the large-scale, multi-location and multi-season field trials that are obligatory under the national biosafety regulations and present the outcome of the trials to GEAC, on the basis of which GEAC would decide whether or not to approve a given GM-crop for general release and commercialisation. Second, they have to negotiate with seed production and marketing firms (in the private and public sectors) the terms and conditions of technology transfer agreements, under which the firms would be willing to take over the innovations and produce and market the GM-crop seeds (planting material). *This second stage involves also the potentially contentious issue of intellectual property rights of foreign owners of the GM-technology that almost all Indian work on GM-crops is currently based on.* We will deal in detail with biosafety issues in Section 5 below entitled "The Biosafety Regulatory Regime". In the rest of the present section we indicate the measures that need to be in place for traversing the two stages. Pending the introduction and implementation of the measures sketched below, one can say that, a*s of late 2004, no public sector R&D institution had yet embarked on the stage of large-scale, multi-location field trials and therefore the prospect of a public sector GM-crop innovation being commercialised remains a distant one*[46].

In their comments on the final draft version of the present study, DBT advance the following arguments (*we quote from DBT's text, subject to our slight editing):*
"There are several reasons for the slow progress of development and commercialisation of transgenic crops in India. These can be summarised as:
- Limited availability of transgenes, promoters and transformation protocols.
- Excessive focus on academic research and consequently weak focus on product development
- Stand-alone research efforts with little or no networking and pooling of R & D strengths
- Poor infrastructure
- Little private sector investment in R & D

However during the last decade several useful lessons have been learnt from the successes and failures of public R & D efforts in transgenic crop development. These can be summarised as follows:
- The crops and traits selected so far are more-or-less in line with national priorities.

[46] There are, however, two examples so far of public sector institutions moving directly to transfer their GM-crop innovations to private sector companies, leaving it to the companies to conduct the field trials and obtain GEAC's clearance for commercialisation: transfer of GM-cotton technology by NBRI, Lucknow and CPMB at Osmania University in Hyderabad, to Swarna Bharat Biotechnics in Hyderabad (see the Table in Section 2.2 above). This may set the trend for other institutions to follow.

-Indigenous transgenes and promoters are beginning to become available (as a result of past decisions of public funded research institutions and funding agencies to invest in molecular biology)
Regeneration and transformation protocols are becoming available for indigenous and recalcitrant crops of national interest
-It is time that focus should shift to product development by integrating basic research in functional genomics (identification of transgenes/promoters/regeneration/transformation protocols/generation of multiple transgenic events) and applied research in crop/cultivar development (transferring transgenes to superior varieties/testing)
-A much larger number of transgenic events have to be generated as opposed to the small numbers at present.
-Work on transgenics for complex traits like yield and abiotic stress need to be initiated

Policies to tackle the many complex problems that face development, testing and commercialisation of transgenic crops in India are in the process of evolution. This should be regarded as an opportunity to strengthen the structure of regulatory controls and to put policy measures in place."

4.3.2.1 Stage 1: Demonstration of the technological feasibility and biosafety of GM-crop innovations: The critical role of ICAR

No public sector R&D institution in India can by itself muster the financial, personnel and infrastructural resources required for conducting the large-scale, multi-location and multi-season field trials that are legally obligatory. In the public sector, only ICAR has ready access to such resources. It has a nationwide coordinated and well-functioning system for conducting a large number of field trials. Under ICAR's all India coordinated system, which has been in operation for a long time in the area of conventional, non-GM crops, the decision about field trials are taken at the annual meetings attended by crop scientists, crop breeders, agronomists and other practitioners from related disciplines (from both the public and private sectors). At these meetings, the participants decide which crop lines (out of the many on offer) to take on board and work out the plan for conducting the field trials, which involves, among other things, the assigning of the trials and the resources (provided by ICAR) to participating institutions, the logistics of and reporting from the trials, etc. Unless this system is extended to GM-crops, public sector institutions cannot generate the data on the environmental and agronomic impact of the crops required by GEAC for reaching a verdict on general release and marketing.

Similarly, the institutions would need resources from research councils to pay for the services of laboratories that specialise in testing the GM-crops' potential impact on the health safety of humans and livestock, and for commissioning social science research centres to conduct studies on the potential impact of the GM-crops on farmers, traders, consumers and other sections of society and economy.

Several hypotheses can be advanced to account for ICAR's reluctance, until December 2003, to enter the field of GM-crops in a direct and decisive manner [47]: Scepticism about the relevance and feasibility of the GM-route to increased crop productivity, given ICAR's long-standing commitment to conventional methods of combating certain biotic and abiotic stresses to which crops are prone in India; Reluctance to cut back on conventional methods by redirecting part of its resources to the GM-effort; Difficulty in overcoming the 'institutional inertia' that tends to hold down big and well established institutions to 'old and proven furrows'; Sensitivity about encroaching a terrain that DBT had marked out as its own; Nervousness about being drawn into the fierce public controversy between the GM protagonists and antagonists; Waiting until GoI was prepared to provide extra funding and

[47] However, since the early 1990s, ICAR has been *indirectly* involved in promoting rice biotechnology (both the non-GM and GM categories) in India, through the participation of the rice researching institutions under its aegis (in the agricultural universities and specialist institutions outside the university system) in the Rockefeller Foundation's International Programme for Rice Biotechnology in Asia (IPRB; see Section 7.2 below for details). The capacity and the stake in rice biotechnology created by IPRB in ICAR-supported institutions lie behind ICAR's decision in 2002, jointly with DBT, to promote the transfer, backcrossing and testing of the so called 'Golden Rice' technology, innovated at the Swiss Federal Institute of Technology (ETH) in Zurich, which incorporates genes to produce the vitamin A precursor beta carotene into rice (see Section 7.2 for details).

specific powers to ICAR for entering the field of GM-crops. It would have been of interest to test the degrees of validity of these hypotheses, but that exercise is beyond the scope of the present study.

A statement by the Minister for Agriculture in December 2003 commits ICAR explicitly to a policy of direct support to the R&D of about a dozen GM-crops in the agricultural universities and other agricultural research institutions that come under the financing umbrella of ICAR (see Section 3 above for a listing of the crops and the traits that will be aimed at). The Minister said that GoI will at this stage commit (through ICAR) about 9 million US dollars to this programme, which includes upgrading the GM-labs in selected agricultural universities and research institutions[48]. Some of our interviewees were of the opinion that this policy announcement is a result of persistent lobbying by some sections of the R&D establishment in ICAR-funded institutions, and associations representing the more well off farmers and large-scale seed breeding and marketing companies. As of late 2004, the details of how this policy will be implemented and what criteria and procedures will be employed for approving projects and funds were not available. It is also not clear whether and how the announced funding (9 million US$) will be shared out between ongoing projects of many years standing (funded by DBT) and entirely new projects, which are still at the stage of proposals. Past experience in India and the OECD region tells us that new projects could take between ten and fifteen years before resulting in commercial innovations, if at all. This means that GM-crops from *entirely new* projects approved under the new ICAR-initiative are unlikely to appear on the Indian market before 2014 (assuming that the new, as well as the ongoing projects, will not be allowed to 'cut corners' in fulfilling the provisions of the biosafety regulatory regime, because of the 'privilege' of belonging to the public sector).

4.3.2.2 Stage 2: In-country transfer of technology to market actors and the question of intellectual property rights

Assuming that the field trials, health tests and social science studies succeed in demonstrating the technological feasibility and biosafety of a given GM-crop innovation under the conditions of cultivation that actually obtain in the countryside, *a stage which no public sector R&D institution in India had yet managed to complete by early 2005*, one would then have to demonstrate the innovation's economic viability to the farming community and the market actors, if commercialisation is to succeed.

Diffusion of innovations to market actors is a very complex process, not least because of the different types of actors involved. Small- and medium-scale seed breeding and marketing entrepreneurs would be on the look out for low risk and quick return ventures that can be initiated with modest investment, but large companies would be able to tolerate higher risks, longer periods of return and higher levels of investment. Small farmers and peasants in India have very low operational margins[49] and their tolerance of risk is virtually zero. In order to tailor GM-crop innovations to meet the range and variability of the market actor-specific and the farmers' location-specific factors, in particular the challenge of 'near zero risk', the R&D institutions would have to collaborate closely with institutions with proven professional competence in applied social sciences (agricultural and trade economics, rural sociology, rural governance, laws regulating trade, etc.).

As in the medical/pharmaceutical sectors, the food and feed crops sector at the global level is characterised by a massive concentration of technology, patents and IPR-covered genetic material[50] in the hands of a few transnational corporations (TNCs). Thus, access to the state-of-the-art biotechnology and its products is strictly regulated, which has profound implications for public sector

[48] See http://www.business-standard.com/today/story.asp?Menu=22&story=30130
[49] The production costs they can afford are dictated by what the local traders are prepared to pay for each harvest, which can vary from harvest to harvest
[50] Six agro-chemical TNCs currently dominate the global market in food and feed crops, including GM-crops and -technology: Monsanto, Aventis, Syngenta, DuPont, Dow and BASF

R&D institutions in developing countries, including India, that are attempting to develop and diffuse GM-crops to local farming communities. As pointed out above, almost all current GM-crop work in public sector R&D institutions in India is being conducted on the basis of the GM-techniques patented either by the TNCs or by some advanced research institutions in the OECD region. The GoI, through DBT, the Ministry of Agriculture, the Ministry of Commerce (Trade), etc., would therefore have to negotiate with the TNCs and foreign research institutions affordable terms and conditions for using patented GM-technologies (processes) and GM-products, *including the conditions that will govern the institutions' own IPRs vis-à-vis the indigenous market actors (the so-called "freedom to operate" clauses*). These negotiations presume the existence of IPR-focused institutional capacities and strategies within GoI, of which we found no readily available evidence either in the public domain or through our interviews with selected officials.

In principle, IPR-agreements between TNCs, foreign research institutions, Indian public sector research institutions and the Indian government would affect the approach adopted by public sector R&D institutions in their own IPR-negotiations with the indigenous local market actors. It is too early to say how this will work out in practice [51]. In any case, in such negotiations, the institutions would have to be sensitive to a variety of responses by the indigenous local market actors when confronted by the institutions' IPR demands, which are determined by the actors' heterogeneity, differential access to resources and differing motivations in entering the GM-crops arena. In order to initiate and successfully conclude such negotiations, and to administer and manage the ensuing agreements, the R&D institutions would need recourse to capacities in a variety of fields in the social sciences, management and legal disciplines. Since any given R&D institution is highly unlikely to have all the required capacities within its walls, it would have to access the capacities from a range of institutions that lie outside the GM-arena. In our questionnaire surveys and personal interviews, we found no evidence whatsoever that GM-active R&D institutions have begun to seriously address the capacity challenge that the IPR-issue poses.

GoI has deployed some policy measures and instruments to steer R&D institutions towards establishing linkages with, and working on problems of practical importance to, local market actors, e.g. tax breaks, reduced customs duties on imports of R&D inputs, ready access to training and service infrastructure. These will be mentioned briefly in the following sub- section.

4.4 Post-2002 initiatives that may shape future policy on biotechnology and biosafety

In 2003, the Ministry of Agriculture, acting on the advice of ICAR, appointed a Taskforce under the chairmanship of Dr M. S. Swaminathan[52] to examine how the current biosafety regulatory regime was affecting the development of agricultural biotechnology and to submit recommendations. (A similar task force has been set up by GoI, under the chairmanship of Dr R. A. Mashelkar, the Director General of CSIR, in the medical/pharmaceutical sector.) The Swaminathan Taskforce submitted its report to the Union Minister of Agriculture in early June 2004. It makes fairly radical recommendations on reforming the biosafety regulatory regime. The Panel's recommendations have been criticised rather strongly by leading GM-concerned CSOs and pro-GM stakeholders in the private sector. It remains to be seen which of the Taskforce's recommendations will be implemented by GoI. We will present the Taskforce's recommendations and its critique in Section 5 below on the "Biosafety Regulatory Regime".

[51] In this context, it would be of interest to examine the terms and conditions governing the transfer of the foreign IPR-based GM-cotton technology that NBRI, Lucknow and CPMB, Osmania University have transferred to the Indian company Swarna Bharat Biotechnics.

[52] Dr Swaminathan is an eminent scientist of international repute in crop breeding. He was the Head of the Indian Agricultural Research Institute in Pusa in Delhi in the 1960s and 1970s, and later became the Head of the International Rice Research Institute in the Philippines, a CGIAR-institution. He is widely credited with the 'launching' of the Green Revolution in India and he made decisive interventions at GoI levels that contributed to its success. He has been honoured by a number of international awards. On retirement, he set up the M. S. Swaminathan Science Research Foundation in his native city of Madras (now Chennai).

In early 2004, GoI set up a National Commission on Farmers with the wide mandate to review the status of Indian agriculture, assess the conditions of different categories of farmers in various regions, identify factors responsible for imbalances and disparities, and suggest policies, programmes and measures for diversifying and accelerating agricultural development. As part of its brief, the commission has also been directed to address the question of improving the delivery of production inputs, upgrading of agricultural technology and *creating a farmer-friendly framework for the promotion of agricultural biotechnology* [53].

In January 2004, at the Indian Science Congress held in Chandigarh (the state capital of Punjab), GoI announced a six year plan entitled "The Plant Genome Research Road Map" to further promote R&D in GM-crops. In introducing the plan, the representative of GoI stressed that unless agricultural production kept pace with the increasing population, India would have to import, in fifteen years time, substantial quantities of staple cereals, legumes (pulses, the main source of protein for the majority in India) and other agricultural commodities [54].

In a statement issued on 1 September 2004, the Union Minister for Science and Technology, Mr Kapil Sibal, said that a new policy on biotechnology and biosafety could be in place in about nine months. One of the aims of the new policy would be to restructure GEAC and speed up the biosafety assessment process. But he conceded that although several GM-crops were being field tested, it would take many years before the next GM-crop could be approved (the only GM-crop approved so far is GM-cotton and that was in March/April 2002). He emphasised that while GoI placed considerable importance on developing crops that were resistant to pests and more tolerant to climatic stress like drought, it was equally keen on biosafety standards being complied with. He pointed out that India would have to double its crop productivity by the year 2025 to produce the 420 million tonnes of food grains needed to feed its growing population (which is estimated to reach 1.3 billion by 2025). He welcomed research collaboration and joint ventures in biotechnology with foreign institutions and companies, but stressed that these would be welcome only if they ensured biosafety. "Biotechnology and biosafety must go hand in hand", he said [55]. In an earlier related move, the Secretary of DBT, Dr M. K. Bhan, announced that "a group of experts will be set up to suggest models for public-private partnerships in the biotech sector. (DBT) will invest in the creation of innovation centres within the existing academic and research institutions." [56]

In the wake of Minister Kapil Sibal's statement, GoI set up a **Taskforce on New Biotechnology Policy** in late October 2004, under the **chairmanship of the Secretary of DBT, Dr M. K. Bhan**. It includes:

- Dr M. S. Swaminathan, Chairman of the GoI-appointed Agricultural Biotechnology Taskforce mentioned above, whose report has already been submitted to the MoA
- Dr R. A. Mashelkar, Director General of CSIR and Chairman of the GoI-appointed Recombinant Pharmaceuticals Biotechnology Taskforce, whose report is due for submission soon
- The Secretaries of the Ministries of Agriculture, Health, Environment and Forests, Commerce, Industrial Policy and Information Technology
- Representatives of private sector industry
- Dr Suman Sahai, Director of Gene Campaign, New Delhi, the sole representative of GM-concerned CSOs/NgOs
- Dr Mangla Rai, the Director General of ICAR
- Dr N. K. Ganguly, Director General of ICMR
- Prof. G. Padmanaban, Former Director of, and Emeritus Professor in, the Indian Institute of Science, Bangalore

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[53] Report in www.agbioworld.org, Feb 13, 2004
[54] BBC news report by Richard Black, Jan. 5, 2004, http://news.bbc.co.uk/1/hi/sci/tech/3369263.stm
[55] See Reuters news report datelined Atul Prakash, 1 Sept 04, "India to promote GMO crops in New Policy", quoted at http://www.agbios.com/main.php?action=ShowNewsItem&id=5811 and the 8 Sept 04 report in www.agbioworld.org
[56] See 16 July 04 report in www.agbioworld.org and also http://www.isaaa.org/kc/Bin/cbtupdate/index.htm, http://www.ciol.com/content/news/2004/104071204.asp.

- Prof P. N. Tandon, Chairman, National Brain Research Centre, New Delhi
- Dr Bala Subramanian, Director, LV Prasad Eye Institute
- Dr. Renu Swarup, a Director in DBT, will act as the secretary (member-secretary, in Indian designation) of the Taskforce.

The terms of reference of the Bhan Taskforce include making recommendations "on strategies for translation of the biotech policy towards full utilisation of the potential of the technology for human welfare and economic development, --- on setting up of sub-committees in different sub-sectors (of biotechnology) and their roadmaps ---- for the next 10 years, --- on modifications to the existing laws and procedures --- (concerning) regulation of transgenic products, --- on incentives for promotion of trade and investment in biotechnology and on measures for creating awareness (in the country) of the overall status (of) and new initiatives (in biotechnology)[57].

It is expected that the reports by the Swaminathan and Mashelkar Taskforces will have a significant impact on the deliberations of the Bhan Taskforce. News reports indicate that GoI may also set up a taskforce to make recommendations on the use of GM-crops and GM-products in the food and feed processing industries [58].

4.5 Legislation other than in biosafety with important bearing on GM-crops

As indicated at several places in the preceding sections, biosafety is perhaps legally the most decisive factor in the R&D and commercialisation of GM-crops in India. We will analyse the biosafety regulatory regime in Section 5 below. But legislation in other fields than biosafety also affects the R&D and commercialisation of GM-crops. We touch upon them briefly in the following sub-sections.

4.5.1 The Patents Act and Intellectual Property Rights

As a member of the World Trade Organisation (WTO), India is obliged to abide by the provisions of the WTO's agreement on trade related intellectual property rights (TRIPS), which also cover the trade in biotechnology products and processes in all sectors of biotechnology (medical/pharmaceutical, agricultural, industrial and environmental). In order to align Indian legislation with TRIPS, the Indian parliament amended the earlier patents legislation by passing the Patents (second) Amendment Bill 1999 in May 2002[59].

Various stakeholders in the biotechnology arena in India (e.g. parts of the biotechnology industry, farmers' associations, non-governmental and civil society organisations, etc.) have long been deeply concerned about the impact on India of the patents legislation in leading OECD economies (e.g. the USA, EU, Japan, etc.) that allows for the patenting of genetically modified organisms and life-forms. The OECD legislation is understandably designed to protect and promote the IPR interests of OECD-based companies. What has worried the Indian stakeholders is the fact that while TRIPS goes a long way in accommodating OECD interests, it has not sufficiently taken into account the actual and potential negative impact of OECD patents legislation on the developing world, as mediated by the TNCs. For instance, according to US legislation, a US-based company's IPR over a transgene or a genetically modified trait gives the company, in effect, IPR control over any crop into which the transgene/trait finds its way. In other words, the IPR covers the company's GM-technology and thus any crop into which this technology gets embedded, irrespective of whether or not the particular crop was developed and patented by the company and irrespective of the origin of the original crop variety and the traditional knowledge of farming and crop breeding communities that has gone into its development.

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[57] See the news report by Ashok B. Sharma in the Financial Express (India) on October 20, 2004, http://www.financialexpress.com
[58] ibid
[59] "Patents Bill passed by Lok Sabha", Economic Times, 15.5.2002

Propelled by the above concerns, and under pressure from a broad-based front of stakeholders, the May 2002 amendment to the Indian Patents Act expressly forbids the patenting of traditional knowledge and life forms. Not all stakeholders are happy with this safeguard. A section of the private sector industry in India, in particular in the medical and pharmaceutical sectors, is worried that it may seriously obstruct the transfer of GM-technology from the OECD region into India and thus hamper local R&D, production and marketing of biotechnology products and processes [60].

It remains to be seen how the Indian legislative safeguards to ensure the non-patentability of traditional knowledge and life forms will stand up to the challenge that is likely to be mounted in time to come by the corporate sector. The following examples involving Monsanto could be indicative of the conflicts that may arise.

Since the mid 1990s, Monsanto has produced and marketed a variety of the oilseed canola that is genetically modified to tolerate Monsanto's broad-spectrum glyphosate herbicide marketed under the brand name Roundup. The Roundup herbicide is designed to wipe out all vegetation in the sprayed area, except the Roundup tolerant GM-crop. In 1997, a Canadian farmer, Percy Schmeiser, was sued by Monsanto, alleging that he had deliberately planted the Roundup Ready canola on his land without paying for the GM-seed, thus infringing Monsanto's IPR on the GM-crop. This was disputed by Mr Schmeiser, who maintained that the Roundup canola had landed on his field 'accidentally'. Over a seven year period, the case made its way through the lower courts to the Canadian Supreme Court, whose ruling on 21 May 2004 upheld Monsanto's IPR to the transgene but left the wider question of what kinds of rights Monsanto has over the GM-plant unresolved. To quote from a report in the Canadian press, "the lower courts rejected Schmeiser's claim that the canola landed on his fields by accident, but didn't deal with the deeper issue of whether Monsanto can control use of a plant because it has patented a gene in the plant. (The supreme court) ruled that Monsanto has a legal claim to such control. The court ruled earlier in the case of the Harvard mouse, that higher life forms cannot be patented and Schmeiser based his case on a claim that a plant, too, is a higher life form, and exempt from patent. The court agreed that the plant is a higher life form and cannot be patented, but said the patent does apply to the gene. Steven Garland, vice-president of the Intellectual Property Institute of Canada, said the main question was what kind of rights Monsanto enjoyed as a result of its patent on one gene in Roundup Ready canola."[61]

The Canadian case is reminiscent of the one that Monsanto lodged against a Mississippi farmer, Homan Mcfarling, in a US federal court. Mcfarling bought Monsanto's Roundup Ready soya bean seeds in the market quite legally, but saved seeds from the harvest and replanted them. Monsanto argued that the replanting of saved seeds infringed its IPR and claimed damage payment from Mcfarling. But on 9 April 2004 the US federal court ruled against Monsanto [62].

On 21 May 2003, the European Patent Office (EPO) in Munich granted Monsanto a patent on a wheat variety called 'Galahad 7' or 'Galatea'. In 1998, Monsanto acquired the wheat division of the transnational corporation Unilever and thus the rights to 'Galahad 7' ('Galatea') that Unilever had developed based on the Indian hard wheat landrace variety 'Nap Hal' and the European soft wheat 'Siccio'. It combines the low elasticity and low gluten content of 'Nap Hal' with the easy milling property of 'Siccio'. It is expected to be particularly attractive to manufacturers of baked wheat products (bread, biscuits, etc.)

A leading Indian civil society organisation (CSO) based in New Delhi, the Research Foundation for Science, Technology and Environment (RFSTE) and the international CSO Greenpeace jointly lodged a petition, on 17 February 2004, in the Supreme Court of India in New Delhi and at the EPO in Munich, asking Monsanto's patent to be revoked. The two CSOs point out that 'Nap Hal' is an Indian traditional variety that has been bred by generations of Indian farmers on the basis of their traditional

[60] "Patent laws a hurdle for biotech R&D", Hindu Business Line, 21.1.2002

[61] http://www.thestar.com/, 22 May 2004. See also Philippe Cullet's article "Farmer Liability and GM Contamination: Schmeiser Judgment" in Economic and Political Weekly, Mumbai (Bombay), Vol 39 No 25 June 19, 2004, www.epw.org.in

[62] See the report by Jeffrey L Fox in Nature Biotechnology 22, 791, July, 2004

knowledge. Its flour is used by the great majority of Indian households on a daily basis for making flat unleavened bread called 'chapati'. They argue further that "the traits of low elasticity and low gluten which are being patented are not inventions, but derived from an Indian variety. The crossing with a soft milling variety is an obvious step to any breeder. The patent is based on piracy and not on non-obvious novelty---. The broad scope of the patent covering products made with Indian wheat robs Indian food processors and biscuit manufacturers of their legitimate export market and could in future affect (Indian) domestic food sovereignty. ---- If such biopiracy based patents are not challenged, and crop lines and products based on unique properties evolved through indigenous breeding become the monopoly of MNCs, in future we (Indians) will be paying royalties for our innovations especially in light of the Patent Cooperation Treaty and the upward harmonization of patent law"[63]. These arguments are rejected by Monsanto, who point out that the patent does not apply to 'Nap Hal' as such but to 'Galahad 7' and therefore does not in any way infringe the rights of Indian farmers, manufacturers and consumers with to respect to 'Nap Hal' and products thereof [64]. The EPO patent has been validated in only four European countries: Denmark, France, Germany and the UK. But, as of mid 2004, 'Galahad 7' had not been commercialised anywhere.

4.5.2 The Seeds Act

A draft Seeds Act of 2001 was being finalised on the basis of the recommendations of Seed Policy Review Group. It would replace the existing Seeds Act of 1966 and Seed (Control) Order of 1983. It proposes the establishment of a National Seeds Board and the compulsory registration by the Board of any seed or planting material (produced in India or imported) that is intended for sowing (planting). Any Indian firm that produces and /or imports seeds and planting material will be required to declare whether such material is a product of genetic modification and incorporates Genetic Use Restriction Technology (the so called 'terminator technology')[65].

4.5.3 Protection of Plant Varieties and Farmers' Rights Act

The government's Seed Law was modelled on the Plant Breeders' Rights of the Union for the Protection of New Plant Varieties (UPOV). UPOV is an organisation based in Europe and its members are only western countries. For India the law would have to be fundamentally different since unlike in the Europe where it is to protect the interests of powerful seed system, here the Farmer would also have to be given a right over his seed[66].

But with the new legislation, India has put in place a law that grants, for the first time in India, Plant Breeders' Rights and Farmers' Rights on new varieties of seeds and planting material. This legislation was necessitated by the commitments that India has accepted by ratifying the WTO's Trade Related Intellectual Property Rights (TRIPS) Agreement. Article 27.3(b) of TRIPS, which deals with the protection of new plant varieties, offers three options. Protection will have to be granted by a patent, an effective *sui generis* system or by a combination of the two. The *sui generis* system refers to Plant Breeders' Rights, without however defining what kind of system except to say that it should be 'effective'. India opted for the *sui generis* option, which was preceded by a determined but unsuccessful struggle by a few leading CSOs to stop India from legislating to allow patents on seeds and planting material[67] (see the section below on the new Seeds Act). Some CSOs also campaigned against India joining UPOV, with the New Delhi based Gene Campaign seeking a court injunction to

[63] See Vandana Shiva's (Director of RFSTE) article entitled "Monsanto's Biopiracy" in the 27 April 2004 report in www.countercurrents.org/en-shiva270404.htm. Also see the article "Wheat Biopiracy Challenge in the Supreme Court of India" in www.peoplesfoodsovereignty.org/news/2004/05.htm
[64] See the 27 April 2004 report in www. agbioworld.org
[65] "Draft Seeds Act being finalised", Economic Times, 18.3.2002
[66] "Plant Variety Act - The Government's New Seed Law", Gene Campaign. This NGO works in 17 states has played a significant role in formulating the national policy and drafting legislation. www.genecampaign.org
[67] "Pant Variety Protection and Farmers' Rights Act, 2001", Suman Sahai, Gene Campaign, www.genecampaign.org See also "An Act that sows success", The Hindu, December 17, 2001.

ensure that Indian farmers are not required to forfeit any of the traditional rights that they have hitherto enjoyed[68].

With the passage of the 'Protection of Plant Varieties and Farmers' Rights Act', India is no longer bound by the earlier international understanding that plant genetic resources are the 'common heritage of mankind' and should therefore be made freely available. Instead, the way is open for India, as one the 'centres of origin of biological resources', to negotiate with foreign firms and institutions for a fair and equitable share of the benefits accruing to them from the use of and the innovations based on India's genetic resources[69]. Since then, the FAO sponsored International Treaty on Plant Genetic Resources for Food and Agriculture has come into force, giving international legal validity to the principle of linking access to benefit sharing [70].

4.5.4 The Biological Diversity Act

The Indian parliament passed the Biological Diversity Act in December 2002[71]. In its preamble the Act says that it provides for the "conservation of biological diversity, sustainable use of its components and equitable sharing of the benefits arising out of the use of biological resources"[72].

In addition to an apex National Biodiversity Authority, the Act calls for the setting up of State Biodiversity Boards and State Biodiversity Management Committees, with the mandate and responsibility to regulate access to the country's plant and animal genetic resources. It also calls for a nationwide 'Biodiversity Registers Programme' to collect and preserve local knowledge [73].

But the Bill as such has not been widely accepted. Bio-piracy is a hotly debated topic in this context. Where the local industries feel they will be hampered by the law[74], the NGOs feel that the Act facilitates and legalises biopiracy[75].

4.6 Policy controversies and the lack of trust between the main stakeholders

There is mutual distrust between the government regulatory agencies, the GM-concerned CSOs (NGOs), private sector firms involved in GM-crops and agro-biotech R&D institutions in the public sector. The non-governmental stakeholders in the private sector and in civil society contend that the Indian biotechnology policy and regulatory regime is more influenced by the legislation and practice in some leading OECD countries than by the realities of the Indian situation. This perception has resulted in some hostility and resistance towards the policy and regulatory authorities.

The DBT is seen as being secretive and non-transparent. Most of the non-governmental stakeholders are frustrated and angry at being denied meaningful and effective access to policy-making bodies and officials to put forward their views and complaints. They say that the policy and regulatory agencies

[68] "NGOs warn government against joining UPOV", Economic Times, 21 October 2002. See also www.genecampaign.org/focus_area/food_livelihood_2.html
[69] an argument for this is seen in "An Activist's Handbook on Intellectual Property Rights and Patents", RFSTE
[70] The treaty came into force on 27 July 2004, having been ratified by 55 countries (including India). See the news release from FAO at http://www.fao.org/newsroom/en/news/2004/47027/index.html. For the text of the treaty see www.fao.org.
[71] "Lok Sabha passes Biodiversity Bill", Economic Times, 3.12.2002
[72] The Biological Diversity Bill, 2000
[73] The idea of a nationwide 'Biodiversity Registers Programme' originates in an initiative launched in April 1995 by the CSO, Foundation for Revitalization of Local Health Traditions, at a workshop held at the Indian Institute of Science in Bangalore. Following the workshop, this CSO began a necessarily modest "biodiversity registers programme" in the State of Karnataka and elsewhere for documenting local communities' (primarily rural and forest dwelling) understanding and knowledge of living organisms and their ecological setting. See M. Gadgil, P.R.Seshagiri Rao, G.Utkarsh, P. Pramod and A. Chhatre, and members of the People's Biodiversity Initiative, 2000, "New meanings for old knowledge: the people's biodiversity registers program", *Ecological Applications*, 10(5), October 2000, pp.1307-17. See also the report on the launching meeting on 7 July 2004 in New Delhi at Gene Campaign on he "Project on Protection of Indigenous Knowledge of Biodiversity", www.genecampaign.org
[74] "Bio-diversity bill: choking bio-piracy or research?", Hindu Business Line, December 15, 2002
[75] "Will the Biodiversity Act to the job?", in a middle page column called 'Face-Off ' between Vandana Shiva, Director, RFSTE and B.Bhattacharya, Dean, Indian Institute of Foreign Trade, in Economic Times, 25.12.2002

do not even acknowledge receiving their letters, memoranda and submissions, let alone responding to them.

The private sector agro-biotech companies and the entrepreneurs who act as facilitators between venture capital and small-scale firms complain that they have to deal with several government departments and agencies in processing their applications for GM-crops related activities (import of GM-seeds and planting material, transfer of technology from abroad, conducting R&D and field trials and commercialisation). They would like the present dispersed system to be replaced by a ‘single window’ mechanism.

5. THE BIOSAFETY REGULATORY REGIME

5.1 Introduction

As pointed out earlier, the introduction of GM-crops entails potential risks and benefits. Governments that intend to promote GM-crops would therefore have to carefully assess the potential risks and weigh them against potential benefits in taking decisions about the import, commercial cultivation and development of GM-crops. If a decision is taken, say with respect to a given GM-crop, to accept certain potential risks because they are greatly outweighed by potential benefits, then a system has to be in place for managing the risks. The responsibilities and tasks involved in assessing risks and benefits, in striking balances between the two, in managing and monitoring the risks, in taking and implementing decisions about the R&D and commercialisation of GM-crops, etc., need to be codified, legislated and institutionalised in a system of biosafety regulations and structures. North America, Western Europe and Australia were among the first to embark of this path, followed in due course by countries in other parts of the world, India among them.

In India, the first national biosafety rules were issued by the Ministry of Environment and Forests (MoEF) as a Notification, and published in the Gazette of India, Extraordinary, Part II 3(i) on 5 December 1989. These 1989 rules are entitled *"Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms or Cells"*. They were followed in 1990 by DBT's *"Recombinant DNA Safety Guidelines"*, which were then revised, expanded and published in 1994 by DBT as the "*Revised Guidelines for Safety in Biotechnology"*. These three documents cover all the four main sectors of biotechnology: medical/pharmaceutical, agricultural, industrial and environmental. Four years later, the agricultural biosafety guidelines were separated out, expanded, further revised and published by DBT in August 1998 as the "*Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts"*.

The 1989 Rules, as well as the Guidelines of 1990, 1994 and 1998 guidelines, have been made mandatory for all practitioners in India of genetic modification technologies under the Environment (Protection) Act of 1986. These four documents together constitute the national biosafety regulations of India. The 1998 Guidelines were amended in 1999 to clarify the mandates and roles of the RCGM and the GEAC with respect to small-scale and large-scale field trials, and to establish the MEC (see Section 5.2 below) [76].

The concept of *"biosafety"* used in the regulations is a broad one. It covers the health safety of humans and livestock, environmental safety (ecology and biodiversity) and economic impact. Health and environment safety aspects dominate the regulations, with economic impact given less prominence.

In addition to creating the RCGM and the GEAC at the central national level in New Delhi, and specifying their composition, the 1989 Rules also contain directives about the establishing and composition of biosafety committees at the institutional, state and district levels. But, as will become clear later on in the present Section, the directive about creating state and district level biosafety committees has been ignored almost completely, with only three states having formally set up the state-level committees. District level committees are entirely absent. As for MEC, its composition is laid down in the 1998 Regulations.

The Indian biosafety regulations are modelled closely on the OECD guidelines. They cover most of the safety aspects that are likely to arise in the context of R&D in the laboratory and greenhouse, contained tests on small plots (hereinafter also referred to as 'contained small-scale field tests' or simply as 'contained field tests'), large-scale field trials out in the open, general release to farming and

[76] Our interviews in Delhi indicate that the amendment was the result of the public interest litigation brought by a leading GM-concerned civil society organisation.

trading communities, commercialisation and trade. They are mandatory for all Indian institutions and companies that deal in GMOs. As with the regulations in force in the European Union (EU), they are based on the precautionary principle[77], applied on a case-by-case[78] and use a step-by-step[79] approach. *They are generally regarded as being one of the most comprehensive, detailed and stringent biosafety regulations in the world.*

GMOs cannot be imported without the explicit permission of the regulatory authorities. The same regulations apply to both locally developed and imported GMOs.

Extensive and detailed requirements have been laid out for conducting tests and trials, which are different for greenhouse and contained field tests and large-scale field trials.

At present, the Indian government seems positive to the idea of imposing mandatory GM-labelling of foods, livestock feeds and other agricultural products that contain GMOs, when the time comes to approve them for commercial release, but has not yet legislated on this issue. The UN/FAO Codex Alimentarius Commission's recommendations and the EU directives on mandatory GM-labelling (that came into force in April 2004) may well influence India's decision on labelling[80].

The UN-sponsored international Cartagena Biosafety Protocol to the Convention on Biological Diversity governing the transboundary (i.e. inter-country) movement of living modified organisms (LMOs)[81] was agreed in Montreal in January 2000. It came into force in September 2003, having been ratified by the requisite number of countries. Although India has ratified the Cartagena Protocol, there is no information in the public domain to confirm that MoEF (which represents India in the CBD arena) or DBT has undertaken a formal and in-depth review of the relevant Indian national legislation to see whether and how the regulations need to be revised to accord to the provisions of the Protocol.

5.2 The structure and functioning of the regulatory edifice

In India, GM-crops are regulated by the following **three-tier** structure:

- The *Review Committee on Genetic Manipulation (RCGM)* under the Department of Biotechnology (DBT) of the Ministry of Science and Technology (MoST);
- The *Genetic Engineering Approval Committee (GEAC)* under the Ministry of Environment and Forestry (MoEF);
- The *Monitoring and Evaluation Committee (MEC)* under DBT/MoST;

DBT provides the secretariat for RCGM and MEC, and the MoEF for GEAC.

RCGM's mandate is to assess and decide on the applications submitted by institutions and companies for conducting R&D work, greenhouse tests and contained field tests *on plots of less than one acre in size*. Institutions and companies wishing to proceed beyond these stages towards general release and commercialisation of GM-crops must conduct open, large-scale and multi-location field trials that are mandatory under the biosafety regulations. GEAC enters into the picture at this stage.

GEAC has the sole responsibility and power (i) to authorise the large-scale and multi-location field trials, (ii) to asses the 'output' of the trials (information, data, findings and results) and if it so deems

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[77] The "precautionary principle" is here defined as the principle that allows action on the suspicion of any potential damage to the environment and the health of humans and livestock, without first requiring full scientific proof

[78] *Case-by-case* assessment implies that as long as the experiences with GMOs are limited, each GMO case has to be assessed on an individual basis in relation to its potential impact on the environment and health.

[79] The *step-by-step process* implies that tests (greenhouse, contained and large-scale field) involving GMOs are done in a stepwise manner building on experience from previous tests. This means that large-scale field trials have to be preceded by greenhouse and contained tests.

[80] China, for instance, already has mandatory regulations on labelling, but reports indicate that they are being ignored by importers and traders.

[81] The Protocol defines an LMO as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology" and that is "capable of transferring or replicating genetic material".

to direct the applicant to provide further 'output', if necessary by conducting further trials, (iii) on the basis of its assessment of the 'output' of the trials, to approve, reject or put on hold the applicant's request for general release of the GM-crop for commercial planting, and (iv) to impose conditions under which the general release can take place [82]. GEAC may request ICAR to check and validate the ´output' of the field trials submitted by the applicant, if necessary by conducting its own field trials.

The MoEF officials we interviewed were emphatic that GEAC's mandate is limited to ensuring biosafety and it does not extend to the active promotion of biotechnology use and development. According to them, the latter responsibility falls on other departments and agencies of GoI.

MEC monitors the small-scale contained field tests (RCGM's ambit) and the open larger-scale field trials (GEAC's sphere), and submits its reports to RCGM, which are then made available by DBT to GEAC. MEC's monitoring work and reports are expected to cover all the main aspects of biosafety, i.e. the impact of the GM-crop on the environment (ecology and biodiversity), the agronomy (crop production science and farm-level economy), the health of humans and livestock and the livelihoods of the farming community. But, in its practice so far, MEC has limited its monitoring work to (i) the impact of GM-crops on some selected plants and insects in the trail plots and their immediate neighbourhood, (ii) to documenting the frequency and intensity of sprayings of selected pesticides and herbicides, and (iii) recording the crop yields. MEC tends to delegate the actual monitoring work to state- and district-level teams comprising expertise from state-level agricultural universities and research institutions (see Section 7.1 below for our findings on MEC's monitoring of Mahyco-Monsanto's Bt-cotton field trials).

Having negotiated a passage through these three tiers, the application lands finally at the MoA, whose responsibility it is to make sure that the application fulfils the provisions of the Seeds Act [83], and if it does, to register the crop the Seeds Act, whereupon it is allowed to enter the market [84].

The first GM-crop that has passed through the entire regulatory system in India and been approved for general release and commercialisation is Mahyco-Monsanto's Bt-cotton. The whole process took about seven years: the DBT stage from 1995-1997, the MEC and GEAC stages 1997-2001 and the ICAR and MoA stages 2001-2002 (see Section 7.1 below for a full exposition and analysis of the Bt-cotton saga). Further, one ought to bear in mind that that it took Monsanto many years to develop its original Bt-cotton in its US labs, which was then transferred to its subsidiaries and joint-ventures in other countries (Mahyco in the case of India) for backcrossing into local cotton cultivars.

RCGM, GEAC and MEC are made up of representatives of (i) DBT, MoST, MoEF, MoA, as well as the ministries of health, industry, commerce (trade), and law and justice, (ii) the central government funded national research councils dealing with science, technology, agriculture, health and industry, and (iii) the public sector R&D institutions in the several areas of science and technology that form the foundations of the biotechnology (medical/pharmaceutical, agricultural, industrial and environmental). We refer the reader to Appendix 1 at the end of this Section for the composition of the three committees in 2003.

*A striking feature of the composition of RCGM, GEAC and MEC is the **absence** of the representatives of other crucial stakeholders, e.g. civil society organisations (CSOs, including NGOs), private sector companies and institutions, and the central government funded Indian Council for Social Science Research (ICSSR). Leading GM-concerned CSOs have repeatedly complained about this and asked that civil society be represented in the regulatory structures, but have been met with a wall of silence,*

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[82] For a summarised description of the roles that the different parts of the biosafety regulatory system are expected to play, see P. K. Ghosh and T. V. Ramanaiah: "*Indian Rules, Regulations and Procedures for Handling Transgenic Plants*", Journal of Scientific and Industrial Research, Vol 59, February 2000, pp 114-120

[83] It is unclear as to which ministries or departments of GoI have the responsibility to ensure that the application also conforms to other relevant Acts, i.e. The Biodiversity Act, The Protection of Plant Varieties and Farmers' Act and The Patents Act (that incorporates IPR provisions).

[84] ICAR (which falls under the MoA) administers the national registry of seeds that have been approved and certified for general release and marketing.

which leads to the conclusion that their exclusion is the result of an implicit policy by the authorities [85]*.*

While the 1989 Rules do explicitly say that the RCGM, the GEAC, the SBCCs and the DLCs may co-opt other members/experts as necessary, they neither explicitly include nor exclude representatives of CSOs /NGOs and the private sector. In practice, however, these non-governmental stakeholders have been excluded.

Following the example of some leading OECD countries, the 1989 Rules require that any institution that handles micro-organisms or genetically modified organisms shall set up an in-house Institutional Biosafety Committee (IBSC), to ensure that biosafety measures are in place. The 1989 Rules indicate, in broad terms, the composition and responsibilities of the IBSCs. DBT is represented on the IBSC by its own nominee, usually a senior research scientist from a leading public sector research institution.

The 1989 Rules classify R&D work involving GMOs in all sectors of biotechnology into *four risk categories*, and provide lists of bacterial, fungal, parasitic and viral agents that fall into each category. The 1998 Regulations reaffirm this classification and specify the roles of the institution, the IBSC and the RCGM *vis à vis* the risk categories:

Category I comprises *routine* recombinant DNA experiments conducted inside a laboratory, e.g. "routine cloning of defined genes, defined non-coding DNA, and open reading frames in defined genes in *E-coli* or other bacterial and fungal hosts, which are generally considered as safe to humans, animals and plants"). *It does not require any clearance by the IBSC or the RCGM*, but the research leader (principal investigator) must inform the IBSC that it is being carried out.

Category II consists of both laboratory and greenhouse experiments involving transgenes with constitutive, tissue specific and chimeric promoters, marker genes, gene tagging, genes that confer resistance to herbicides, biotic and abiotic stresses, and plant pathogens, genes for the production of antibodies, etc. *Permission by the IBSC is obligatory for conducting this kind work, but permission by the RCGM is not required.* It is, however, obligatory for the IBSC to inform the RCGM of its approval, prior to the commencement of the work.

The national biosafety guidelines and regulations lay down in detail the laboratory and greenhouse infrastructure and practice that need to be in place.

Categories III and IV comprise "high risk experiments where the escape of transgenic traits into the open environment could cause significant alterations in the biosphere, the ecosystem, the plants and animals by dispersing new genetic traits, the effects of which cannot be judged precisely. All experiments conducted in green house and open field conditions not belonging to the above Category I and Category II types, would fall under Category III risks"[86]. *All such work requires prior clearance by the RCGM and notification to that effect by DBT.*

The biosafety rules pertaining to Category I and II activities demonstrate clearly that a great deal of the responsibility for ensuring biosafety has been delegated by the central authorities to the R&D institutions and their IBSCs. In effect, therefore, a major part of the regulatory system has been decentralised and dispersed. This raises the critical question of biosafety accountability of the institutions and IBSCs vis à vis the local environment and local population, and of the accountability of the central regulatory authorities as the bearers of ultimate responsibility. Our research reveals that neither the various stakeholders nor the general public know whether there is a system and a process of accountability and how they operate.

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[85] Our interviews in Delhi
[86] See pages 4 and 5 of the 1998 Regulations

Under the 1989 Rules, each of the twenty-three states that make up the Indian Union is expected to set up *state-level and district- level biosafety committees (SBCC and DLC).* The biosafety committees at the central-national, state and district levels are expected to interact closely. The State Biotechnology Co-ordination Committee (SBCC) has the authority to (i) coordinate with the central government ministries the GM-activities (R&D work, field trials, etc.) being conducted within the state, (ii) nominate state government representatives on the teams empowered to conduct inspections of the GM-activities, and (ii) investigate whether the GM-activities are complying with the provisions of the statutory national biosafety regulations and take punitive measures in cases of violations. The role of the District Level Committee (DLC) is to monitor the compliance of the biosafety regulations by all those who are conducting GM-activities within the district.

Appendix 2 at the end of the present Section lists the composition of IBSCs, SBCCS and DLCs, according to the 1989 Rules

According to the latest information available to us (as of late 2004), only Andhra Pradesh, Himachal Pradesh and Karnataka have established their respective SBCCs, but no state has yet set up a DLC. The 'formally existing' SBCCs in the three states have, however, shown little sign of being actually active. And there is nothing to indicate that RCGM, GEAC, MEC and the IBSCs have interacted with the three 'formally existing' SBCCs, and *vice versa*, as the regulations require[87]. In view of this, the following injunction by the 1989 Rules (see page 170 of the Gazette referred to in which the Rules have been notified) remains a dead letter:
" (any institution) handling micro-organisms/genetically engineered organisms shall prepare with the assistance of the Institutional Biosafety Committee (IBSC) an up-to-date on-site emergency plan according to the manuals/guidelines of the RCGM and make available copies to the District Level Committee/State Biotechnology Co-ordinating Committee and the Genetic Engineering Approval Committee."

As agricultural policy and its implementation come under the jurisdiction of the state governments, the SBCCs and DLCs could, constitutionally speaking, intervene decisively in the processes leading to field trials and commercialisation of GM crops. For instance, the state government of Karnataka in South India had provisionally blocked the commercial release of Mahyco-Monsanto's GM-cotton (Bt-cotton) within the state, following a campaign by local CSOs. An exchange of communication between central and state government authorities led to the ban being lifted soon thereafter, without however an explanation being provided to civil society (see Section 7.1 below).

RCGM, GEAC and MEC are required to interact closely with the Ministries of Agriculture, Health, Industry, Commerce (Trade) and Law and Justice, whose representatives sit on these three committees. While this may well be the case in the committees' routine meetings, the processes of coordination between, and of arriving at consensual decisions by, the concerned ministries seem to be dormant [88]. This became evident in the run up to and the aftermath of the first really critical decision that had to be taken by the authorities, i.e. the approval of Mahyco-Monsanto's BT-cotton for commercial release (see Section 5.3 below).

5.3 The Question of 'Conflict of Interest' in the RCGM

R&D work on GM-crops occurs almost entirely in public sector institutions. In so far as their work is confined to the laboratory and to greenhouse tests, they and their IBSCs have been able to live with the 1998 guidelines, without the need to actively seek reviews and revisions of the regulations. They have had no serious problems in getting their applications for permission to conduct R&D approved. The presence of the representatives of public sector institutions on the RCGM has ensured that they have a channel to put across their views and concerns informally.

[87] Our interviews in Andhra Pradesh, Karnataka and Delhi
[88] Our interviews in Delhi

On the other hand, this 'cosy relationship' puts the spotlight on a very sensitive issue. It is the case that the R&D institutions represented on the RCGM would be in receipt of project and/or core support by DBT. And, at some time or other, DBT would be processing applications by these institutions for renewal of current grants and/or for award of new grants. *Clearly, therefore, a situation of* ***serious conflict of interest*** *arises due to the simultaneous roles played by the representatives of R&D institutions as applicants for grants and as biosafety regulators.* No action has been taken by the authorities to rectify this situation, which has persisted since the inception of the committees. *This has led, repeatedly, to questions being raised by GM-concerned CSOs in India about the credibility of RCGM as impartial and unbiased regulators and the legitimacy of the decisions they arrive at.*

5.4 The Question of Public Trust in the Biosafety Regulatory Regime

Despite repeated representations made to the authorities, civil society organisations (CSOs) dealing with biotechnology and biosafety issues have been *excluded* from the RCGM, the GEAC and the MEC. Evidently, there is an implicit government policy at work here. One of the gravest consequences of denying the CSOs the opportunity and the facility to officially participate in the biosafety regulatory processes is to deepen civil society's and the media's suspicion and distrust of the biosafety regulatory authorities, the public sector R&D establishment and the biotechnological companies (in particular, subsidiaries of multinational corporations). It is not surprising therefore that activist CSOs have repeatedly launched legal suits against the authorities at the highest levels (in the High Courts at the state level and the Supreme Court at the central level) to halt field-trials, burnt GM-crops on trial plots and mobilised farmers' demonstrations.

5.5 The implementation of the regulations

The framework of the 1998 regulations, and the very detailed procedures for risk assessment that are set out in them, are based on those in force in leading OECD countries. There are prescribed standard application forms that the applicant institution has to fill in. The information and data required are predominantly biological, ecological and agronomic in nature, and quantitative in kind. Biosafety data from other countries may be used as reference, but locally generated, site-specific data are considered to be of critical importance and are obligatory.

It is the responsibility of the applying institution to generate the required information and data during contained tests and open field trials. Where the applying institution has no capacity of its own to generate some specific data, it commissions some other institutions to do the work for an agreed fee. Occasionally, RCGM and GEAC may themselves direct the applicant to commission some selected "third party" public sector institution with the requisite capacity to test the applicant's data. But, as a rule, the applicant's submission is accepted in good faith. It is often the case that, after due scrutiny, the applicant is asked to provide additional data and conduct further tests and trials. For applications seeking permission for large-scale trials and commercial release (e.g. Bt-cotton and Bt-mustard), this procedure has been repeated several times, stretching over many years.

The evidence from our empirical research is that both public and private sector institutions do actually comply with the biosafety regulations. (There has been one recent very well publicised violation of this rule in the case of Bt-cotton that we discuss in Section 7.1 below. In-depth research is required to explore whether there are others that have not yet surfaced into the public view.)

All the institutions, both public and private, that are currently actively involved in the development of GM-crops [89] have set up IBSCs. They provide the information required by and cooperate with the regulatory authorities. However, a fair number of institutions are of the opinion that the regulations are

[89] Twenty-two public sector R&D institutions, two international centres and ten private sector companies (see the tables in Sections 2.1 and 2.2 above)

unnecessarily stringent, cumbersome and bureaucratic, and their implementation entails several years' of contained tests and open field trials at great expense[90].

Our field research on Mahyco-Monsanto's BT-cotton open field trials in Karnataka and the associated interviews in Bangalore and Delhi (see Section 7.1 below) show that MEC confines its monitoring and evaluation of field trials to a few on-site visits, which are pre-arranged with the applicant and the monitored farms. MEC depends almost entirely on the applicant institution and the monitoring teams that the applicant deploys for the risk assessment data it requires. It has no unit of its own with the capacity to gather and test data independently of the monitored institutions. We found no instance of MEC having implemented a policy (if there is one) of commissioning biosafety data gathering and testing by independent third party institutions. Under these circumstances, the credible validating of the data supplied by the monitored applicant remains problematic.

In our field research on Bt-cotton field trials, we found grave shortcomings in the implementation of the procedures laid out in the 1998 regulations (see Section 7.1). These may be partly due to a lack of appropriate mobilisation of existing capacity. India has adequate capacity in terms of competence, expertise and infrastructure, in the relevant government ministries and public sector R&D institutions. But these have not been adequately mobilised into the "right shape" (i.e. teams, structures and instruments), "rightly orientation" through purpose-made specialist training, and "right interaction" through less-bureaucratic modes of inter-institutional communication and coordination.

5.6 Deficiencies in the implementation of the regulatory regime

The first real test of how well the Indian biosafety regulatory regime would perform came with the processing of Mahyco-Monsanto's application to the regulatory authorities for the approval of the field trials, and subsequent general release and marketing, of their Bt-cotton varieties. Significant deficiencies in the implementation of the regulatory procedures, substantial shortfalls in implementation capacities and other problems came to the fore over the five years (1997-2002) that it took to complete the Mahyco-Monsanto processing. Our questionnaire surveys, interviews, field research and analysis of reports in the media point to the following:

- Lack of serious consultation and interaction between the central government regulatory authorities and state government authorities;

- Legal challenges by CSOs to the validity of the field trial approvals and subsequent biosafety clearances issued by RCGM/DBT, which were one among several important factors leading to the 1998 revision of the 1994 guidelines to extend the mandate of RCGM/DBT to small-scale limited field trials and the creation of MEC;

- MEC's lack of capacity to ensure independent, extensive and intensive assessment of certain kinds risks, e.g. (i) pollen and gene flow to other plant species in the near environment, (ii) the impact on the health of the livestock that were allowed to feed on the Bt-cotton seeds by the farmers on whose the plots the trials were conducted, and (iii) letting the plot owners sell the Bt-cotton harvest and store the post-harvest residues for own use, instead of burning the harvest and the residues after the trials were over, as the regulations stipulate;

- The uncovering by the media that, while the Mahyco field trials and the processing of its application to GEAC were still ongoing, a small private seed company, Navbharat Seeds (wholly Indian owned and registered in the state of Gujarat), had illegally acquired Bt-cotton seeds (from a still undeclared source), backcrossed it, bred the hybrids and sold the bollworm resistant hybrid seeds, in 2000/2001, to a large number of farmers in Gujarat and beyond. The farmers had sold the resulting Bt-cotton harvest in 2001 to dealers in the market. Apparently, this illegal activity had gone on without the knowledge of the regulatory authorities.

[90] Our interviews

- The 1998 regulations stipulate that (i) MEC should *"collect or cause to collect information on the comparative agronomic advantages of the transgenic plants" and "advise the RCGM on the risks and benefits from the use of the transgenic plants" being evaluated,* and (ii) that the institution applying to the GEAC should submit for assessment only those transgenic crops that are *"found to be environmentally and economically viable by the RCGM"* (see page 6 of the 1998 regulations). But MEC has neither conducted studies of its own, nor commissioned studies from the research community, on the potential agronomic and socio-economic impact of Bt-cotton. If it is indeed the case that RCGM has found Mahyco-Monsanto's BT-cotton to be "economically viable" and presented that assessment to GEAC, then the process and the studies behind that assessment have not been put into the public domain by RCGM or DBT. It is however revealing that one of the several conditions under which GEAC gave its approval in March/April 2002 for the general release and marketing of three varieties of Mahyco-Monsanto's Bt-cotton was that *Mahyco itself* should undertake studies on the presumed agronomic and economic benefits of its Bt-cotton hybrids following their commercial release and production. We find this quite extraordinary.

5.7 Stakeholders' experience, perceptions, warnings and complaints

In general, the scientists accept that biosafety regulations are necessary and should be strict, and feel that their implementation needs to be made more effective. However, some of the researchers we interviewed were of the opinion that many of the provisions were inappropriate and that even some of the appropriate ones were very difficult to implement. The paper work involved is heavy.

Research institutions and private companies would like to see the concept of 'case by case' applied to transgenes (gene constructs) rather than to each variety of a given GM-crop, i.e. if a GM-crop variety with a particular transgene has been given biosafety clearance by the authorities, then the clearance should apply automatically to all other GM- varieties of the same crop containing the same transgene, without these varieties having to go through the entire, several years long, process of field trials and assessments. A case in point is the Mahyco-Monsanto's Bt-cotton. One of the three hybrids (Bt MECH12, 162 and 184)) approved by GEAC is characterised by the transgene Cry 1Ac, but when RASI Seeds applied to GEAC for approval of the Bt-cotton variety it had bred (under licence from Mahyco-Monsanto) containing the same transgene, it was nevertheless obliged to go through the field trials-cum-assessment process (see Section 7.1).

GM-concerned CSOs, as well as researchers in agricultural universities, have underlined the impossibility of small farmers (with holdings of one to two hectares) being able to comply with the biosafety directive that they must surround the field sown with GM-seeds by a non-GM sown area that is at least twenty percent of the GM-acreage to act as a biodiversity *refuge* to ensure that GM-resistant pests and weeds (which are bound to develop) do not, in the course of a few years, completely out-compete non-resistant ones. This warning has in fact been substantiated by the actual practice of Bt-cotton farmers in the cotton-growing states of India. Since the concept of *'refugia'* is unworkable and unenforceable in the Indian context, researchers and CSOs are challenging the authorities to address the issue of whether GM-crops can be grown in India without GM-resistant pests and weeds taking over entirely in GM-growing areas and the loss of biodiversity in those areas.

Another issue flagged by the stakeholders is the incoherence and confusion that prevail at the policy-making and policy-implementation levels within GoI in agricultural biotechnology, which they attribute, among other things, to the lack *real* (as opposed to formal and ritual) communication and coordination among the several GoI departments and ministries involved (directly and indirectly) in agricultural biotechnology (DBT, MoST, ICAR, MoA, MoEF, MoH, MoC, MoLJ, etc.). As an example of this, one of our interviewees cited the case of GM-soya bean, whose import was approved by the Ministry of Commerce (MoC) without MoEF being consulted. Another example concerns the recommendation by the Ministry of Law and Justice (MoLJ) to DBT that the 'notification' of the 1998 regulations under the Environment Protection Act was inadequate and as such would not 'stand in court' if challenged. MoLJ wanted action by DBT to correct this and recommended that DBT organise a meeting with concerned CSOs to clarify the issue, but apparently to no avail.

The SBCCs too have come in for some strong criticism. Commenting on the SBCC in Karnataka, some of our interviewees pointed out that its entire membership is made up of state government officials, most of whom lack even generalist acquaintance in areas of knowledge relevant to biosafety. The couple of government scientists on the committee were likely to be too diffident to express their real views and opinions, being considerably lower down the bureaucratic hierarchy than some of the other members. Meetings have been convened on an *ad hoc* basis and at very short notice and some have been cancelled at the last moment citing 'other pressing matters' that the top officials had to attend to. Important issues have been sidelined in the few meetings that have been held. No policy guidelines have been issued that would help to steer the committee's work. The existence of the SBCs is virtually unknown to the local stakeholders in agricultural biotechnology, including the scientists in the state agricultural universities.

Although DLCs have not yet been set up in any state, some of our interviewees had firm opinions about how, in theory, DLCs ought to work. They should acquire a proper understanding of, and critically scrutinise, the way field trials of GM-crops are conducted. To be able to do this, they need to induct crop scientists and other expertise (e.g. in the social sciences) into the committee, in particular those who have a good grasp of the local agronomy (crop production science and farm level economics) and the local rural economy and society.

It is symptomatic of the lack of confidence in the biosafety regulatory regime that it has come under vigorous attack by both the GM-believers and the GM-agnostics. The critique by the GM-supporters is in sum as follows:

- GEAC does not have the scientific expertise to perform the tasks it is mandated to. Like its chairperson, the more influential of its members are top civil servants with administrative abilities and experience but not scientific ones;

- GEAC does not meet often enough to be able to deal expeditiously with the applications, which, in combination with its slow and inefficient way of working, leads to great delays in processing the applications;

- GEAC should restrict itself to assessing the biosafety of transgenes (gene constructs), but not of each hybrid into which the transgene is inserted;

- The present three-tier regulatory structure should be replaced by a 'single window' agency with a mandate that stretches from R&D to commercialisation;

- The several Acts of parliament (see Section 4.4), whose provisions have to be met prior to a GM-crop being approved for general release and commercialisation, should be harmonised, and a single agency ('single window') mandated to ensure that the provisions are met. At present, the applying institution has to make its way through each ministry that administers its specific Act.

- Whereas the criticism by GM-supporters is directed mainly at GEAC, the complaints by GM-sceptics apply to the entire regulatory system (the RCGM, the GEAC and the MEC) in its *present* form and functioning [91]. They point out that:

- the representatives of civil society (CSOs / NGOs) have been deliberately excluded from the RCGM, the GEAC and the MEC (hereinafter *'the system'*);

[91] See the Notice posted on http://www.genecampaign.org /news/notice_pil.html

- the system has not even acknowledged, let alone responded to, the queries, letters and submissions sent to them by civil society;

- the applications processed by the system, the proceedings and minutes relating to the processing, and the written 'output' (e.g. data, information, reports, etc.) from the field trials, have not been put into the public domain, despite repeated requests;

- the system has neither imposed penalties and nor taken punitive action against the institutions and companies that have failed to comply with the biosafety regulations;

- the system is non-transparent and lacks public accountability;

- with the exception Andhra Pradesh, Himachal Pradesh and Karnataka, no other state has established a SBCC, while no DLCs have been set up anywhere.

5.8 Initiative to reform the biosafety regulatory regime

The intensity and persistence of the critique levelled at the current biosafety regulatory regime may have induced ICAR to join the fray with its own initiative. Acting under ICAR's advice, the MoA (ICAR's parent ministry) set up an Agricultural Biotechnology Taskforce in 2003 under the chairmanship of Dr M. S. Swaminathan[92] with the terms of reference to consult a wide range of stakeholders and on that basis make recommendations for reforming the regime. The Swaminathan Taskforce submitted its Interim and Final Reports to the Minister of Agriculture in April and June 2004, respectively. The Report has not yet been made public, but the Executive Summary of the Interim Report was sent to various stakeholders and the media.

The Swaminathan Taskforce's Report is very likely to have a major impact on the deliberations of another (potentially most decisive) Taskforce set up by GoI in late October 2004, under the chairmanship of Dr M. K. Bhan, Secretary of DBT, to formulate a ***new biotechnology policy****. Dr Swaminathan is a member of this* ***new biotechnology policy taskforce****.* The reader is referred to Section 4 above for the news report on the setting up and composition of this taskforce.

The Swaminathan Taskforce's Report recommends that[93]:

- an autonomous Agricultural Biotechnology Regulatory Authority (ABRA) be set up

- pending the creation of an ABRA, (i) the GEAC should be split into two separate wings, one dealing with transgenic crops and the other with transgenic medical and pharmaceutical products, (ii) GEAC's role be limited to 'environmental clearance', and the authority for deciding on the commercial release of GM-crops transferred to ICAR and MoA, (iii) the RGCM should be authorised to grant approvals for open field testing for biosafety, while ICAR and the applicant company should be asked to conduct large-scale field trials, and (iv) the post-release monitoring of GM-crops be done by MoA and ICAR.

- if "a transgene has been declared bio-safe, its derivatives need not always be evaluated for bio-safety again"

- farmers' and consumers' organisations be invited to participate in the process of assessing GM-crops, but not other GM-concerned NGOs/CSOs, with the farmers' and consumers' organisations given complete information on the benefits and risks associated with GM crops

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[92] See the footnote in Section 4 for Dr Swaminathan's background
[93] Ashok B Sharma in the Financial Express (India), April 27, 2004:
India: Panel For Clipping GEAC Wingshttp://www.financialexpress.com/fe_full_story.php?content_id=57937

- before embarking on the development of any specific GM-crop, "the alternatives available for meeting the food and nutritional needs should be reviewed comprehensively and the export market should be kept in view”

- GM- foods and products be labelled as such, along the lines of the recommendations by the UN’s Codex Alimentarius

- organic farming zones and agro-biodiversity sanctuaries be established to prevent GM-plants from cross-pollinating non-GM plants,

- the impact of GM-feeds and GM-vaccines on milk, meat and eggs be studied

- the government creates special insurance schemes, provides venture capital for and promotes public-private partnerships for the production and marketing of GM-seeds

- government agencies be created at the state and district levels for preventing the proliferation of illegal GM-seeds

- a ‘single window information centre’ be created for providing information on all aspects of bioethics and biosafety

The two GM-concerned leading CSOs in India, Gene Campaign and Greenpeace India, both of which were consulted by the Taskforce, have strongly questioned several of its key recommendations. The Director of Gene Campaign, Dr Suman Sahai [94], is of the view that [95] :

- the proposed segregation of GM and non-GM crops by zones may not be feasible and "the only way for protecting native germplasm from foreign genes with likely negative impact, like herbicide tolerance, is to disallow the GM version of that particular crop."

- since GM technology “has implications for life forms unlike other technologies and that there are social, economic and ethical concerns associated with it, it would be wise to set up a National Bioethics Commission to steward this technology with responsibility and sensitivity"

- -it is a "dangerous suggestion" to assert that once a transgene is tested for biosafety in a particular crop it need not undergo tests while implanted in other crops.

For his part, the scientific adviser of Greenpeace India, Dr Ashesh Tayal, has concentrated on the areas where the Taskforce had overstepped its Terms of Reference, the lack of clarity on some issues and several shortcomings. He pointed out that [96]:

- the Taskforce had “deviated” from its main task, which was to propose a “long-term biotechnology policy---. Instead it focussed on administrative changes, --- going even so far as to define the qualifications of the person who shall head the proposed ABRA”

- besides administrative recommendations, the Taskforce makes scientific ones, for which it lacks the requisite scientific expertise

- in the “suggested changes in modalities of operation (of the present regulatory system) --- the three-tier system remain the same (but) in a more complicated form. It has not clarified how the

[94] Dr Sahai has been included in the new biotechnology policy taskforce referred to above. She is the sole representative of GM-concerned CSOs/NGOs on the taskforce.
[95] Ashok B Sharma, Financial Express (India), May 2, 2004: 'Committee's Suggestions For Clearance By Farm Ministry, ICAR, Pending The Formation Of ABRA Comes In For Sharp Criticism'
http://www.financialexpress.com/fe_full_story.php?content_id=58327
[96] ibid

(new) system proposes to reduce (the time taken for processing applications) without compromising the biosafety aspects. ---The panel (Taskforce) has totally overlooked the needs of toxicological and other biosafety studies"

- that the Taskforce has avoided the issue of (the government's and/or the private sector's) accountability in case of failures in ensuring biosafety, citing as an example the hitherto unanswered question of who would be held responsible if Bt-resistant bollworms were to proliferate following the cultivation of Bt-cotton

The Final Report of the Taskforce was submitted to the Union Minister of Agriculture, Mr Sharad Pawar, on 2 June 2004. Minister Pawar is quoted as saying that "the Secretaries of --- the Food and Agriculture Ministries would review the report. After the review (GoI) will be able to come to a definite conclusion. --- (I am) agreeable to any suggestion which would help in ensuring better crop productivity and food security." [97]

5. 9Appendix 1: The composition of RCGM, MEC and GEAC in 2003

Review Committee on Genetic Manipulation (RCGM)

Chairperson
Dr. C. M. Gupta
Director, Central Drug Research Institute, Lucknow

Secretary (The Indian designation is *Member-Secretary*)
Dr. T. V. Ramanaiah, Scientist-F, DBT, New Delhi

Members
Dr. S. Nagarajan, Director, Indian Agricultural Research Institute, New Delhi
Dr. Amit Ghosh, Director, Institute of Microbial Technology, Chandigarh
Dr. K. Veluthambi, Professor & Head, Department of Plant Biotechnology, School of Biotechnology, Madurai
Dr. Sudhir Sopori, Scientist, International Centre for Genetic Engineering and Biotechnology (ICGEB), New Delhi
Dr. P. Kondaiah, Associate Professor, Department of Molecular Reproduction, Development & Genetics, Indian Institute of Science, Bangalore
Dr. C.D. Mayee, Director, Central Institute for Cotton Research, Nagpur
Prof. J.B. Joshi, Director, Department of Chemical Technology, Mumbai
Prof. V.K. Khanna, Professor, Department of Genetics and Plant Breeding, Govind Ballabh Pant University of Agriculture & Technology, Pantnagar
Dr. K.R. Koundal, *(ICAR Nominee)*, In-charge Project Director, National Research Centre on Plant Biotechnology, New Delhi
Dr. O.P. Agarwal, Head, *(CSIR Nominee)*, Research Planning Business Development Group (RPBD), Council of Scientific and Industrial Research, New Delhi
Dr. Vasantha Muthuswamy, Indian Council of Medical Research, New Delhi
Dr. Ranjini Warrier, Additional Director & *Member-Secretary of GEAC, Ministry of Environment & Forests*, New Delhi
Dr. B.S. Dhillon, Director, National Bureau of Plant Genetic Resources, New Delhi
Mr. A.B. Ramteke, Drugs Controller General (India), Directorate General of Health Services, Nirman Bhawan, New Delhi

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[97] Ashok B Sharma, Financial Express (India), June 3, 2004: *M S Swaminathan panel favours Autonomous Regulator.* http://www.financialexpress.com/fe_full_story.php?content_id=60491

DBT officials serving as Members:
Dr. V.K. Vinayak, Adviser-Gr.I,
Dr. (Mrs.) Bindu Dey, Director, DBT, New Delhi
Dr. V.P. Gupta, Adviser
Dr. Renu Swarup, Director, DBT, New Delhi

Monitoring-cum-Evaluation Committee (MEC) of the RCGM

Chairperson
Dr. S. Nagarajan
Director, Indian Agricultural Research Institute (IARI), New Delhi

Secretary (The Indian designation is *Member-Secretary*)
Dr. T. V. Ramanaiah, Scientist-F, DBT, New Delhi

Members
Prof. Akhilesh Tyagi, Head, Department of Plant Molecular Biology, University of Delhi, South Campus, New Delhi
Dr. Anand Kumar, Scientist, National Research Centre on Plant Biotechnology, New Delhi
Dr. H.S. Dhaliwal, Professor of Biotechnology, Department of Genetics & Biotechnology, Punjab Agriculture University, Ludhiana
Dr. H.S. Gupta, Director, Vivekananda Parvatiya Krishi Anusandhan Sansthan (Vivekananda Institute of Hill Agriculture), Almora
Dr. S.P. Sharma, Professor, Division of Seed Science & Technology, Indian Agricultural Research Institute (IARI), New Delhi
Dr. Rajendra Kumar, Head, Division of Seed Science & Technology, Indian Agricultural Research Institute (IARI), New Delhi
Dr. V.P. Singh, Principal Scientist, Division of Genetics, Indian Agricultural Research Institute (IARI), New Delhi
Dr. P.S. Singh, Head, Division of Vegetable Crops, Indian Agricultural Research Institute (IARI), New Delhi
Dr. S.S. Singh, Principal Scientist, Division of Genetics, Indian Agricultural Research Institute (IARI), New Delhi
Dr. Ajay Parida, Principal Scientist, M.S. Swaminathan Research Foundation, Chennai
Dr. (Mrs.) Asha A. Juwarkar, Deputy Director, Environmental Biotechnology Division, National Environmental Engineering Research Institute (NEERI), Nagpur
Dr. J.L. Karihaloo, Project Director, National Research Centre on DNA Fingerprinting, National Bureau of Plant Genetic Resources, New Delhi
Dr. Ranjini Warrier, *Member-Secretary, GEAC, MoEF,* New Delhi
Shri M.K. Sharma, Deputy Legal Adviser, Department of Legal Affairs, Ministry of Law, Justice & Company Affairs, New Delhi

DBT officials serving as Members:
Dr. K.K. Tripathi, Adviser, Department of Biotechnology, New Delhi
Dr. K.S.Charak, Scientist-F, Department of Biotechnology, New Delhi

Genetic Engineering Approval Committee (GEAC)

Chairperson
A top MoEF official of the rank of Additional Secretary/Joint Secretary

(As of early 2004, Ms Bina Choudhary was holding this position. Between March 2002 and February 2004, five persons have held the chair including Ms Choudhary [98].)

Co-Chairperson
In December 2003, it was being reported that GoI was considering appointing Dr Sushil Kumar to this position. He was the Director of the Central Institute of Medical and Aromatic Plants (CIMAP) in Lucknow. In late 2003, he was holding a professorship at the National Centre for Plant Genome Research (NCPGR) in Jawaharlal Nehru University (JNU), New Delhi [99].

Secretary (Member-Secretary)
Dr. Ranjini Warrier, Additional Director, *MoEF*, New Delhi

Members (ex-officio)
-Top officials representing the DBT, the MoA, the MoEF, the MoH and the MoIC
- Directors General of ICAR, ICMR and CSIR
- Director General of General Health Services
- Plant Protection Adviser, Directorate of Plant Protection, Quarantine and Storage
- Chairman, Central Pollution Control Board

Senior scientist members
Until the end of 2003, there were no scientists on the committee in their personal *(non-ex-officio)* capacity. But according to a news report in December 2003, GoI was considering nominating four senior scientists on to the committee [100]. This move may have been prompted by the strong and persistent criticism by private sector as well as civil society GM-stakeholders that GEAC lacked the scientific expertise required for credibly conducting biosafety assessment work.

[98] Ashok B Sharma, Financial Express (India), February 8, 2004: Govt to Revamp GEAC after Swaminathan Panel Submits Report. http://www.financialexpress.com/fe_full_story.php?content_id=52231. In his dispatch, Sharma speculates on the possible reason for this rapid turnover.
[99] Report in BioSpectrum, December 11, 2003: *Meena Gupta is new GEAC chief.* www.biospectrumindia.com/content /biopeople/ 103121101.asp
[100] *ibid*

5.10 Appendix 2: The composition IBSCs, SBCCs and DLCs, according to the 1989 Rules

IBSCs should consist of
(i) the Head of the Institution
(ii) the scientists engaged in DNA work
(iii) a medical expert, and
(iv) a nominee of DBT

SBCCs should comprise the

(i) Chief Secretary of the State (i.e. the head of the civil service at the state level), as the chairperson of the SBCC
(ii) Secretary (i.e. the head of a government department) of the Department of Environment, as the secretary of the SBCC (also called 'member-secretary' in Indian designation)
(iii) Secretary, Department of Health
(iv) Secretary, Department of Agriculture
(v) Secretary, Department of Industries and Commerce
(vi) Secretary, Department of Forests
(vii) Secretary, Department of Public Works
(viii) Chief Engineer, Department of Public Health Engineering
(ix) Chairman of the State Pollution Control Board
(x) State Microbiologist
(xi) State Pathologist

DLCs should consist of the

(i) District Collector (i.e. the top government official in the district), as of the chairperson of the DLC
(ii) Chief Medical Officer of the district (District Health Officer), as the convenor of the DLC
(iii) Inspector of factories
(iv) Representative of the State Pollution Control Board
(v) District Agricultural Officer
(vi) Representative of the Public Health Engineering Department
(vii) Commissioner of the Municipal Corporation
(viii) District Microbiologist
(ix) District Pathologist

6. CIVIL SOCIETY AND BIOTECHNOLOGY

6.1 Introduction

In the following, we will use the term *'civil society organisation (CSO)´* to denote several kinds of institutions: voluntary, non-governmental, non-state (a term of Indian usage), and community based. We use these concepts interchangeably, as the occasion demands. We include the non-state controlled media in the CSO concept, but *exclude* both private and public sector companies, as well the public sector knowledge-generating and knowledge-disseminating institutions (e.g. public sector universities, research institutes and centres, laboratories and other R&D institutions, which being publicly funded are liable to state control).

From the 1950s onwards, the number of CSOs in India has grown steadily, the increase being phenomenal over the last three decades. Some estimates put the current number at about 1.2 million, divided roughly equally between the rural and urban areas[101]. Although non-governmental and non-state, they have been, and continue to be, involved in the implementation of development projects launched by the central and state governments, within the framework of successive Five Year Plans (ten so far)[102]. The alliance is not without its tensions, contradictions and conflicts, but these are usually handled by making compromises within the framework of a well-established plural and democratic politics (albeit very imperfect). In recent years, the CSOs have been at the forefront of the demand for 'good governance', transparency and accountability in the affairs of the state, the public sector and the private sector, reflecting a growing trend among the CSOs worldwide.

Although only a few CSOs have been energetically involved so far in the arena of agricultural biotechnology and biosafety, their impact on and their shaping of public opinion could perhaps prove decisive to the acceptance of genetically modified crops (GM-crops) by the farming community and the consumers. This is particularly true of the flourishing private sector print media (newspapers and periodicals), which have built up a tradition of strongly questioning the doings of the government, the public sector and other state organs. The need for the involvement of the CSOs is all the more important in providing the public with both the pros and cons of GM-crops, because the scientists in the public sector agricultural universities and R&D institutions, who are knowledgeable about both sides of the argument, have deliberately stayed out of the public debate, not wanting to incur the displeasure of either the government authorities (being public sector employees) or the activist CSOs (to avoid being targets of their campaigns)[103].

It was only after 1999, when the public campaigns and legal challenges mounted by GM-concerned CSOs about the roles of the DBT, RCGM, GEAC and MoEF in the approval of large-scale field trials and subsequent commercialisation of GM-cotton had been given wide coverage by leading national newspapers (see Section 7 below), and led to questions in the lower house of Parliament (the *Lok Sabha*), that DBT organised some workshops, seminars and awareness programmes, together with the state agricultural universities, to inform the public about biotechnology and biosafety issues. But this effort has not really reached out to a larger audience.

The main issues that are being publicly debated, thanks to the CSOs, are (1) the biosafety of GM-crops, (2) the biosafety regulatory regimes and the formulation of biosafety and biotechnology policies(3) the workings of and the procedures within the biosafety regulatory authorities, and (4) the implementation of biosafety legislation, regulations, and procedures.

The following table lists the CSOs in the biotechnology, biosafety and biodiversity arenas, indicating their main stated activities, objectives and constituencies. We have listed only those that have

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[101] "Planning with NGOs", Hindu Business Line, 15.2.2003
[102] Major examples are the Integrated Rural Development Programme, Training of Rural Youth for Self Employment, the literacy campaigns, and watershed management and agricultural extension programmes.
[103] Our interviews

appeared in the Indian media through their *explicit and visible* involvement in agricultural biotechnology and biosafety issues.

CSO	**Main activities and objectives**	**Main constituencies catered to**
Gene Campaign, New Delhi	Policy issues. Farmers' rights. Studies and research. Dissemination of information and studies through articles, seminars, workshops, etc. Scrutiny of regulatory and policy-making bodies.	Farmers. Media, policy-makers and opinion-makers
Research Foundation for Science, Technology and Ecology (RFSTE), New Delhi and Navadanya, Dehra Dun	Policy issues, with focus on biodiversity, intellectual property rights and international trade. Studies and research. Dissemination of information and studies through articles, books, etc. Scrutiny of regulatory and policy-making bodies. Indigenous knowledge. Sustainability issues Movement for people's control over their own biodiversity-related knowledge	Farmers. Media, policy-makers and opinion-makers
Forum for Biotechnology & Food Security, New Delhi	Analyses of issues and dissemination of information and studies through articles	Media, policy-makers and opinion-makers
M. S. Swaminathan Research Foundation (MSSRF), Chennai	Research in sustainable agriculture and policy issues relating to sustainability	Farmers and the government
Green Foundation, Bangalore	Organic farming and indigenous knowledge	Farmers
Shetkari Sanghatana. A farmers' association, based in Maharashtra State	Farmers' rights and interests. Dialogue with government	Farmer and the government
Karnataka Rajya Raitha Sangha (KRRS). A farmers' association, based in Karnataka State	Farmers' rights and interests. High profile field campaigns.	Farmers. Media, policy-makers and opinion-makers
Karnataka Krishi Sangha (KKS). A farmers' association, based in Karnataka State	Farmers' rights and interests. Agricultural policy.	Farmers. Media, policy-makers and opinion-makers
Federation of Farmers' Associations (FFA), Hyderabad, Andhra Pradesh	Promotion of agriculture as a profitable occupation	Farmers
Centre for Science and Environment, New Delhi	Protection of the environment. Policy issues. Studies and research. Dissemination of information and studies through articles, seminars, workshops, etc.	Media, policy-makers and opinion-makers. Subscribers to CSE's journal "Down to Earth"
Greenpeace India. A member of Greenpeace International, London. .	High profile campaigns for the protection of the environment. Policy issues. Dissemination of information and studies through articles, workshops and seminars	Media, policy-makers and opinion-makers. Own subscribing membership. The general public.
AgBioIndia	Network for information dissemination and campaigning	Media, policy-makers and opinion-makers
Foundation for Biotechnology Awareness and Education, Bangalore	Dissemination of information through articles, workshops and seminars	Media, policy-makers and opinion-makers
All India Biotech Association, New Delhi	Exchange and dissemination of information through meetings, workshops and seminars A scientific and industrial lobby	Government, research funding councils and industry
Consumer Voice, New Delhi	Food safety and consumer protection	Media, policy-makers and opinion-makers

Source: Compiled by the authors from response to questionnaires, interviews and media reports

The capacities of the CSOs to fulfil their own stated objectives, ambitions and tasks differ widely in magnitude and quality. The differing capacities and strengths are the result of a number of factors: the dynamism of leadership of the CSO, its geographical location (decisively-placed in New Delhi or in a major State capital, or marginally-located in a district remote from the state-capital), its access to and skill in interacting with the media, sources of funding, constituency and backers, vested interest, and its standing in national and international networks. Only a couple have a nation-wide reach. Most are State-capital-based or district-based. Some concentrate solely on working at the "grass-roots" level among farmers, and rural and forest communities.

A common feature of the CSOs listed above is their stated intention of working towards sustainable agriculture. Most of them seem to have direct links with farmers.. Despite this commonality, there is neither any formal interaction among them, nor a common club, for meeting and sharing, on a regular basis, information and experiences and for forging alliances and joint strategies for action. However, in recent times, they have been meeting in the workshops and seminars held by DBT and the state-level e agricultural universities, as well as in other fora, aimed at increasing public awareness of biotechnology and biosafety issues.

It is, in effect, the English language national press that has acted as the common platform for the GM-concerned CSOs for communication and debate. It has carried articles representing various sides in the debate. A part of the press has been criticised by the scientific establishment and the government agencies for carrying the 'wrong' information and supporting the 'wrong' campaigns[104]. Similar complaints were voiced in the course of our interviews with representatives of the pro-GM camp.

Some of the CSOs have ready access to, and are also actively involving, senior scientists, retired top civil servants and leading "grassroots" activists. Since the authorities respect these eminent individuals, it is hoped that the arguments and views advanced by them will have some impact on government policy-makers and the regulatory agencies.

Of the CSOs listed above, RFSTE, KRRS and Gene Campaign were the first to raise the issues of agricultural biotechnology and biosafety publicly, with several of the leading national English language newspapers giving coverage to their views and reporting on their activities. It was only after the CSOs' concerns began to be publicised, in particular their campaigns and legal challenges in connection with the commercialisation of GM-cotton (see Section 7.1 below), and questions were raised in parliament, that the government regulatory institutions (DBT, RCGM and GEAC) began to provide some information[105] to the public through the media. But for the vigilance of some of the leading GM-concerned CSOs and their efforts over several years, the environmental, health and socio-economic issues linked to the introduction of GM-crops would not have emerged into the public domain at all.

6.2 Issues raised by the CSOs

The potential benefits and risks associated with the introduction and development of agricultural biotechnology (agro-biotechnology) continue to be debated both at the national and international levels by various stakeholders (government entities, agro-chemical TNCs, public and private sector seed companies and CSOs). They can be summarised as follows:

The potential benefits comprise increases in crop yields and thus in farmers' net income, reductions in the use of pesticides and herbicides and corresponding decrease in environmental pollution, and improvement in the nutritional content and storage characteristics of some staple foods.

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[104] See the correspondence in Current *Science*, Vol.80, No.3, 10 February 2001, where the articles in the press are discussed. On the one hand, the correspondents lament the lack of biosafety-related data in the public domain (the government has so far refused to make the data publicly available), which they say compels scientists to depend on the newspapers for their information, On the other hand, they complain that newspaper articles tend to distort facts and provide insufficient information.

[105] "Reluctantly and as little as possible" say some commentators

The potential risks to human and animal health would arise from unexpected consequences of introducing the transgenes, such as the appearance of allergens, toxins and carcinogens in GM-food and -feed. Ecological and other environmental risks could arise from cross-pollination between GM-crops and their indigenous wild relatives, leading to loss of biodiversity, and the emergence and spread of pests, diseases and weeds that could acquire the same resistances as are engineered into the GM-crops. The socio-economic safety of small farmers and the peasantry may be put at risk by the potentially negative impact on their incomes and livelihoods by the trade consequences of GM-crops. There may be concerns about the dominance of agriculture by agro-chemical TNCs, and the invoking of intellectual property rights (IPR) and other trade related rules overseen by the World Trade Organisation (WTO).

Of these many issues, only some have emerged forcefully into the public domain in India over the last few years, brought to a head by two cases: First, the field trials and commercialisation of GM-cotton, and second, the transfer of the GM-rice technology aimed at vitamin A enrichment. The GM-cotton case is of particular importance, as it is the first and so far the only GM-crop to have been approved for general release and commercialisation by the regulatory authority GEAC, and therefore the manner in which the controversies surrounding GM-cotton have played out is bound to strongly influence the attempts to move other GM-crops 'from the lab to the market'. While we refer the reader to Section 7 for detailed presentations and analyses of the issues that have dominated the GM-cotton and GM-rice cases, we briefly sketch below the main arguments fuelling the controversies not only between CSOs, government entities and private sector companies, *but also between the CSOs themselves, in particular pro- and anti-GM farmers' associations*[106]

As in Southern Africa in 2002, the controversy about GM-crops has also affected the imports of into India of some foreign donations of food. With the approval of the central government Department of Woman and Child Development, the international aid organisation CARE (an international CSO) CARE, brought in shipments of corn-soya-blend and vegetable oil. Alerted by GM-concerned CSOs, the press in India carried reports indicating that these foods were perhaps based on GM-crops, in which case their imports had to be approved by GEAC. Questions were raised in parliament [107], with the upshot that the government directed CARE to confirm whether or not the imports were based on GM-crops, pending which CARE was ordered to halt their distribution. CARE has delayed its response, prompting the government to give it a second chance to put its case to GEAC [108].

6.2.1 Pest control, crop yields and farmers' incomes

In a joint venture, the US-based agro-chemical TNC Monsanto and the Indian seed breeding and marketing company MAHYCO developed several GM-cotton cultivars, based on Monsanto's GM-technology, incorporating genes from the agro-bacterium Bacillus Thurengiensis (Bt) that produce toxins fatal to bollworm, the main cotton pest. Of these Bt-cotton cultivars, three were approved for commercial release by GEAC in March/April 2002. The Monsanto-Mahyco Bt-cotton seeds were bought and sown by farmers in several states, and the crop was harvested and sold in late 2002.

Monsanto-Mahyco make the claim that the Bt-cotton yields per unit acreage sown were substantially higher than the yields of conventional non-GM yields, leading to higher net incomes for farmers, linking these outcomes to the success of the GM-variety in combating the bollworm. These claims have been strongly refuted by Gene Campaign (India's leading GM-activist CSO), on the basis of extensive field surveys it carried out in late 2002 and early 2003. Similar claims and counter claims

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[106] For example, of the farmers' associations listed in the table of CSOs above, the FFA based in Andhra Pradesh is staunchly pro-GM, while the Karnataka State based KRRS is vehemently anti-GM. In an interesting twist, some of the pro-GM stakeholders hold the opinion that the government lacks the will to promote GM-crops sufficiently vigourously. In an interview with one of the authors, the President of the FFA, Mr P. Chengal Reddy, remarked that the government was succumbing to the pressure exerted by the anti-GM stakeholders. See also the article by him in the Hindu, dated the 27th November 2001, entitled "Fictional agriculture of environmentalists".

[107] "News item on lakhs being fed genetically modified food", Rajya Sabha Unstarred Question NO.1581, answered on 6.8.2001 by Shri.A.Raja, Minister of State in the Ministry of Health and Family Welfare.

[108] "Decision on GM seeds today", Deccan Herald, 6.3.2003

have been made abut the 2003 harvests, with other stakeholders (CSOs, central and state government officials, agricultural scientists, etc.) joining the contenders on both sides of the divide.

6.2.2 Resistant pests and pest refugia

It is conceded by pro-GM stakeholders (Monsanto-Mahyco, GEAC, etc.) that Bt-resistant bollworms are bound to emerge. As a means of preventing the resistant pest from spreading in an uncontrollable fashion, GEAC has stipulated that the farmers must sow non-Bt seeds around the Bt-plots, with the non-Bt plots being at least twenty percent of the Bt-acreage as a refuge for the Bt-vulnerable bollworm. This measure is to ensure the survival of the Bt-vulnerable bollworm as an effective competitor against the Bt-resistant type. Gene campaign and other like-minded GM-concerned CSOs point out, based on their field research, that the cotton farmers (who are predominantly small-scale) have completely disregarded this rule, because the smallness of their plots (about an hectare or two, on an average) makes it economically impossible. The pro-GM stakeholders have remained silent on this issue.

6.2.3 Implementation of biosafety regulations: The transparency and credibility of the biosafety regulatory regime

During the lead up to the approval of the commercialisation of Bt-cotton and thereafter, serious questions have been raised by GM-concerned CSOs about whether Monsanto-Mahyco have satisfactorily met all the requirements of the biosafety regulations. Besides the monitoring of the impact on the bollworm population, the magnitude and frequency of pesticide spraying and the magnitude of the cotton yields in the field trial plots, the questions asked also concern the monitoring of pollen drift, gene flow and the impact on the ecology and biodiversity of the areas around the plots. To reassure themselves and the public on these issues, the leading GM-concerned CSOs have repeatedly requested the biosafety regulatory bodies (GEAC/MoEF and MEC/ DBT) to make public all the data and the information submitted by Monsanto-Mahyco based on their field trials, and the assessment of that data and information by MEC/DBT. The authorities have so far refused these requests. They have also entirely disregarded the demand by the CSOs to be represented in RCGM, GEAC and MEC, so that the public's concerns could be adequately taken into account in the implementation of the regulations. The resulting lack of transparency and trust has seriously dented the credibility of the regulatory bodies among the GM-concerned CSOs, including part of the media.

6.2.4 Intellectual property rights, and the rights of farmers and plant breeders

Several of the leading GM-concerned CSOs (e.g. RFSTE, Gene Campaign) have also been active on these fronts, conducting public debate in the run up to the enactment by parliament of the new Patents Act, the Seeds Act and the Biological Diversity Act (see Sections 4 and 5 above), as well as thereafter.

In 2002, the Indian parliament passed a new Patents Act, amending the earlier one, to bring the patent legislation into line with the requirements of WTO's TRIPS (Trade Related Intellectual Property Rights System) agreement to which India is a signatory[109]. In part due to the intervention by CSOs, the Patents Act of 2002 does not permit the patenting of traditional knowledge and life forms.[110] These safeguards were built in to protect the rights of the Indian public and Indian institutions and organisations (including public and private sector companies) to the traditional knowledge that the farming, rural and other communities in India have generated and developed and the life forms they have cultivated and conserved. In recent years, one has seen several TNCs attempting to patent entire plants on the basis of the patents granted to them in the West on GMOs they have developed in relation to the plants. The CSOs argued successfully that if not countered by appropriate national

[109] This applies to all sectors of production and trade: agricultural, industrial, medical and pharmaceutical.
[110] See, "Patent laws a hurdle for biotech R&D", Hindu Business Line, 21.1.2002; "Patents Bill passed by Lok Sabha", Economic Times, 15.5.2002.

legislation by third world countries, the TNCs would usurp the rights that third world societies have regarded as being self-evidently theirs from times immemorial.

The new Seeds Act has established a National Seeds Board with the mandate and the responsibility to register all the seeds sown in the country, whether domestically developed or imported. Thanks to the vigorous campaign mounted by the leading GM-concerned CSOs, the new Seeds Act expressly forbids the import, development and sowing of GM-seeds that incorporate Gene Use Restriction Technology (GURT or so called 'Terminator Technology') and thus rendered useless for replanting. Among other things, seed importers have to declare to the Board whether the imported seeds are transgenic (i.e. genetically manipulated) and incorporate GURT.

India's Plant Variety Act enacted in 2002 is modelled on the provisions of the international Union for the Protection of New Plant Varieties (UPOV). It is the first piece of Indian legislation to accord Plant Breeders' Rights to Indian farmers. In defining the rights, it has opted for the *sui generis* option, an outcome strongly advocated by some of the CSOs. It has had a mixed reception among the stakeholders. Some have warmly welcomed the Act, while others continue to oppose it, convinced that it jeopardises the age-old traditional rights of farmers to the plants they have cultivated. Gene Campaign has filed a legal petition in a New Delhi court challenging the UPOV-modelled provisions of the Act and is seeking an injunction to ensure that Indian farmers are not required to forfeit any of their earlier rights[111]

The debate and controversy engendered by the Act have forcefully projected the issue of genetic resources onto the media and the public arena.. With the passing of the Act, India has rejected the contention (held principally in the industrialised countries and espoused by the IARCS of the CGIAR-system) that genetic resources constitute a "common heritage of mankind". Instead, it asserts the principle that the country of origin of biological resources can negotiate for a fair and equitable sharing of the benefits arising from the use of the resources[112], a move welcomed by some leading GM-concerned CSOs, which campaigned strongly on promoting this stance [113].

The Biological Diversity Act [114] was passed in 2002. It provides for the establishment of an apex National Biodiversity Authority to regulate access to the plant and animal genetic resources, as well as Biodiversity Boards and Management Committees in each state. It also stipulates that a Biodiversity Registers Program should be put in place, so that local knowledge is protected. Interestingly, a program of "People's Biodiversity Registers" was initiated by the CSO, the Foundation for Revitalization of Local Health Traditions, following a national workshop it organised at the Indian Institute of Science in Bangalore in April 1995 [115]. Its objective is to document the knowledge that ordinary people have, primarily among rural and forest-dwelling communities, of living organisms and their ecological setting.

There is sharp disagreement about the implications of parts of the Biodiversity Act. While some leading CSOs argue that the Act facilitates and legalises bio-piracy by foreign companies and institutions, other stakeholders feel that it will hamper the development of local industry based on genetic resources[116].

[111] "An Act that sows success", The Hindu, December 17, 2001; "NGOs warn government against joining UPOV", Economic Times, 21 October 2002; "Pant Variety Protection and Farmers' Rights Act, 2001", Suman Sahai, Gene Campaign;
[112] This will affect, for instance, the use of Indian genetic resources by agro-chemical TNCs and companies.
[113] For the arguments advancing the case for 'fair and equitable share of benefits', see "An Activist's Handbook on Intellectual Property Rights and Patents", by RFSTE, New Delhi
[114] "Lok Sabha passes Biodiversity Bill", Economic Times, 3.12.2002
[115] Gadgil, Madhav, P.R.Seshagiri Rao, G.Utkarsh, P.Pramod, Ashwini Chhatre, and members of the People's Biodiversity Initiative, 2000, "New meanings for old knowledge: the people's biodiversity registers program", *Ecological Applications*, 10(5), October, pp.1307-17.
[116]See the debate between Vandana Shiva, the Director of RFSTE, New Delhi and B.Bhattacharya, Dean, of the Indian Institute of Foreign Trade, New Delhi, in Economic Times, New Delhi, 25.12.2002: " Will the Biodiversity Act do the job? "

6.2.5 Shortcomings in the design and functioning of the biosafety regulatory regime

It can be argued that the acrimony of the debate on GM-crops is in large measure due to the lack of public trust in the biosafety regulatory authorities, brought on by the secretiveness of the authorities and the excluding of GM-concerned CSOs from the biosafety regulatory institutions (GEAC/MoEF, RCGM/DBT and MEC/DBT), an issue that we have touched upon above. One of the principal objections by the CSOs is that current biosafety regulations originate from and are heavily influenced by the OECD guidelines, and do not therefore adequately take into account the specificities of the Indian scene.

A cause for great concern is the unwillingness or inability of the authorities to enforce the regulations and to impose penalties on companies and institutions (both in the private and public sectors) that have demonstrably flouted the regulations (see the GM-cotton case presented in Section 7 below). When it transpires that leading public sector R&D institutions can at times break the rules with impunity, the mistrust in the regulatory authorities deepens [117]. It has also led to some unhappiness among a section of agricultural scientists who privately blame the authorities of favouring GM-work at the expense of non-GM research [118].

Private sector companies, pro-GM CSOs and entrepreneurs who act as intermediaries between small firms, venture capitalists and the government have repeatedly complained that the present biosafety regulatory structure involving RCGM, GEAC and several ministries (e.g. agriculture, health and trade) is much too complicated, confusing and cumbersome. They point out that not only does this lead to inordinate delays in arriving at decisions, but also to lack of clarity about which government institution constitutes the final instance with the ultimate responsibility. They are lobbying energetically for a ‘single window’ structure that incorporates and streamlines all the stages involved in the biosafety assessment process[119].

Both pro- and anti-GM CSOs complain that the biosafety regulatory authorities (DBT and GEAC/MoEF) have systematically ignored their requests for information and consultation. Their chief source of information about what is going on behind the tightly closed doors of the biosafety and biopolicy authorities are the occasional reports in leading English language national newspapers, based on the interviews given by the authorities to journalists[120]. As a rule, CSOs find it impossible to gain access to policy-makers. Under these circumstances, parliament remains the only channel through which the CSOs and the public can oblige authorities and government officials to provide information. Over the last several years, members of parliament have been tabling questions on the R&D, field trials, commercialisation and the biosafety of GM-crops, to which ministers of environment, agriculture and science and technology have been obliged to reply. An analysis of the ministerial replies reveals that the information provided is minimal, leaving parliament and the public none the wiser about the about the reasoning and the processes behind the moves made by the government institutions.

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[117] An example that came to light several years ago illustrates this tendency. The Indian Agricultural Research Institute (IARI) in Delhi, an autonomous institute under the Ministry of Agriculture, began GM-work on a native variety (*Solanum melongen)* of aubergine (called eggplant in India). The IARI scientists introduced a Bt-toxin gene, Cry1A (b), obtained from Japan, into the native variety. Without first securing the legally obligatory approval of RCGM/DBT, the IARI team grew the transgenic eggplant, in 1996, in an open experimental plot of 60 square meters within the IARI compound in Delhi. When the media uncovered this non-compliance of the biosafety regulations, it caused grave embarrassment to the authorities, who ordered IARI the burn down the plot. But no further disciplinary action seems to have been taken.

[118] Our interviews

[119] In the first Foundation Speech to the CSO ‘Trust for Advancement of Agricultural Sciences (TAAS)’ on 17 October 2003, in New Delhi, the Secretary of DBT has come out strongly against the ‘single window’ idea, arguing that the present multi-tier structure is necessary to ensure that all aspects of biosafety are taken into account properly, citing the multi-tier models of the USA and Europe in support of her contention.

[120] Our interviews

6.3 Impact of CSOs' campaigns and advocacy:

CSOs have conducted their public awareness campaigns and policy advocacy through several types of activity: Articles and reports in the English language press, publication and dissemination of own reports and papers (printed and electronic on websites), questions in parliament, legal challenges in courts, conferences, seminars and symposia, street demonstrations, and under exceptional circumstances and very rarely, militant physical action like uprooting and burning of GM-crops grown in field trials. These have been described and analysed in Section 7 below in the context of the two cases where much of the activity has taken place: GM-cotton and GM-rice.

As pointed out above, the principal demands of the CSOs are transparency in the workings of the biopolicy and biosafety regulatory institutions (RCGM, GEAC and MEC), full disclosure to the public of the biopolicy and biosafety related information that the GM-active institutions and companies have submitted to the authorities in support of their applications for biosafety approval, serious implementation and enforcement of the legally binding biosafety regulations, serious monitoring of the GM-activities of institutions and companies and the inclusion of GM-concerned CSOs in RCGM, GEAC and MEC. These demands have either been brushed aside or stonewalled by the authorities. In response to the insistence on access to information, DBT has held a few 'public relations oriented' seminars and workshops.

Despite several years of campaigns, advocacy and legal challenges, the GM-concerned CSOs do not seem to have succeeded in obliging the authorities to alter any of their key decisions or reform their decision-making processes. But the public interest lawsuits, the publicity in the press, the street demonstrations and the militant action that have preceded and followed the commercialisation of GM-cotton have made the authorities much more cautious in their attitude towards and response to the applications by companies (subsidiaries of TNCs) for conducting field trials and marketing other GM-crops. For instance, the decision on Proagro's GM-mustard has been shelved indefinitely by GEAC, following the controversy about the scope, content and reliability of the field trials conducted by Proagro[121].

Another striking example of CSO intervention concerns the import of the GM-maize brand- named 'StarLink' from the USA. The heat tolerant Bt-protein introduced into StarLink was thought to have allergenic potential in humans and was therefore initially *approved for animal consumption only* by the United States Food and Drugs Agency (USFDA)[122]. Two non-governmental international charity organisations (CARE India and Catholic Relief Services) attempted to distribute the StarLink they had imported into India as food aid to some of the poorest sections of the population in the country. But this move was halted decisively by GEAC after the intervention by the CSO AgBioIndia, which publicised the potential risks to human health associated with StarLink [123].

One particularly important outcome of CSO-activity, which may lead to significant changes in the government's future handling of agricultural biotechnology, occurred towards the end of 2003. Gene Campaign held a two-day national symposium in New Delhi, in November 2003, on "The Relevance of GM Technology to Indian Agriculture and Food Security" [124]. The unusual and noteworthy feature of the symposium was that it brought together influential participants and speakers from a range of pro-GM, GM-concerned and anti-GM institutions. They represented the GEAC, several ministries and research councils, agricultural universities, R&D institutions, social science and policy research

[121] www.genecampaign.org
[122] Notwithstanding the conditions laid down by the US Environment Protection Agency (USEPA), traces of StarLink were found in food products on sale in supermarkets in the USA. The StarLink incident has led to some serious rethinking about the biosafety regulatory regime in the USA. Addressing the Advisory Committee on Biotechnology in Washington, DC, the US Department of Agriculture (USDA) Secretary Ann M.Veneman stressed that the USA 'needed to really understand, better define the appropriate role of government regulatory systems to make sure that we didn't 't undermine the consumer confidence in our food supply.' Secretary Veneman went on to say that the USDA had taken the lead in bringing an inter-agency process to determine the appropriate regulatory responsibility necessary for 'the diverse nature of biotech that we 're dealing with today.' See http://www.usda.gov/Newsroom/0220.04.html.
[123] See the bulletin put out by the Norfolk Genetic Information Network (ngin) on 17 Jan 03: "US GM Food Aid to India stands Rejected", http://ngin.tripod.com/170103b.htm
[124] www.genecampaign.org

institutions, CSOs (in particular farmers', consumers' and environmental organisations), private sector seed companies, Indian subsidiaries of agro-chemical TNCs, and the media.

Gene Campaign has presented a set of twenty recommendations that emerged from the symposium to the Government of India (GoI). We reproduce them below, as they reflect the broadly consensual views of prominent stakeholders in India in the areas of agricultural biotechnology and GM-crops. Due in part to this submission, as well as mounting pressure from a number of influential stakeholders, GoI set up a Panel, in early 2004, under the chairmanship of Dr M. S. Swaminathan (one of India's most eminent crop scientists), to submit a report on 'streamlining' the biotechnology and biosafety regulatory structures and procedures, after consulting a range of stakeholders [125]. Fundamental changes in the biosafety regulatory structures have been repeatedly called for by pro-GM, anti-GM and GM-concerned CSOs.

Recommendations from Gene Campaign's National Symposium are as follows [126]:

1. A distinct law should be enacted to oversee Genetic Modification Technology and its implementation. This law must harmonise with other laws and national and international agreements.
2. A comprehensive biotechnology policy should be developed in consultation with all stakeholders.
3. A statutory National Bioethics Commission must be set up.
4. There should be a consultative and participatory process to prioritise crops and traits for genetic improvement through biotechnology with the goal of addressing the needs of small farmers and Indian agriculture.
5. Investment in public sector research should be increased and strengthened. Novel gene discovery in crops of relevance to India should get highest priority.
6. 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.
7. The Herbicide Tolerance trait should be subject to rigorous cost and risk benefit analysis before being considered for adoption.
8. Alternatives to the GM approach must be carefully evaluated in each case before deciding on the GM route. A cost and risk benefit analysis must be conducted before deciding on a GM product.
9. Protocol for food safety tests must be vastly improved and mechanisms for long term monitoring of human health (post GM food release) be put in place.
10. Develop a stringent protocol to assess environmental and ecological impact.
11. There should be provisions for post-market surveillance and monitoring of GM products.
12. Have a policy to deal with bio terrorism urgently.
13. India must exercise caution in the IPR regime that it adopts. The current PPV-FR should be retained since it balances Breeders and Farmers' Rights.
14. A new statutory, independent National Biotechnology Regulatory Authority must be established.
15. Make GEAC more competent, transparent and accountable. Post data on research and development of GM crops and products on websites and local newspapers.
16. An annual review of all decisions on GM products must be presented to Parliament.
17. Conduct a scientifically sound study to assess attitudes and perceptions about GM technology among stakeholders in India.
18. Undertake a program of awareness about GM technology to educate the public.
19. Organize 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.
20. 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.

[125] Financial Express (India), 8 Feb2004: Govt To Revamp GEAC After Swaminathan Panel Submits Report. The Swaminathan Pane's Report was submitted to the Ministry of Agriculture in June 2004 (See Section 5.5 above).
[126] www.genecampaign.org

7. THE CASE OF BT-COTTON IN INDIA

7.1. Introduction

India is the third largest producer of cotton in the world after China and the USA, with nearly five percent of its agricultural land devoted to this crop[127]. Cotton accounts for about 30 per cent of the country's agricultural GDP and the livelihood of about 60 million people engaged in various economic activities related to farming, trade and textile industry, and generates a third of the country's export earnings[128]. But with an area of around 8.3 million hectares under cotton in 2000-2001, India produced only 2.7 million tons, while China produced 50% more (4.2 million tons) on less than half the area (4.1 million hectares). The low yield (0.3 tons per hectare) is adversely affecting the cotton economy of the country, in particular its competitiveness on the market. According to cotton industry sources, the main problems of the sector are low yield, inconsistent quality of the fibre and lack of scientific farming[129].

In common with most agricultural commodities in India, cotton too is predominantly a product of small-scale farming, with average holdings barely a hectare or two. But unlike some staples, the bulk of the cotton production is concentrated to about half a dozen states, due to soil conditions, rainfall patterns, coverage by canal irrigation and historically determined economic and social conditions prevailing in the farming communities. As the Table below shows, seven states (Maharashtra, Gujarat, Andhra Pradesh, Haryana, Rajasthan, Punjab and Karnataka) account for over 90 per cent of cotton production.

Area, production and yield of cotton during 1999-2000
Area is in million hectares, production is in million bales of 170 kg each and yield is in kg/hectare
States have been arranged in order of descending percentage share of production during 1999-2000

State	Area	% of total area	Production	% of tot prodn	Cumulative % of tot prodn	Yield
Maharashtra	3.25	37.10	3.10	26.63	26.63	162
Gujarat	1.54	17.58	2.09	17.96	44.59	230
Andhra Pradesh	1.04	11.87	1.60	13.75	58.33	261
Haryana	0.55	6.28	1.31	11.25	69.59	408
Rajasthan	0.58	6.62	0.98	8.42	78.01	287
Punjab	0.48	5.48	0.95	8.16	86.17	340
Karnataka	0.54	6.16	0.76	6.53	92.70	239
Madhya Pradesh	0.53	6.05	0.46	3.95	96.65	148
Tamil Nadu	0.18	2.05	0.29	2.49	99.14	265
All other states	0.07	0.80	0.10	0.86	100.00	243*
All India	8.76	100.00	11.64	100.00		226

* Averaged over "All other states"
Source: Agricultural Statistics at a Glance, 2001, Ministry of Agriculture, Government t of India

[127] Agricultural Statistics at a Glance, 2001, Ministry of Agriculture, Government of India, New Delhi
[128] Sundaram, V., Basu, A.K., Krishna Iyer, K.R., Narayanan, S.S. and Rajendran, T. P. (1999). *Handbook of cotton in Indi*a. Mumbai, India: Indian Society for Cotton Improvement.
[129] "Indian cotton 'fares badly'", Hindu Business Line, 17 November 2001. See also "What ails the cotton industry?" Economic Times, 26 November 2001

One of main reasons for the low yield is the damage inflicted on the crop by several pests, of which the American bollworm is perhaps the most dreaded. It is estimated that nearly 13 percent of the annual crop is lost to the bollworm[130].

Bollworm is a severe problem facing most cotton producers in the world. In order to combat it, farmers have until recently had recourse only to heavy spraying of chemical pesticide, new versions of which had to be designed to keep up with the resistance developed by the pest. However, the naturally occurring agro bacterium Bacillus Thuringiensis (Bt) produces a protein that is toxic to the bollworm. The US-based agrochemical multinational corporation (MNC) Monsanto has succeeded in developing genetically modified varieties of cotton that incorporate a modified version of the Bt-toxin producing gene Cry1Ac. Bollworm populations that feed on present varieties of Monsanto's Bt-cotton do not survive[131]. Monsanto's Bt-cotton, marketed under the trademark "Bollgard" and "Ingard GM", is grown commercially in the United States, China, Australia, Argentina, Mexico, South Africa and Indonesia[132].

In India, in a joint venture with Monsanto, the Maharashtra Hybrid Seeds Company (Mahyco) has produced Bt-cotton hybrid lines by backcrossing the Monsanto's Bt-lines with selected local cultivars. They have been named MECH (Mahyco's Early Cotton Hybrid) with a number suffixed such as 12, 162, 184 and 915. These numbers help to identify the parental lines used. The work on backcrossing began after the Government of India (GoI) approved, in March 1995, Mahyco's import of Monsanto's Bt-cotton seeds for that purpose. Permission to conduct large-scale and multi-locational field trials of the hybrids followed in 1997. In March/April 2002, GoI approved three of Mahyco's Bt-cotton hybrid lines for general commercial release. In order to market the seeds, the joint-venture company Mahyco Monsanto Biotech (MMB) India, Ltd., was set up. MMB is the sole licensee and patent holder in India of the approved Bt-cotton hybrids.

Bt-cotton is the first genetically modified crop (GM-crop) to have been approved by the Indian biosafety regulatory authorities for commercial release. The "approval process" has been a bumpy ride for all the main "actors" involved, to put it mildly. The Bt-cotton thread weaves itself into an interesting story of conflicting interests and unresolved issues. One hopes that it has been a salutary experience and a prime learning process for both the protagonists and the antagonists of GM-crops on how to handle (and *not* handle) the challenges that are bound to arise in the effort to integrate biosafety into biotechnology development.

In the following we will present an analysis of how Monsanto's Bt-cotton came to be established in India and how the decisions were made at various levels, followed by our empirical field study on how the Indian biosafety regulatory authorities actually monitored Mahyco's Bt-cotton field trials in the state of Karnataka. We end the section with some conclusions and questions.

7.2 The Biosafety Regulatory Structure

From Section 5 above of the present study, where we have examined the biosafety regulatory regime in India, we recall that three central government authorities (biosafety committees) are involved in implementing and monitoring the biosafety regulations:

The *Review Committee on Genetic Manipulation (RCGM)* under the Department of Biotechnology (DBT) of the Ministry of Science and Technology (MoST)

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[130] In a statement to the Lok Sabha, Agriculture Minister, Mr. Ajit Singh. See the news report "Cotton crop loss seen at Rs.1, 364 crore (a crore is 10 million)", Hindu Business Line, 26 November 2001. This loss was in the north of India.

[131] However, several years from now, they will have developed resistance to these varieties and new Bt-varieties will have to be genetically engineered.

[132] In 2003, Monsanto put a new variety "Bollgard II" on the market (e.g. in Australia), anticipating the resistance that the bollworm is bound to develop to "Bollgard" and "Ingard GM". Meanwhile, two Indian scientists claim to have discovered that the bollworm develops resistance to the toxins produced by the three Bt-genes CRY1Aa, Ab and Ac within six years (see footnote 156 for the reference).

The *Genetic Engineering Approval Committee (GEAC)* under the Ministry of Environment and Forestry (MoEF)

The *Monitoring and Evaluation Committee (MEC)* under DBT/MoST

The current regulations governing biosafety in agricultural biotechnology are contained in *"The Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts"*. This document was issued in August 1998 by the DBT, and it is legislated under the Environment (Protection) Act of 1988.

The 1998 document is the second revision of a set of guidelines first issued in 1990 by DBT under the title *"Recombinant DNA Safety Guidelines"*. The first revision of was carried out in 1994 and issued under the title *"Revised Guidelines for Safety in Biotechnology"*. The revisions were made to take account of the implications of the rapid changes in the biotechnology arena and to clarify the specific mandates and responsibilities of the several biosafety authorities (committees) involved in implementing the regulations.

The concept of **"biosafety"** employed in the regulations is broad and covers the safety of the environment (ecology and biodiversity), the safety of human and animal health, and the socio-economic safety of farmers, the majority of whom in India are small-scale and peasant cultivators.

RCGM's mandate is limited to R&D activities, including greenhouse testing and limited-scale field trials in a few locations on plots of less than one acre in size. Large-scale, multi-locational field trials on acreages bigger than one acre, aimed at securing permission for commercial release, come under the purview of the GEAC. It is MEC's responsibility to monitor and evaluate the field trials conducted by applicant institutions, and report back to the RCGM and the GEAC. DBT provides the secretariat for RCGM and MEC, and the MoEF for GEAC.

Each of these three committees comprises members representing (i) MoST, MoEF and the central government ministries of agriculture, industry, commerce (trade), health and law & justice, (ii) the central government national research councils dealing with science, technology, agriculture, industry and health, and (iii) the public sector R&D institutions in the several scientific disciplines that form the foundation of biotechnology (agricultural, industrial, medical and environmental). What is striking, however, is the **lack of representation**[133] in these committees of civil society organisations that are active in the biosafety and biotechnology arena, the central government national research council for the social sciences and private sector institutions.

7.3 Coming of Bt-cotton to India

Monsanto approached GoI in 1991 with a proposal to introduce its Bt-cotton into India. (At that point in time it was still undergoing field trials in the US, as part of the process for obtaining approval for commercial release.) Negotiations were conducted for a technology transfer package comprising the two gene constructs Cry1Ac and Cry1Ab, the transformed E.coli competent to express these two Cry genes, the transgenic cotton seeds Coker-312 containing the Cry1Ac gene, and the training of Indian scientists in genetic modification techniques of specific relevance to cotton transformation. In the event, the negotiations broke down. Two reasons have been advanced by the Indian authorities for this: First, a disagreement over the financial terms for the technology transfer[134]. Second, public sector R&D work on GM-cotton was in any case underway and deserved higher priority and stronger support

[133] This was the case as until the completion of the Draft of the present study in December 2003
[134] See the Correspondence in Current Science, Vol.80, No.3, 10 February 2001.
There is an interesting first hand account by Pushpa M. Bhargava in EPW of August 23, 2003.
"High Stakes in Agro-research: Resisting the Push", EPW Commentary, August 23, 2003. According to the author, Monsanto offered to transfer the Bt-cotton technology for Rs.600 million.

than technology transfer[135]. Scepticism about this being the entire story is justified, given the fact that over the last few decades Indian public sector companies have had no problems in agreeing to handsome royalty payments to US and European MNCs in a very large number of agreements for the transfer of *industrial* technologies, despite the (nominal) industrial R&D work going on in scores of Indian public sector *industrial technology* research institutions. A strong hypothesis, that needs to be tested in future independent research, would be that there were problems regarding the transfer of crucial parts of the "know-how" and "know-why" to Indian public sector R&D institutions, as well as other aspects of the intellectual property rights of Monsanto.

Two years later, in 1993, the Indian private sector company *Mahyco* (Maharashtra Hybrid Seeds Company) began discussions with Monsanto about licensing its Bt-cotton technology in 1993. Mahyco has a very substantial part of the seed market in India. Its main research station is in Jalna, in Maharashtra, which is the largest cotton producing state in India. Following an agreement between the two companies, Mahyco was granted permission by DBT in March 1995, under the existing regulations for GM-R&D, to import Monsanto's Coker-312 seeds from the USA[136]. Mahyco crossed the transgenic trait into Indian elite cotton cultivars for six generations under controlled greenhouse conditions and then generated stable lines to breed hybrids. Eight hybrids containing the Cry 1Ac gene were developed.

Following the greenhouse testing of the hybrids, DBT approved Mahyco's application in 1996 to conduct limited field trials in 'open contained' plots of about 200 square meters each, spread over different locations in the states of Andhra Pradesh, Haryana, Karnataka, Maharashtra and Tamil Nadu. Copies of the approval letter were sent to the governments of these five states (addressed to the Chief Secretary, the head of the civil service at the state level). The Government of Karnataka (in the person of its Chief Secretary) refused to accept this central directive, sending it back to DBT, on the grounds that the State Government had not been kept informed about and consulted on Mahyco's application to conduct the trials in Karnataka[137]. So the initial response by Karnataka was to deny Mahyco permission to conduct the trials within the boundaries of the state. According to the DBT this was the result of a 'misunderstanding' by Karnataka[138]. It cited a communication by its Secretary dating back to 1990 to all the state governments, pointing out the location-specific nature of agricultural biotechnology, whose development would be dependent on the cooperation and involvement of the state governments[139]. Karnataka's brusque response seems to have galvanised the DBT into active and serious consultations with the state government, resulting in the state government's acquiescence with DBT's approval of Mahyco's application.

The limited field trials in the above-mentioned five states began in November 1997. They were followed in 1998 by multi-locational field trials in forty sites, on the basis of the permission granted by RCGM of DBT to Mahyco in April 1998. These trials were met by protest campaigns by a few of the more active civil society organisations (CSOs) opposed to the introduction of GM-crops in India. A dramatic example was the burning of the trial crops in some test plots in Karnataka, in November 1998, by members of a local CSO[140], which claims to represent the interest of the farmers in the state, under the slogan "Operation Cremation Monsanto". During the protests, the CSOs raised the issue of

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[135] The failure of the negotiations has been lamented by senior scientists who are active in GM-R&D in the public sector, who felt that India had lost a valuable early opportunity to establish itself in GM-agriculture (Interviews).

[136] Mahyco was established in 1964. It is India's largest private sector seed company. It produces and markets quality hybrid seeds, and conducts applied research into crop breeding. see www.mahyco.com/overview.html

In 1998, Mahyco allowed Monsanto to acquire 26 percent of its shares, making it a joint venture with the US-based agro-chemical TNC. In 2002, the two partners set up the joint-venture company Mahyco Monsanto Biotech (MMB) India Ltd (apparently on a 50-50 equity basis). A highly placed executive of Monsanto is reported to have said that the company's stake in Mahyco would allow Monsanto to "penetrate in the Indian agriculture sector in a big way", for which "Mahyco is a good vehicle." See "Globalisation and threat to seed security – case of transgenic cotton trials in India" by Vandana Shiva, *et al* in *Economic and Political Weekly*, March 6-12 and 13-19, 1999.

[137] Agriculture falls under the jurisdiction of the State Governments and not the central federal government (GoI) in New Delhi

[138] Interview at DBT

[139] See DBT's Annual Report 1990-91, pp.74.

[140] The *Rajya Raitha Sangha* (translates from Kannada, state language of Karnataka approximately as the 'State Farmers' Association').

A telling slogan was coined in the local regional language Kannada "*bitti kottaru Bt beda*", meaning that 'even if given free we don't want Bt' See www.tao.ca/~denny/monsantocremation.htm the so-called 'terminator technology'[141], although that particular R&D work then ongoing at Monsanto's headquarters in the USA had nothing whatever to do with the "Bollgard" Bt-cotton technology that Monsanto had transferred to Mahyco[142].

Meanwhile, another activist CSO, the New Delhi based Research Foundation for Science, Technology and Environment (RFSTE) filed a case against the GoI in the Supreme Court challenging the legality of the permission granted by the RCGM (located under DBT) to Mahyco to conduct the multi-locational field trials, on the grounds that the 1990 Guidelines (see above) restricted RCGM's mandate to limited, contained field tests for strictly R&D purposes and did not extend to field trials conducted as inputs into an envisaged application by Mahyco to the GEAC (located under the MoEF) for general commercial release. This put the spotlight not only on the lacunae in the 1990 Guidelines but also on the sensitive question of whether the RCGM (DBT) had encroached on the territory of GEAC (MoEF), for it was the latter rather than the former that had been specifically empowered by the GoI to handle all the aspects that had a direct bearing on the commercial *release of GM-crops*. One of the lacunae, which surfaced in the discussions held between DBT and Mahyco[143], concerned the health safety of the animals that would feed on the residues of GM-crops. In the case of cotton, this meant the cottonseeds, a by-product of ginning the cotton). Traditionally, nutritionally rich cottonseed has been a very important feed for farmers' livestock (cattle, goats and sheep). Compelled into an open acknowledgment of these critical issues by non-governmental stakeholders (e.g. RFSTE and Mahyco), the GoI (through DBT) moved quickly to issue the 1998 Revised Guidelines (see above), which, among other things, extends the mandate of the RCGM to cover multi-locational field trials on *small* plots and prescribes the testing of the health impact (e.g. toxicity and allergenicity) of GM-feeds on animals as an obligatory part of the application for commercial release.

One of the significant outcomes of the events leading up to the 1998 revision was to make RCGM and DBT aware of the need to monitor the field trials, which led to the creation of the Monitoring and Evaluation Committee (MEC) and its formal activation in relation to the Mahyco trials. To begin with, MEC seems to have been content with limiting its monitoring activity to some spot checks at a few field sites. But it soon seems to have dawned on MEC and DBT that a credible monitoring process would have to be more interventionist and more receptive to State level concerns by involving scientists from the State Government funded agricultural universities in the monitoring exercise. Our Karnataka empirical case study presented below in Section 7.1.7 examines how the monitoring took place in practice, uncovering its several shortcomings.

Mahyco added another eleven field trials to the ongoing forty. This was countered by RFSTE by filing a case in January 1999 against the GoI (DBT) at the Supreme Court, under Article 32 of the Indian Constitution[144], challenging the legality of the Mahyco trials.

In the judgment delivered in 2001 on the cases filed by the RFSTE, the Supreme Court found for the GoI. While RFSTE lost the cases, it was nevertheless partly instrumental in moving the GoI to make some crucial revisions in the biosafety regulations and to initiate the monitoring of the field trials.

On the basis of the data generated by its field trials (nearly fifty), Mahyco made a presentation to the GEAC, in support of its application for commercial release of its Bt-cotton varieties. GEAC issued a preliminary approval in mid-2000, which however was immediately challenged by activist CSOs, on the grounds that the data were not credible. The CSOs marshalled two main arguments. Firstly, the trial seeds were sown two months late in 1999, thus sparing the Bt-cotton crop the full onslaught of the bollworm, which would have peaked two months before the Bt-cotton crop was due. Secondly, given

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[141] Gene use restriction technology (GURT), or the so called 'terminator technology', "genetically compromises the fertility or the performance of a *cultivar* so that harvested grains cannot germinate without agrochemical treatment". The technology is intended "to protect the market of the seed producer". In other words, GURT makes the harvested seeds sterile and thus useless for replanting by farmers.

[142] Following the pressure exerted by international CSOs and other international organisations, and the attendant exposure in international media, Monsanto abandoned its R&D work on "terminator technology" in 2001.

[143] Interviews at DBT

[144] This article permits citizens to move the highest court over issues of violation of fundamental rights

the smallness of their holdings (usually less than two hectares), the cotton farmers could not afford to (and in the later post-trial period would not) set aside the stipulated twenty percent as a refuge to trap the Bt-cotton pollen, as mandated by the biosafety regulations, to prevent GM-contamination of non-GM plants.

Meanwhile, a public interest petition was filed in the Delhi High Court by Gene Campaign, an activist CSO based in New Delhi, against the GoI, alleging negligence on the part of GEAC/MoEF in permitting large-scale field trials of Bt-cotton by Mahyco-Monsanto, without first ensuring that appropriate safety and monitoring measures were in place. Despite this move, and without awaiting the court's verdict, the large-scale field trials were allowed to continue.

The challenges raised by the activist CSOs prompted the GEAC into action on two fronts: First, it asked Mahyco to conduct further trials ensuring that the Bt-cotton seeds were sown at the beginning of the growing season. Second, through an amendment to the regulations in 2001, it obliged the central government funded Indian Council for Agricultural Research (ICAR, under the Ministry of Agriculture) to conduct its own field trials of the Mahyco Bt-cotton varieties, *independently of Mahyco.* In February 2002, both ICAR and Mahyco submitted the results of the new trials to GEAC.

In a separate and unrelated move, Monsanto was invited in 1997 by the Indian Institute of Science (IISc) in Bangalore to start a research wing on its premises. What prompted the step seems to have been the realisation that even after a decade of effort, Indian research institutions had been unable to "catch up" with Western state-of-the-art in agricultural biotechnology and arrive at marketable innovations. The initiative had the informal approval of DBT's Scientific Advisory Committee, which felt that it would serve the dual purpose of 'reining in' the agrochemical MNCs that were attempting to enter the Indian market and at the same time benefiting Indian public sector R&D scientifically and technologically. A provisional agreement was reached in May 1997 between the IISc, the (Indian) Society for Innovation and Development and Monsanto for collaborative research in the fields of GM-biology and physiology (plant and animal) and genomics[145]. On hearing about this, a couple of activist CSOs mounted a vigorous campaign to halt the initiative. Among the arguments they used against letting Monsanto establish R&D collaboration in India was the report that Monsanto was developing the 'terminator technology'. Despite the protests, IISc went ahead with the collaboration and allowed Monsanto to set up a research unit with a greenhouse on its premises[146].

7.4 The Navbharat Episode

In October 2001, reports appeared in the Indian press that Bt-cotton was had been grown by farmers in the State of Gujarat on a total acreage of about 10, 000 hectares. The reports quoted the farmers' claim that the Bt-cotton yield per unit of land sown was substantially bigger than the conventional non-GM yields. The GEAC and the other central biosafety regulatory authorities in New Delhi seem to have been caught completely unawares by the news[147]. Members of the MEC were sent to Gujarat to investigate and their report to GEAC and DBT confirmed the veracity of the newspaper reports. As Bt-cotton had not yet been approved by the central regulatory authorities for general commercial release, the cultivation of Bt-cotton was, at that stage, clearly illegal, prompting GEAC to issue a directive to the State Government in Gujarat to burn the standing crop. Where the BT-crop had already been harvested and sold, the Gujarat government was further directed to buy up the Bt-cotton from the market paying the prevailing officially decreed 'minimum support price', separate the seed from the lint, store the seed for testing later and send the lint for testing to the Central Institute for Cotton Research (CICR) at Nagpur in the adjoining state of Maharashtra. Meanwhile, reports emerged about Bt-cotton sales in Maharashtra as well[148].

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[145] Interviews at IISc, Bangalore

[146] Interviews at IISC. It should be noted that although IISc has ongoing R&D in some areas of bio-medical and industrial biotechnology, it has none in agricultural biotechnology. Therefore the move to invite Monsanto into IISc was seen by some as anomalous.

[147] "GM cotton fields in Gujarat alarm GEAC", Economic Times, 10 October 2001

[148] "CICR confirms Bt cotton sale in Maharashtra", The Hindu Business Line, 17 December 2001.

The Gujarat Government did not act on any of these directives. As the written correspondence and other communication between the State and Central Government authorities on this matter has not been made public, one can only make some plausible guesses about the reasons for the inaction. A principal reason would be the sheer impracticality of identifying and burning the crop on a statewide basis in the teeth of the farmers' opposition and of buying up the sold produce from a widely dispersed market. Further, the political support of the farming community is of crucial importance to the ruling political class. Farmers' organisations had the potential to cause serious trouble through militant action[149]. Moving against the farmers would jeopardise the benefits that accrued to the top levels of government and the bureaucracy from their power of patronage. The controversy created by the directives continued well into early 2002 in Parliament[150] and the media.

An investigation into how the Bt-cotton seeds came to be sold illegally in Gujarat and elsewhere In India revealed that an Indian company based in Hyderabad (the state capital of Andhra Pradesh), The Navbharat Seeds Private Ltd., had procured the original GM-seeds from the USA (from a still unidentified source, the GM-seeds being presumably the same as the ones developed by Monsanto) and then backcrossed it with local cultivars to produce a hybrid, which it had then put on the market under its own brand name, the Navbharat 151. Although the gene construct that leads to the production of the Bt-toxin in Navbharat 151 is the same as the one in Monsanto's Bt-cotton, i.e. Cry1Ac, Navbharat claims not to have procured the original seeds either from Monsanto or Mahyco. Since the proprietor of Navbharat was earlier an employee of Mahyco, it was alleged that he had taken the Monsanto seeds from Mahyco. But this allegation was dismissed in some quarters (among others by some GEAC and MoEF staff[151]), on the grounds that the proprietor had left Mahyco in 1986, which was nine years before Mahyco bought the Monsanto seeds to develop its hybrids. MoEF has filed a case in the Gujarat High Court against Navbharat.

7.5 Approval of Mahyco-Monsanto hybrids[152]

Taking into account the results of the new (year 2001) trials submitted by Mahyco and ICAR in February 2002, GEAC announced in March 2002 that it was approving three hybrid varieties, Bt MECH 12, Bt MECH 162 and Bt MECH 184, for commercial release[153], *making Bt-cotton the first GM-crop to be so approved in India*[154]. The approval was accompanied by the conditions that: (a) it was valid for the three-year period April 2002-March 2005, (b) the size of the pollen refuge belt surrounding a Bt-cotton field shall be such as to accommodate at least five rows of non-Bt cotton or twenty percent of the total sown area, whichever is more, (c) each packet of seeds of the approved varieties shall be accompanied by a separate packet of the seeds of the same non-Bt cotton variety which is sufficient for planting in the refuge prescribed as above, and (d) Mahyco shall submit annual reports to GEAC/MoEF by the end of March each year on the use the approved Bt cotton hybrid varieties specifying, among other things, the dealers (seed selling firms), the acreage planted and the localities of planting (state and region). Further, MoEF reserved the right to stipulate additional conditions during the period of validity of the approval, and the right to revoke the approval, if the implementation of the conditions were not satisfactory.

GEAC has, however, turned down Monsanto-Mahyco's application for marketing the three varieties in the northern states of Punjab, Haryana and Uttar Pradesh, citing their susceptibility to the leaf curl virus. Monsanto-Mahyco is now in the process of developing Bt-cotton varieties suitable to the northern states.

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149 For instance, in a newspaper article entitled *"Jhootistan strikes against cotton farmers"*, the leader of the farmers' organisation *'Shetkari Sanghatana' accused the government of working against the interests of the farmers by not expediting the adoption of GM-cotton.* See his article in the Hindu Business Line, 7 November 2001. 'Jhootistan' is a coined word to mean 'The Land of Falsehood', here denoting a government that is telling lies.

150 Questions were raised in the Upper House of Parliament (The *Rajya Sabha*). See Unstarred Question No.950, "Reconsideration of Order on Bt cotton", Rajya Sabha, answered on 8.3.2002 by Minister of Environment and Forests; Unstarred question No. 945, "Destruction of Bt cotton crops", Rajya Sabha, answered on 8.3.2002 by Minister of Environment and Forests.

151 Interviews at the GEAC secretariat in MoEF

152 The website www.mahyco.com/btcotton.html gives the chronology of events of Bt-cotton release by Mahyco

153 The Mahyco office in New Delhi was officially informed of this decision by MoEF through D.O No.10/1 /2002-CS, dated 5 April 5 2002.

154 And, as until mid-2003, it was also the only such crop

7.6 Approval of RASI's application to market Bt-cotton hybrids

In mid-2003, GEAC approved the application by the Indian seeds company RASI to produce Bt-cotton seeds in the "Early Kharif"[155] planting season of 2004 (March to May) on its 100, 000 hectare farm, in readiness for harvesting and commercial release in June-October. RASI's Bt-cotton contains the same transgene (Cry1Ac) as the three MECH varieties mentioned above, which it has obtained on license from Monsanto.

In March 2004, GEAC approved the release of RASI's Bt-cotton RCH 2 for marketing only in three southern and two central states (Andhra Pradesh, Karnataka and Tamil Nadu; Madhya Pradesh and Chattisgarh) [156]. GEAC has imposed the same conditions on the marketing and cultivation of RCH 2 as on Monsanto-Mahyco's three MECH varieties, including the refusal for marketing in the northern states. Further, GEAC has also approved RASI's application to conduct large-scale field trials of Bt-cotton varieties that it is developing for commercial cultivation in the northern states.

Serious questions have been raised by leading CSOs about the legitimacy and validity of the decision taken by GEAC[157]: Firstly, there were significant variations in the yields from the 2002 commercial plantings of Mahyco-Monsanto's three approved hybrids (i.e. Bt-MECH 12, 162 and 184) depending on the hybrid planted and the planting location. Multi-locational yields from the RASI product needed to be critically monitored and compared with the MECH yields to see whether the yield-claims made by RASI were justified. This has not been done. Secondly, the CSOs claim that the correct instance for permitting the *commercialisation* of the Mahyco-Monsanto and the RASI seeds is not the GEAC, but GoI's Commission for Agricultural Costs and Prices (CACP). GEAC's mandate is to pronounce on the biosafety of GM-products submitted for clearance for commercial release, and not to actually authorise the marketing, which is the provenance of the CACP, which covers all the seeds marketed in India.

GEAC has not responded to these questions. Nor has it made public the application and the supporting data and documentary material submitted by RASI (and by Mahyco-Monsanto), despite repeated calls by India's leading GM-activist CSO, The Gene Campaign, New Delhi, and exhortations by newspaper editorials[158]. It is unclear whether GEAC/MoEF is obliged, as a public body, to put into the public domain the material submitted to it by applicants (e.g. Mahyco-Monsanto, RASI, etc.) and whether in not doing so it is in breach of the law. The same question applies, of course, to the RCGM/DBT. In any case, in not responding to the requests by CSOs and the media, the biosafety regulatory authorities are fuelling the distrust in which they are held by the CSOs, the media and the leaders of public opinion.

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[155] 'Kharif' crop cultivation is divided into two periods, "Kharif Early" and "Kharif Late", to correspond to the two monsoon-rain seasons, the southwest (June to September) and the northeast. (November-December). "Rabi" crop cultivation is timed for the northeast monsoon period.

	Planting	Harvesting
Kharif Early	March-may	June-October
Kharif Late	June-October	November-February
Rabi	November-February	March-June

[156] "Rasi Seeds Receives Nod For Cultivation Of Bt Cotton", News item in the Financial Express, by Ashok B. Sharma, April 4, 2004 http://www.financialexpress.com/fe_full_story.php?content_id=56343

[157] See Sharad Joshi's article in The Hindu, 3 July 2003, www.hinduonnet.com See also 16 June 2003 news release by Gene Campaign, New Delhi, in www.genecampaign.org

[158] www.genecampaign.org , 16 June 2003 news release

7.7 Empirical study of the monitoring of Mahyco field trials in the state of Karnataka

Our field study was conducted in 2002 at three separate locations in a district of Karnataka that is one of the largest producers of cotton in the state[159]. We interviewed farmers who had grown the trial Bt-cotton in the "Late Kharif" [160] season of 2001, as well as several scientists from the regional university of agricultural sciences who were in the committee set up by DBT to monitor the trials.

The farmers are old customers of Mahyco, having purchased seeds from the company over the past fifteen years. They said they were satisfied with the products they had bought from Mahyco all these years. They had volunteered to participate in the trials when the company's representative talked to them during one his routine visits. The representative had explained the properties of Bt-cotton and the advantages of growing it.

Mahyco had selected all the trial farms in Karnataka in accordance with the following criteria: The trial farm had to be (i) rectangular in shape, (ii) at least one acre in size (40 guntas in local measure), and (iii) near an all-weather road ("*pucca* road" in Indian usage).

According to the norms prescribed by DBT, each of the three varieties, i.e. Non-Bt, Bt and 'check´[161], were to be sown strictly in that sequence, on three separate plots each of quarter of an acre (10 guntas), with a gap of five metres between each plot. In addition, the three plots were to be enclosed in a fence made up of five guard rows (border rows) of ordinary cotton. And the 'isolation distance' between the fenced trial plots and the neighbouring non-trial fields had be at least 50 metres. This pattern was dictated by the need to track the drift of pollen, the growth of the bollworm population and the migration of bollworms across plots and fields.

Mahyco was late in supplying the seeds, considerably delaying the sowing. It is curious that the delay should recur, since the 2001 trials were ordered by GEAC precisely to meet the objections of the CSOs that the pre-2001 trials, being delayed, were invalid, because the bollworm attack would have peaked by the time the Bt-cotton boles appeared.

According to the farmers, the pest-load (i.e. the number of bollworms per cotton bole) was much higher in 2001 than in the previous years. Nevertheless, the farmers found that the pest-load in the Bt-plots was much less than in the non-BT and check plots. Thus, the Bt-plots required much less pesticide spraying than the other two. They claimed that the yields in the Bt-plots were three times the yields in the non-Bt and check plots. However, some of the farmers said that to properly judge the yield potential, the crop had to be grown on a larger scale, as the yield depends on the differential quality of the soils and the methods actually employed in cultivating cotton on a routine, normal basis (in contrast to small plot trials). But, overall, the farmers seemed happy about the test results.

From the farmers' point of view, the significance of Bt-Cotton lies in its requiring substantially less spraying by pesticide than non-Bt varieties, thus cutting down on their heavy expenditure on pesticides. Substantial *indirect* gains would also accrue: The amounts of pesticide washed away by rain would be less. The reduced frequency of spraying would cut down on labour costs. The farmers have to hire labour for spraying, but the scarcity of labour during the spraying periods makes labour availability on time very problematic, besides the added burden of increased labour costs that the scarcity creates. With less number of sprays required, the farmers and their households could do more of the spraying themselves.

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[159] Mahyco were very cooperative and made data available on the 37 farms which grew Bt-cotton in the *Kharif* season of 2001 in the districts of Dharwad, Gadag and Haveri. Out of the 37, we selected seven farms in three taluks of Haveri district, viz. Ranebennur, Haveri and Hanagal.

[160] See footnote 155 above for definition of "Kharif" and "Rabi" crop cultivation seasons

[161] While the Bt and non-Bt seeds were the ones specifically supplied by Mahyco for purposes of the trial, the 'check' was the conventional variety (the so-called 'regular cotton') that the farmers in this region usually grow, which also happens to be a Mahyco product (MHH-44)

But they pointed out that the advantage that Bt-cotton enjoyed against bollworm did not extend to a number of other pests that attacked the cotton fields (e.g. the so-called ‘sucking pests’ comprising aphids, jassids, whiteflies, throps, etc.) The farmers had to spray against these pests with the same intensity and frequency as before.

It is worth noting, in this context, that the cotton farmers in this region had no knowledge of, and did not practice, integrated pest management (IPM) techniques, which would have cut down on pesticide use even with conventional non-GM cotton. These techniques are well established in several parts of India. In Karnataka, as in all other states, the responsibility for the promotion of IPM lies with Department of Agriculture of the State Government, as well as the agricultural extension services of the institutions funded by ICAR, such as the government funded Universities of Agricultural Sciences (UAS) in the state. It is part of the mandate of the State Governments’ Departments of Agriculture to promote IPM.

The cotton farmers in this region were vehemently opposed to the militant anti-GM action (e.g. uprooting and burning of Bt-cotton trial crops, and explicit and implicit threats directed at the trial farmers) of the Bangalore-based CSO, the *Rajya Raitha Sangha*. They said that the leadership of this CSO had no convincing arguments to offer against GM-crops and no alternative solutions that could efficiently, effectively and speedily deal with the bollworm problem.

Our enquiries revealed that none of the local CSOs[162] have initiated or taken part in anti-GM action. They cited the lack of financial resources and technical expertise as the major constraints for their non-involvement in issues relating to agricultural biotechnology, rather than lack of interest and concern.

One of the farmers said that in order to test if there was any truth in the assertion by activist CSOs that Monsanto (through Mahyco) was introducing ‘terminator technology’, he had replanted the seeds from the ‘first generation’ Bt-cotton trial harvest and found that the ‘second generation’ plants grew well and yielded a crop (albeit a smaller one than the original), thus negating the CSOs’ assertion. (Incidentally, one wonders whether this farmer and his colleagues had been informed by Mahyco and the monitoring team that re-sowing was strictly illegal until Bt-cotton had been cleared for general commercial release by GEAC. One can reasonably assume that the re-sowing is very unlikely to have been an isolated incident and that it would have taken place fairly widely among the trial farmers not only in Karnataka but also in the other four states where the trials took place.)

It was most revealing to find out that the farmers had not been obliged either by Mahyco or by monitoring committee to destroy the Bt-crop and the post-harvest residues *on site* after the trials were over. Instead, they were permitted to harvest the Bt-crop and sell it on the market, feed the post-ginning BT-cotton seeds to their livestock and use the Bt-cotton stalks as household fuel. The farmers were clearly pleased with this arrangement, especially as they had not incurred the expense of paying for the Bt-seeds (nor presumably for the pesticides sprayed). This of course was a clear violation of not only the prevailing biosafety regulations but also the conditions that RCGM/DBT and GEAC/MoEF had attached to the Mahyco trials. It was extraordinary to discover that Mahyco’s trial Bt-cotton had reached the market (albeit in very small quantities), either by default or by negligence on the part of Mahyco and the monitoring committee, in clear breach of the regulations. This raises the valid and disturbing questions of whether (i) RCGM/DBT and GEAC/MoEF were aware of how the trials were actually being conducted not only in Karnataka but also in Andhra Pradesh, Haryana, Maharashtra and Tamil Nadu, and (ii) took steps to cross-check the veracity of the field trial reports submitted by Mahyco.

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[162] The Bharat Agro India Foundation (BAIF), the Institute for Studies in Agriculture and Rural Development, the Institute of Development Studies and the Agriculture Science Foundation. They are based in the districts of Dharwar, Gadag and Haveri. BAIF, which is headquartered in Pune in Maharashtra State, works in the villages of eight states.

7.7.1 The setting-up, composition and work of the monitoring committee

The biosafety regulatory regime stipulates that field trials be monitored by experts who are independent of the company conducting the trials. However, DBT apparently allowed Mahyco to take the initiative in setting up the monitoring committees, permitting the company to identify and draft members into the committees[163]. The monitoring committees comprised only natural science (biotechnology-related) and agricultural science (including agronomy, i.e. farm-level economy) specialists, *with social science disciplines, and CSO representatives excluded* *(see the Appendix in Section 7.1.10 below for a list of the members and their professions comprising the monitoring committee sent to Karnataka).* Our team conducted interviews with two members of the committee that monitored the trials in Karnataka, both of whom are agricultural science specialists from the University of Agricultural Sciences in Dharwad (UASD).

Out of the 37 farms in Karnataka where the trials were conducted, Mahyco picked only five for monitoring by the committee, which concentrated on four tasks: Measurement of (i) reduction in pesticide use, as determined by the number of sprayings (ii) pest-load (i.e. number of pests per bole) (iii) the tolerance capacity of the plants to pest-incidence and (iv) the yield potential of the three types of plots (Bt, non-Bt and check). The committee also checked whether the layout of the trial plots conformed to the pattern prescribed by DBT (see the section above).

Our interviews with some senior scientists at the UASD, officials in the DoA/KSG and representatives of local CSOs, elicited the following information, views and critique:

- Mahyco's strong lobbying of the authorities in New Delhi and Bangalore may have unduly influenced the composition and working of the monitoring team, which raises questions about the team's independence.
- It is unclear who paid the expenses incurred by the team during the field monitoring visits. It was alleged by some interviewees that Mahyco "looked after and provided hospitality to the team".
- The team was not present during the sowing process, but began its work only after the plants were well grown and the pesticide sprayings had begun. In other words, the farmers did the sowing without the team's oversight. It is unclear whether Mahyco's representatives were present during the sowing and the spraying processes.
- The team's visits to the trial plots were limited to about one a month. It is alleged that its work was desultory and its checking of the technical details (see the four tasks mentioned above) was not rigorous.
- The team concentrated on agronomic aspects that had a direct bearing on the yield, i.e. frequency and intensity of pesticide spraying, pest-load and pest-migration. No attention seems to have been paid to other crucial biosafety aspects contained in the biosafety regulations, e.g. ecology (e.g. GM-pollen-drift, GM-pollen-contamination and gene-flow), agricultural biodiversity, animal health safety (use Bt-cotton seeds as animal feed) and socio-economy. We have not been able to verify the validity of these and other remarks pertaining to the work by the monitoring teams, as the reports submitted by Mahyco to GEAC have not been made public.

7.7.2 The Role of the Karnataka State Government (KSG) and the state government funded Universities of Agricultural Sciences (UASs)

The postures maintained by the Karnataka State Government (KSG), through its Department of Agriculture (DoA/KSG) and higher instances, about the Bt-cotton trials and generally about GM-crops, seems to have been rather confused and contradictory. When DBT went ahead and approved the Mahyco trials, merely informing the KSG about the move, the KSG felt very offended at being by-passed by the central authorities and forbade the trials. But when, spurred by this ban, DBT got in touch with the KSG and explained the background and the process leading up to the approval, the

[163] Interviews at DBT, New Delhi

KSG withdrew its ban without much ado[164]. As the trials went on, the KSG and the state-funded UASs, expressed their dissatisfaction with the narrowness of the agronomy-focused terms of reference (ToR) issued to the monitoring committee by DBT and GEAC. They would have liked much wider ToR, encompassing issues that would have had a bearing on the active promotion of GM-crops, on which the KSG had meanwhile become very keen[165].

Notwithstanding its dissatisfaction with the conduct of the trials, the KSG expressed its concern at the delay by the GEAC in arriving at a decision, urging it to approve the Bt-cotton hybrids for commercial release. This apparently contradictory stance becomes understandable, if one notes the explicitly stated policy goal of the KSG to put the state at the forefront of biotechnology development and application in India, at a par with the status that the state, in its capital city Bangalore, has acquired in information technology. This ambition covers all the three sectors of biotechnology: agricultural, medical and industrial.

Given this keenness to make Karnataka the leading state in agricultural biotechnology, it is surprising that the KSG did not actively participate in the preliminaries leading to and the actual implementation of the trials, including the process of monitoring, instead of leaving the process entirely to Mahyco, DBT and GEAC/MoEF. In fact, agriculture being the preserve of the state governments and not the GoI, new crops cannot be launched on the market within Karnataka's boundaries without the explicit authorisation by KSG. Equally, no programme for introducing a new crop is likely to succeed in Karnataka, without the active involvement of its extension services.

Karnataka is one of the very few states to have formally set up a District Level Biosafety Committee (DLBC), as required by national biosafety regulations. The DLBCs have legally mandated powers, duties and responsibilities with regard to monitoring and ensuring the implementation of biosafety regulations within the states' boundaries (see Section 5 above of the present study).

In Haveri, the district in which our field study was carried out, our research team met and talked to the Joint Director of Agriculture, the District Health Officer and a Commissioner of the Municipal Corporation, who are all supposed to be members of the DLBC, according to a directive by the KSG. They said that none of them were involved in the processes leading up to the field trials of the Bt-cotton and their aftermath. Let alone that, they maintained that they were neither aware of the formation of the DLBC, nor of their induction into it by the KSG! Mystified, they checked with their junior staff, who confirmed that their departments had received *no* notification from the state government about the formation of the DLBC. (One wonders if the same applies to all other districts of the state, not only in Karnataka, but also in Andhra Pradesh, Haryana, Maharashtra and Tamil Nadu, where the trials took place. It ought be in the national interest for RCGM/DBT and GEAC/MoEF to find out.) So it seems as though the drive to promote biotechnology has not yet got beyond the policy statement level in Bangalore.

Following the approval by GEAC in March/April 2002, Mahyco-Monsanto put the three approved hybrids on the market. Farmers in Karnataka, as in a few other states, began sowing them. Meanwhile, a research report from China was made public in May 2002 indicating that bollworms were very likely to develop resistance to Bt-cotton within a period of eight to ten years[166]. At this, activist CSOs based in Bangalore and New Delhi raised the alarm again, which resulted in the KSG imposing a temporary moratorium on the planting of Bt-cotton[167].

7.8 Claims, controversy and confrontation about Bt-cotton performance

Mahyco-Monsanto's three Bt-cotton hybrids (MECH 12, 162, and 184) were approved by GEAC/MoEF in March/April 2002 for commercial release. They were put on the market soon

[164] Interviews at DBT, New Delhi
[165] Interviews in Bangalore and Dharwad
[166] Report by the Nanjing Institute of Environmental Sciences and the State Environmental Protection Administration of China
[167] "Bt cotton under fire after bad news from China", Deccan Herald, Bangalore, 6 June 2002.

thereafter at *four times* the price of the traditional non-Bt varieties. It is estimated that about 55,000 farming households, spread over Andhra Pradesh, Gujarat, Karnataka, Madhya Pradesh, Maharashtra and Tamil Nadu, planted the Bt-varieties on a total acreage of about 42, 000 hectares[168] (an average of less than one hectare per farming household, an indication of how very small the land holdings of Indian farmers are!). The Bt-cotton was harvested in November/December 2002 (the first legal commercial one in India, in contrast to the 2001 harvests from the illegal Navbharat 151 seeds).

During 2002, the first year of Bt-cotton's *legal* commercial cultivation, its acreage was about 38,000 hectares, which rose to about 92,000 hectares in 2003, representing 0.4 and 1 percent, respectively, of the all India total cotton acreage of 9.1 million hectares. However, according to Mahyco, its sales had risen very sharply in 2004 to a level that would cover about 1.2 million acres [169].

Mahyco-Monsanto Biotech (MMB) claims that the Bt-yields per unit of land sown were substantially higher than the traditional non-Bt ones and that the farmers have accordingly derived considerably greater net returns from their Bt-harvests than from the traditional ones[170]. We recall that the monetary gains are predicated on Bt-cotton's resistance to the bollworm and the associated reduction in pesticide spraying. According to MMB, in the southern states of Andhra Pradesh, Karnataka and Tamil Nadu, the sowing of Bt-cotton had reduced pesticide use by up to 70 per cent, led to yield increases of about 30 per cent and resulted in additional net income of Rs 7,000 per acre (Rs. 17,500 per hectare)[171].

In early 2003, India's leading GM-activist CSO Gene Campaign published the results of an extensive field research study it had conducted in late 2002 in two states (Andhra Pradesh and Maharashtra) into the comparative performances of Bt and non-Bt cotton harvests (see the section below). The study's main conclusion is that the yields of, and economic benefits from, Mahyco's Bt-cotton varieties, at the farm level, are not higher than in the non-Bt cases (see Section 7.1.8.2 below). Prompted perhaps by the findings of Gene Campaign, MMB commissioned a study by the Indian subsidiary of the Netherlands based international marketing research firm AC Nielsen Org-MARG. The Nielsen field surveys, which were conducted in five states (Andhra Pradesh, Gujarat, Karnataka, Madhya Pradesh and Maharashtra) in late 2003, support MMB's claims about the benefits accruing from its Bt-cotton varieties. The Nielsen conclusions, in summary, are as follows [172]:
- Bt-yields are approximately 30 percent higher (up from non-Bt's 600 kg per acre to Bt's 770 kg)
- Net profits per acre are about 80 percent higher
- Number of anti-bollworm pesticide sprayings cut down by two or three, per season, resulting in an average saving of about Rs 1300 per acre

In a paper published in November 2004, four researchers working at Mahyco (*Barwale at al* [173]) report their findings on increases in yields and farm incomes, and decreases in pesticide sprays, attendant on Bt-cotton cultivation, and their estimates for the growth in Bt-cotton acreage over the period 2002/2003 – 2004/2005. Their surveys cover the crop harvested at the beginning of the winter of 2002 (i.e. at the end of the 'kharif' season of June-December 2002) in a total sample of 1069 farms in six states: Andhra Pradesh, Gujarat, Karnataka, Madhya Pradesh, Maharashtra and Tamil Nadu. They found that the yield *(weighted average over all the farms)* was higher by about 60 percent (from 1325 kilograms of non-Bt to 2135 kilograms of Bt, *per hectare*) and the farm income had risen by approximately 18,000 Rupees *per hectare*, while the number of insecticide sprays had fallen from about three sprays to one spray (the averaged decrease in number of sprays shows a spread of 1.33 in

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[168] See Asha Krishnakumar's article " A lesson from the field" in the magazine Frontline, May 24 – June 06, Vol 20, Issue 11 (published by the national daily newspaper The Hindu), www.flonnet.com
[169] "Farmers are too impatient to wait for government approval", K.S. Jayaraman, Nature Biotechnology 22, 1333 – 1334, Nov. 2004. www.nature.com/nbt
[170] See the article in Times of India, 12 March 2003, that presents the views of Mahyco-Monsanto by the company's spokesperson, Ms Ranjana Smetacek
[171] See Asha Krishnakumar, *op cit*
[172] Contact for detailed information: Ranjit Panda of ACNielsen ORG-MARG at ranjit.panda@orgcsr.org.
See also http://www.cropdecisions.com/show_story.php?id=24256
[173] Barwale, R.B., Gadwal, V.R., Zehr, U., & Zehr, B. (2004). Prospects for Bt cotton technology in India. *AgBioForum*, *7*(1&2), 23-26. Available on: http://www.agbioforum.org/.

Gujarat to 2.73 in Andhra Pradesh). The total all India acreage planted with Mahyco's three Bt-cotton hybrids in 2002/2003 was about 38,000 hectares and estimated acreages for 2003/2004 and 2004/2005 are about 92,000 and 560,000 hectares, respectively.

The increases in yields and farm incomes, and the decrease in bollworm sprays, reported by the Mahyco *(Barwale et al)* team and the Nielsen team have also been observed by a group of researchers from the University of Reading, U.K (*Bennett et al*[174]). The study by the Reading team compares the commercial harvests of Mahyco-Monsanto's three Bt-cotton hybrids and several non-Bt varieties[175] grown, for the most on the same farms, in 16 districts of the state of Maharashtra during 2002 and 2003. Their data come from random samples of 2709 farms in 2002 and 789 farms in 2003, from a total of 1275 villages. The results are summarised in the table below.

Table Yields, costs and income using Bt cotton in India

	2002	2002	2002	2003	2003	2003
	Bt	**Non Bt**	**Difference**	**Bt**	**Non Bt**	**Difference**
Yield, in tonnes per hectare	2.18	1.5	+ 45 %	2.25	1.38	+ 63 %
Farm income (gross margin), in Rupees/ha	38,796	26,005	+ 49 %	50,904	29,279	+ 74 %
Number of Bollworm Sprays	1.44	3.84	- 63 %	0.71	3.11	- 77 %
Cost of seed, Rs./ha	3,773	1,137	2,636	3,684	1,163	2,521
Cost of seed +insecticide, Rs./ha	5,805	5,061	744	5,451	5,337	114

7..8.1 Mahyco-Monsanto's claims disputed

The positive claims made by Mahyco-Monsanto have been strongly disputed by GM-activist CSOs, in particular by Gene Campaign, which has carried out comparative field research on the November/December 2002 Bt and non-Bt harvests in Andhra Pradesh and Maharashtra (see below). Remarks by state government officials in, and press reports from, Andhra Pradesh, Gujarat and Madhya Pradesh have expressed concern that the 2002 Bt-cotton harvests have 'under performed', that the Bt-plots have not been able to contain the bollworm attack and that the Bt-varieties have been much less resistant to drought than the traditional non-Bt varieties (large parts of India suffered from drought in 2002)[176].

A clear assessment of the performance of Mahyco-Monsanto's Bt-hybrids under *real-life commercial cultivation conditions by farmers* (as opposed to the 1999-2001 field trial cultivation under controlled conditions[177]) has been considerably complicated by several things: in some areas farmers have also sown the first and second generation illegal Navbharat 151 Bt-cotton seeds, along with the Mahyco-Monsanto seeds; most farmers have by and large ignored the GEAC-stipulation to create *refugia* (on at least 20 percent of Bt-sown area); and many farmers have not been able to access the requisite magnitudes of irrigation and other inputs into cultivation, at the optimal times, that the Mahyco-Monsanto seeds are designed for[178].

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[174] R.M. Bennett, Y. Ismael, U. Kambhampati and S. Morse, (2004), Economic Impact of Genetically Modified Cotton in India, AgBioForum, 7(3): 1-5. http://www.agbioforum.org/.
[175] The Bt hybrids were MECH-12, 162 and 184, and the popular non-Bt varieties included Bunny, Tulsi, NHH-44 and JK-666.
[176] see www.gene.ch/genet/2002
[177] See C Kameswara Rao, Foundation for Biotechnology Awareness and Education Bangalore, and www.genecampaign.org, news item dated12 March 2003, for the controversy generated by the field trial yield claims made in the paper by Qaim, M., and Zilbermann, D. Yield of genetically modified crops in developing countries. Science, 299: 900-902, 2003.
[178] www.gene.ch/genet/2002

The sale and planting of illegal Bt-cotton seeds is by now widespread and expanding rapidly, with central and state governments either being unable or unwilling to stop the practice. Some reports estimate that by 2004 about half a million acres in Gujarat had been sown with illegal seeds. Apparently, the illegal seeds being produced in 2004 in Gujarat and Andhra Pradesh in seed breeding farms of the size of 8000 and 4000 acres, respectively, are enough to cover about 2.2 million acres (about 900,000 hectares). The main reason for the market success of the illegal seeds is their lower price, about 600 rupees for a packet of 450 grams compared to 1600 rupees of the legal Mahyco varieties [179].

The Parliamentary Standing Committee on Agriculture has asked the GoI to re-evaluate the economic viability of Bt-cotton. Complaints from the state of Madhya Pradesh in central India obliged GEAC/MoEF to dispatch a team of seven scientists to evaluate the performance of the Mahyco-Monsanto hybrids sown by local cotton farmers. The team reported that while the Bt-cotton crop had largely failed "due to wilting and drying at the peak bolling stage", the traditional non-Bt crops had fared better (a consequence perhaps of the Bt-cotton's greater vulnerability to drought?). On a similar vein, a six-member team appointed by the Rajasthan state government came to the conclusion that Bt-cotton "is unfit for cultivation (in the state) and should be banned". In Andhra Pradesh, the official team charged by the state government to investigate complaints by local cotton farmers came to the conclusion that Bt-yields and Bt-fibre quality were indeed lower than the non-Bt ones. In response to claims for compensation by the Andhra Pradesh farmers, MMB is reported to be willing to "compensate farmers only for (proven) failure of (MMB Bt-seeds) to germinate and (proven lack) of genetic purity of (MMB Bt-seeds), and not for yield losses"[180] (see Section 7.1.8.2 below for more on the compensation question).

Meanwhile, GEAC/MoEF has turned down Mahyco-Monsanto's application for the commercial release of MECH 915 in the states of Punjab, Haryana and Rajasthan.

7.8.2 Findings from Gene Campaign's field studies in Andhra Pradesh and Maharashtra

Gene Campaign is India's leading GM-activist CSO based in New Delhi. It has access to a network of scientists and activists spread across the country. In late 2002 and early 2003, its research staff, together with scientists from the Agricultural University in Hyderabad (state capital of Andhra Pradesh), conducted a field study of the first commercial harvests of Mahyco-Monsanto's Bt-cotton varieties in Andhra Pradesh and Maharashtra. A total of hundred farms (picked by statistical random sampling) were covered by the survey, 75 in Andhra Pradesh and 25 in Maharashtra. The farms grew both the Bt and the traditional non-Bt varieties. The study's findings, which have been published in an Indian social science journal[181] and also presented to the media[182], are summarised below. They are rather startling and in stark contrast to the findings reported by the Mahyco, Nielsen and Reading teams, and concludes:

- The Bt-cotton yields (average per acre of the MECH 162 and MECH 184 varieties), across all size categories of land holdings, were about 15 percent lower than the non-Bt cotton varieties.

- The Bt-cotton was of lower quality (in terms of length and strength of fibre) than the non-Bt varieties, and given grades B and C, whereas the non-Bt were graded A and B.

- On an average, the Bt product fetched Rs. 300 per quintal less than the non-Bt variety on the market

- The average *net* returns from the Bt-varieties, from all size categories of land holdings, were on lower than the returns from the non-Bt varieties. The farm economics worked out follows:

[179] K.S. Jayaraman, Nature Biotechnology 22, 1333 – 1334, Nov. 2004. www.nature.com/nbt
[180] See Asha Krishnakumar, *op cit*
[181] Suman Sahai and Shakeekur Rahman: Performance of Bt-cotton , Economic and Political Weekly, Mumbai, July 26, 2003, Vol 38 No 30
[182] ; www.genecampaign.org news dated 12 March 2003, 16 June 2003, 5 and 8 August 2003

- Bt-seeds were about four times the price of the 'best' local non-Bt seeds, the difference in price approximating to Rs. 1200 per 450 gm bag.

- Savings on pesticide averaged to about Rs. 220 per acre.

- The investment per acre on Bt-cultivation was, on an average, about Rs. 980 more than on non-Bt cultivation.

- About sixty percent of the farms sustained a loss of about Rs 80 per acre of Bt-cotton

- While the Mahyco-Monsanto Bt-varieties were indeed lethal to the *green* bollworm, they were not to the *pink* bollworm. With competition from the green bollworm eliminated, the pink ones flourished, to the detriment of the crop yield.

Gene Campaign's investigation confirms[183] that state-level and district-level biosafety committees have **not** been set up in Andhra Pradesh and Maharashtra. Despite this, commercial cultivation of a GM-crop (Bt-cotton, in this case) has been permitted in these two states by the respective state governments. This is a breach of the national biosafety regulations, legislated under. The moot questions are, first, whether GEAC/MoEF should have approved the commercial release of Bt-cotton without first ensuring that state and district level biosafety committees had been set up in all cotton growing states, and second, whether, in not doing so, GEAC/MoEF is in breach of the national biosafety regulations legislated under the Environment Protection Act of 1999.

Based on the findings of its field research, Gene Campaign has demanded that Mahyco-Monsanto pay monetary compensation to those farmers who have suffered financial losses as a result of sowing Mahyco-Monsanto's Bt-cotton seeds. This demand is being made under *Section 39.2 of the Protection of Plant Variety and Farmers Rights Act 2001*, which states that "Where any propagating material of a variety registered under this Act has been sold to a farmer or a group of farmers or any organization of farmers, the breeder of such variety shall disclose to the farmer or the group of farmers or the organization of farmers, as the case may be, the expected performance under given conditions, and if such propagating material fails to provide such performance under such given conditions, the farmer or the group of farmers or the organization of farmers, as the case may be, may claim compensation…." [184]

7.8.3 Protests, demonstrations and campaigns

A coalition of Indian GM-activist CSOs, led by the Indian branch of the international CSO Greenpeace, demonstrated at Monsanto's research centre in Bangalore, in March/April 2003. The demonstrators demanded that Monsanto withdraw its Bt-cotton from the Indian market alleging that the poor yields from the first year's (2002) planting belied Monsanto-Mahyco's claims that BT-seeds would lead to dramatically higher yields. The protestors have demanded that Mahyco-Monsanto compensate the farmers for the poor yields. Further, they asserted that Bt-cotton constitutes a potential risk to environmental safety and that Monsanto's long-term strategy is to dominate Indian agriculture[185].

In July 2003 a sustained campaign was launched in Warangal District of Andhra Pradesh by a coalition of twenty-five local CSOs from six cotton growing districts in the state[186], of the with the aim of demonstrating that the 2002 Bt-cotton harvest was a failure. It covered every village in the district, showing videos of cotton fields, backed up with still photographs and printed brochures. The campaign's claims echoed the Bangalore ones, alleging in addition that Monsanto-Mahyco was aiming

[183] As until August 2003
[184] ; www.genecampaign.org news dated 5 and 8 August 2003
[185] www.biospectrumindia.com
[186] Karimnagar, Kurnool, Mehbubnagar, Nalgonda, Ranga Reddy and Warangal

at eliminating local Indian seeds from the market, then increasing the already high price of their Bt-cotton seeds and intending to introduce “terminator technology” sometime in the future. The campaign called for a boycott of Monsanto-Mahyco seeds by local cotton farmers and the withdrawal of the approval given to Monsanto-Mahyco to market the seeds in the state by the Andhra Pradesh State Government[187].

7.1.9 Conclusions

Bt-Cotton is the first genetically modified crop (GM-crop) to be commercialised in India. Our research into the various stages of this process raises some serious questions about the structure and implementation of India’s biosafety regulatory regime, and the roles played by the main stakeholders in the government, the private sector, the public sector R&D establishment and civil society.

The Indian national biosafety regulations (of 1999 1998, 1994 and 1990) fall under the Environment (Protection) Act of 1988 and are therefore legally binding on all institutions involved in GM-related activities, whether in the government or outside it. It is therefore legally incumbent on the biosafety regulatory authorities at the national, state and district levels to fully implement the procedures and measures spelled out in the regulations to ensure that GM-crops do not pose risks to environmental (ecological), health (human and animal) and socio-economic safety.

Since GEAC/MoEF approved the Monsanto-Mahyco Bt-cotton hybrids for commercial release in March/April 2002, one assumes that GEAC would have ensured environmental (ecological), health (cotton seed as animal feed) and socio-economic safety through extensive and rigorous monitoring of Monsanto-Mahyco’s multi-locational and large-scale field trials in five states. However, our field research into the monitoring process conducted on Monsanto-Mahyco’s field trials in a district in Karnataka shows that the monitoring in that district was cursory and very narrowly focussed on only some technical measurements of bollworm-load, frequency and magnitude of pesticide spraying, bollworm migration into non-Bt plots and Bt- and non-Bt yields. We found no evidence of any monitoring of a whole host of other features and indicators that the three broad areas of safety mentioned above dictate. To check whether these lacunae were limited to the district we studied or were generic to all the field trials conducted by Monsanto-Mahyco, one needs to examine in detail the field trial reports submitted by Monsanto-Mahyco to GEAC. But GEAC has neither put these reports, nor the details of its deliberations that led to the approval of Monsanto-Mahyco hybrids, in the public domain, despite calls to that effect by GM-active civil society organisations (CSOs) and sections of the media. Until this is done, big question marks will continue to hang over the legitimacy of the approval process.

The exclusion from GEAC, RCGM, MEC, and the field monitoring teams of independent representatives of the social science research community and the GM-active CSOs causes grave concern. Any process of biosafety scrutiny that wants to be taken seriously by the broad public must necessarily include such representation. In the context of the Monsanto-Mahyco’s field trials and approval process, this exclusion is compounded by the fact that RCGM and GEAC in practice (although perhaps not in formality) handed the tasks of setting up the monitoring teams and the directing of the teams’ work to Monsanto-Mahyco. Needless to say, this has undercut the credibility and legitimacy of the field trials and the approval process. In addition, this raises the question of whether the biosafety regulatory authorities were not in breach of the provision in the biosafety legislation that the monitoring teams be entirely independent of the parties whose GM-crops are being assessed.

The biosafety regulations call for the close involvement of state and district level biosafety committees in the monitoring of the field trials and subsequent commercialisation of GM-crops. Approval to conduct field trials of Bt-cotton should have been contingent on this provision being met. This has

[187] www.indianfarmers.org

clearly not happened. The committees have either not been set up (e.g. Andhra Pradesh and Maharashtra) or been limited merely to dysfunctional paper exercises (e.g. Karnataka). On what legal basis did RCGM and GEAC feel secure enough to ignore this aspect in giving the go ahead to Mahyco-Monsanto? Are not the state governments themselves also completely remiss in not abiding by the legally mandated provisions of the biosafety regulations?

As the Navbharat episode has demonstrated, the central biosafety regulatory authorities have no effective means of keeping themselves informed of what is going on in the various states in the GM-arena and of taking direct punitive action against parties that flout the biosafety regulations. Navbharat has exposed the profound limitations in the functioning of the current biosafety regulatory regime. Have the central and state authorities begun to seriously address this challenge?

We recall that Monsanto approached the DBT in 1991 with the proposal that it facilitate R&D collaboration on Bt-cotton with Indian public-sector research institutions. One of the apparent reasons behind DBT's unwillingness to take up this offer was the case made by some public-sector research institutions that they were well on the way to innovating Bt-cotton on their own. In the event, this claim turned out to be unrealistic and the expected indigenous innovation never materialised[188]. And the upshot was that Monsanto teamed up with Mahyco.

The universities of agricultural sciences (UAS) have missed very valuable opportunities for acquiring some hands-on experience of the 'lab to the market' process by not actively lobbying DBT, ICAR and the state governments for the right to be closely involved in the designing and execution of the Mahyco-Monsanto and RASI field trials. The UASs, after all, have standing and ready access to extensive and well-endowed field trial and extension infrastructure (including staff), thanks to the generous and long-term support by ICAR and the Departments of Agriculture of the state governments.

Given the deeply sceptical attitude of the public sector R&D establishment and the GM-activist CSOs to the private sector actors in GM-agriculture, one would have expected Mahyco-Monsanto and RASI to put into the public domain all the steps they have taken in getting their seeds approved, in particular all the data and information they have submitted to RCGM and GEAC. In addition, it would have been in their own long-term interest to actively maintain a process of dialogue and discussion, on the basis of transparent sharing of information, with these two stakeholder groups. On the contrary, the private sector actors have chosen to ignore the public stakeholders, and when forced by parts of the media to address the public stakeholders' legitimate concerns, have responded with palliative public relations exercises. They ought not be surprised at the severe backlash this tactic has generated.

The threats and militant action that some GM-activist CSOs have directed at the cotton farmers who took part in the field trials, and their attempts to engender unsubstantiated fear of GM-crops in the public at large, has generated counter-productive hostility to the CSOs among all the other stakeholders, e.g. sections of the farming community, the biosafety regulatory authorities, the private sector GM-seed companies, the public sector R&D establishment and parts of the media. Such methods are unlikely to generate *sustained and sustainable* public awareness and public involvement. Rather, the public would be better served and the CSOs goals promoted, if the CSOs devoted themselves to non-polemical and entirely fact-based presentations of biosafety issues, *from their own perspective*, to the public and leading opinion-makers who appear in the media. Meanwhile, the CSOs must make every effort to be represented on GEAC, RCGM and MEC, insisting that the views of the concerned public be seriously taken into account in the deliberations of the biosafety regulatory authorities.

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[188] The reasons for the inability of Indian public-sector research institutions to bridge the gap between R&D and innovation in GM-agriculture have been explored in an earlier section of the present study

7.1.10 Appendix 3

The following has been reproduced from the copy of the DBT's Office Memorandum No.BT/BS/16/08/98-PID, dated 12 January 2001, that our team obtained from DBT. The subject of the Memorandum is the composition of the Monitoring Team constituted by the Monitoring-cum-Evaluation Committee (MEC) in the DBT.

In accordance with the permission given by the GEAC of the MoEF through their letter NO.10-11/2000-IIMSD dated 19.7.2000 for conducting large scale field trials of Bt-cotton by M/s Mahyco Ltd., Mumbai during the Kharif season 2000-2001 in the country and the directions given in the above letter of permission, the MEC constituted in the DBT has constituted 8 monitoring teams for monitoring the large scale field trials of Bt-cotton. The objectives of the large scale field trials and replicated field trials of Bt-cotton are given below:

Large Scale field trial

i) to generate information on yield and insect infestation on Bt-cotton hybrids and their non-Bt counterparts.

Replicated field trials

ii) to evaluate and compare the insect infestation levels of lepidopteron pest load (Bollworm complex) among Bt-cotton hybrids and their non Bt-counterparts

iii) to assess the yield and fibre quality from Bt-cotton hybrids and their non Bt counterparts

iv) to evaluate the insect infestation levels of secondary lepidoptera of cotton (spodoptera litura (tobacco caterpillar), anomis flava (cotton semilooper) and sylepta derogata(leaf roller)

Following is the composition of the Monitoring Team-V that was sent to monitor the field trials in Karnataka:

1. Dr.H.Sekhar Shetty – Leader
   Professor, Downy Mildew Research Laboratory,
   Dept of Studies in Applied Botany,
   Univ of Mysore, Manasagangotri, Mysore 570 006.
2. Dr.P.K.Ghosh, Adviser, DBT – Official Member
3. Dr.M.S.Kairon, Former Director -- Member
   Central Institute of Cotton Research, Nagpur
4. Dr.Nanjappa, Agronomist--- Member
   Univ of Agricultural Sciences, GKVK, Bangalore
5. Dr.A.Nazir Ahmed Khan, Pathologist ---- Member
   Univ of Agricultural Sciences, GKVK, Bangalore
6. Dr.Puttaswamy, Entomologist --- Member
   Univ of Agricultural Sciences, GKVK, Bangalore
7. Dr.Vijay Kumar Giddannavar, Agronomist ---- Member
   UAS, Belgaum Road, Dharwar
8. Dr.Anna Hosur, Pathologist ---- Member
   UAS, Belgaum Road, Dharwar
9. Dr.S.Lingappa, Entomologist --- Member
   UAS, Belgaum Road, Dharwar
10. Dr.B.M.Khadi, Sr.Cotton Breeder --- Member
    Agriculture Research Station, Hebballi Farm, Dharwar
11. Dr.J.Nidagundi, Asst. Cotton Breeder --- Member
    Agriculture Research Station, Sirguppa
12. Dr.Laxmi Raghupati, ADG/Nominee – Official Member
    MoEF, New Delhi

State Govt./ district officials inducted in the monitoring team:

District officials from the state are inducted in the monitoring team to accompany the team while visiting the experimental plots in their respective districts.
Davangere – Shri.H.M.Purushotamappa, JDA, RMC Yard, Dist. Davanagere
Raichur – Shri.Y.B.Patil, DDA, Dept of Agriculture, Raichur
Koppal – Shri. Ramachandrayya, DDA, Dept of Agriculture, Koppal
Bellary – Shri.M.Narayana Reddy, JDA, Dept of Agriculture, Bellary.

Terms and conditions of the site visiting team:
1. the monitoring team shall undertake field visits at the experimental sites in the districts i.e., Davanagere, Raichur, Koppal, and Bellary in the state of Karnataka
2. the monitoring team shall confirm that the large scale field trials and replicated trials are being conducted on bt cotton by M/s Mahyco ltd, Mumbai as per the conditions given in the experimental trials permit issued by the DBT.
3. the monitoring team shall also confirm that the company is collecting data on the objectives of contained ltd open field trials on bt cotton as is mentioned above. The observations may be recorded in the proforma devised by the dept for this purpose.
4. the monitoring team may advise minor modifications in the collection of data based on the prevailing situation at the site of experimentation.
5. the monitoring team shall submit its report to the MEC on conclusion of the visits
6. the monitoring team shall maintain all the information provided by the company and/or collected by the team as confidential
7. the committee shall function for a period of 3 months from the date of notification
8. TA/DA (i.e. travel and living expenses) incurred for undertaking the field visits, shall be reimbursed by the DBT as per the govt rules and regulations to the non-official members of the team.

Issued with the approval of Secretary, DBT.
Signed: T.V.Ramanaiah, Scientist-F

8. TRANSGENIC RICE IN INDIA

8.1. Introduction

Rice and wheat are the main staple cereals in India. Until the mid-1970s, India was often subject to serious shortages in the production of these two cereals, caused by climatic, economic and social reasons, resulting in periods of famine. The turnaround came with the introduction into India of *high-yielding varieties* of rice and wheat, developed during the 1960s in the International Rice Research Institute (IRRI) in the Philippines and the International Maize and Wheat Improvement Center (CIMMYT) in Mexico. Based on the technology transfers from these two publicly funded international agricultural research centres[189], a number of public sector agricultural research institutions in India in turn developed *high-yielding local cultivars* (HYLCs) of rice and wheat. This effort was led by the Indian Agricultural Research Institute (IARI) at Pusa in Delhi, and was funded by the central government's Indian Council for Agricultural Research (ICAR)[190].

8.1.1. The "Green Revolution" in India

In order to realise the inbred high yielding potential, the HYLCs had to be cultivated with optimal 'inputs' of chemical fertilisers, pesticides and herbicides, and irrigation, at optimal periods during the growing season. Sustained and massive efforts by agricultural extension services of state governments, backed up by substantial subsidies by the central and state governments to enable farmers to afford the above-mentioned 'inputs', resulted in dramatic increases in production. The promotion of HYLCs went hand in hand with government pricing and distribution policies[191] that ensured (i) the producers a reasonable procurement price by the authorities, (ii) the building up of large reserve stocks of staple cereals by the public sector grain procuring and distributing agencies, and (iii) fair-priced sales, through retail traders, from the public sector stocks to urban and rural consumers. This radical transformation of rice and wheat agriculture, with its specific combination of technological, economic and social policies, constitutes the *Indian version* of the Asian and Latin American *"Green Revolution"* [192]. As from the mid-1970s onwards, it resulted in (i) production increases by several factors, (ii) fairly reliable access to rice and wheat at affordable prices by most income categories (though perhaps not by the very poor and the entirely marginalized), and (iii) in the prevention of large-scale famines.

While the extensive HYLC research and development (R&D) programme was funded by ICAR, including the large-scale, multi-locational field trials of the new varieties[193], the demonstration of the HYLCs among the local farming communities was carried out by the state governments' agricultural extension services. The commercial production and marketing of the high-yielding seeds were undertaken by a large number of both public sector and private sector seed companies, who were given free and ready access to the HYLC- innovations and technical know-how by the public-sector R&D establishment and ICAR.

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[189] Through its support of research into agricultural technology from the 1940s onwards, starting in Mexico and then extended to other countries, the Rockefeller Foundation has played a pioneering role in helping to bring about the "Green Revolution" of high yielding varieties of maize, rice and wheat. In the 1960s, the Rockefeller and the Ford Foundations together helped to establish the first four international agricultural research centres (IARCs): CYMMIT in Mexico, IRRI in the Philippines, the International Centre for Tropical Agriculture (CIAT) in Colombia and the International Institute of Tropical Agriculture (IITA) in Nigeria. Beginning with these four centres, a group of international donor agencies (including, among a number of others, the Rockefeller and Ford Foundations, the World Bank, FAO and UNDP) launched the Consultative Group on International Agricultural Research (CGIAR) system of IARCs in 1971. The CGIAR is administered by the World Bank and currently comprises 16 IARCs spread over Africa (4), Asia (5), Latin America (3), the Middle East (1), Europe (2) and the USA (1). www.rockfound.org and www.cgiar.org

[190] While ICAR is the main funder of the Indian public-sector agricultural universities and research institutions, which are spread widely over the country, the state governments also make substantial financial and infrastructural contributions, including the acreage at the disposal of the agricultural R&D establishment.

[191] The public sector Food Corporation of India (FCI) was set up in 1964, with the following objectives: "Effective price support operations for safeguarding the interests of the farmers; Distribution of food grains throughout the country for the public distribution system; and Maintaining satisfactory levels of operational and buffer stocks to ensure national food security" http://fciweb.nic.in

[192] For a variety of reasons (historical, climatic, economic, political, social and cultural), the "Green Revolution" never "took off" in sub-Saharan Africa, the exception being the large-scale commercial farms in South Africa and Zimbabwe.

[193] ICAR has a well established system of All India Crop Trials

8.1 2 The Limits of the "Green Revolution"

The overwhelming majority of farmers in India are smallholders owning not more than a hectare or two per household. A small minority of farming households can be very roughly designated, *in the Indian context*, as 'middle-scale' (between three and ten hectares) and 'large-scale' (above ten hectares) [194].

The economic and social impact of the Green Revolution on Indian farming communities has been mixed. While the 'middle-scale' and 'large-scale' farmers, and a great majority of the 'small-scale' farmers, have managed to benefit both economically and socially, a minority of the 'small-scale' farming households have become marginalized.

The environmental legacy of the Green Revolution is bleak. Decades of continuous chemicalisation and irrigation have led to serious and persistent environmental damage of soils and water bodies (e.g. salinity, persistence of pesticide and herbicide residues, emergence of resistant pests and weeds).

During the period 1970-1985, the yield per hectare by HYLC-rice varieties rose steadily (with dips caused by droughts), but then began to level off, reaching a plateau by the mid 1990s. The rise was fairly steep in predominantly irrigated areas (about 21 percent of the total rice acreage), but gradual in areas almost entirely dependent on the monsoon rains (45 percent), with a middle position taken by cultivation that was a mixture of the two (34 percent). As can be seen from the following table, the average yields in the three types of cultivation have levelled off at, respectively, 5.6, 1.9 and 3.1metric tons *(hereinafter 'tons')* per hectare. The following two tables give an indication of the differing yields for the three types, and the average yields recorded in 1997-98, in irrigated cultivation, in five states[195].

Average yields in tons per hectare
(averaged over the whole country)

Type	1970	1985	1995
Irrigated	2.3	5.2	5.6
Rain fed	1.3	1.6	1.9
Mixed	1.6	2.2	3.1

Source: A. Janaiah, see footnote 194

However, there is considerable variation in the productivity figures of individual states, as the following table indicates. For instance, Andhra Pradesh and Karnataka lead the productivity table at about 7 tons per hectare for irrigated cultivation, i.e. about a third higher than the national average.

Average yields in 1997-98, in predominantly
irrigated cultivation, in tons per hectare

State	Yield
Andhra Pradesh	7.2
Karnataka	7.0
Tamil Nadu	5.9
Orissa	5.7
West Bengal	5.1

Source: A. Janaiah, see footnote 194

Within the Indian context then, the highest yield that one can extract from the inbred HYLCs appears to be about 7 tons per hectare, provided cultivation occurs under predominantly irrigated conditions. It seems therefore that the route to increasing the total output of rice in the country, *within the framework*

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194 Indian agricultural reports tend to classify landholdings as follows: Marginal (less than 1 hectare); Small (1.0 to 2.0 hectares); Semi-medium (2.0 to 4.0 hectares); Medium (4.0 to 10 hectares); Large (10.0 and above)

195 Janaiah, A. (2002) Hybrid Rice for Indian Farmers: Myths and Realities, Economic and Political Weekly, Mumbai, October 19, 2002, Vol 37, Number 42, pp 4319-4328

of Green Revolution technology, would be to extend irrigation to the still non-irrigated areas. Implementation of irrigation schemes has been a constant and high priority feature, at both the central and state government levels, for over half a century. But it is a moot question whether one is not approaching a limit there as well. The huge expansion in tube well irrigation has led to alarming falls in groundwater tables in certain parts of country.

8.1.3 Stocks, exports, supply, demand and need: The nature of a possible future problem

As the table below shows[196], India is the second largest producer of rice in the world, after China. If one sets the 'best' Chinese and Indian production figures over the last few years, i.e. 139 million tons in 1999/2000 in China and 92 million tons in 2001/2002 in India, against the total available rice acreages of 32 million hectares (China) and 44 million hectares (India), one finds that the average yields per hectare turn out to be 4.3 tons in China and 2.1 tons in India. The striking difference in productivity by a factor of two is in part due to greater incidence of irrigation and the phenomenal success of hybrid rice cultivation in China (see below).

The main rice producing states in India are West Bengal, Uttar Pradesh, Madhya Pradesh, Orissa and Bihar. But Andhra Pradesh and Karnataka stand out among the states that have delivered higher productivity.

World rice production in 1999/2000 - 2002/2003 (milled basis), in thousand metric tons (referred to as 'tons' in our study)

Country	1999/2000	2000/01	2001/02	2002/03
China	138,936	131,536	124,320	123,200
India	89,700	84,871	91,600	80,000
Indonesia	33,445	32,548	32,422	32,500
Bangladesh	23,066	25,086	25,500	26,000
Vietnam	20,926	20,473	20,670	20,500
Thailand	16,500	16,901	16,500	16,500
Burma	9,860	10,771	10,440	10,440
Philippines	7,772	8,135	8,450	8,300
Japan	8,350	8,636	8,242	8,200
Brazil	7,768	7,062	7,480	7,600
United States	6,502	5,941	6,764	6,457
Korea, South	5,263	5,291	5,515	5,300
Egypt	3,787	3,965	3,575	3,800
Pakistan	5,156	4,700	3,740	3,500
EU	1,751	1,567	1,620	1,792
Taiwan	1,349	1,342	1,245	1,197
Australia	787	1,259	930	965
Others	28,282	27,270	27,575	28,156
WORLD TOTAL	**409,200**	**397,354**	**396,588**	**384,407**

Source: United States Department of Agriculture (USDA), Foreign Agricultural Services (FAS)

The sharp fall in rice production in India in 2002/2003 to 80 million tons (m. t.) from the 91.6 m. t recorded in 2001/2002 was due to severe drought. Faced with this emergency, the Food Corporation of India (FCI) released a substantial part of its stocks of rice and wheat on to the public distribution

[196] www.foodmarketexchage.com

system to avert serious shortages in consumption[197]. With the return of good southwest monsoon rains in the summer, and based on the expectation of good northeast monsoon rains in the winter, rice production is expected to climb back to 90 m. t for the crop year 2003/2004 [198].

As of March 2003, the total stock of rice held by the FCI and some state governments was slightly over 17 m. t., which was 5 m. t. more than the buffer stock that needs to be held for meeting emergencies [199].

India is the second largest exporter of rice (the 2003 estimate is 4 m. t.) after Thailand (7.5), with the other major exporters being Vietnam (3.9), USA (3.6) and Pakistan (1.9). Despite the sharp drop in production in 2002, India exported 4.5 m .t, which is more than export estimate for 2003, despite higher production. But the Indian export figures for both 2002 and 2003 are substantially less than the latest peak of 6.6. m. t.[200] These seemingly puzzling and contradictory export performances are the result of three factors at work, with any one factor dominating the others in a given year: The demand in the main export markets (the Middle East, UK, USA, parts of sub-Saharan Africa, Australia and Europe); the price levels on the domestic Indian market; and the economic and political pressure on FCI to reduce its large stock.

A seemingly paradoxical situation prevails in India as regards domestic consumption of rice and wheat, the two main staple cereals. Domestic demand is being met, exports continue and the FCI is finding it difficult to 'unload' its large stocks. At the same time, despite the FCI's public distribution system (PDS), substantial sections of the poor (both rural and urban), *in certain states*, are not getting adequate amounts of cereals to eat. Several reasons account for this: First, the very poor do not have sufficient cash income to buy the food in the quantities they need, i.e. their 'need' does not translate into 'demand' that manifests itself 'as the ability to pay the prevailing market price'; Second, the poorest in the rural areas tend to be either landless or have too little land, making it impossible to grow the amounts of food they need; Third, retail sales prices in the PDS-retail outlets cannot be lowered below the guaranteed minimum procurement prices that the FCI is obliged to pay the farmers; Four, corrupt officials collude with traders in 'capturing' the grain meant for the most vulnerable and helpless in society (e.g. the tribal peoples).

Projections by researchers at IRRI indicate that the annual growth rate of rice output in India will keep ahead of the rate of demand (domestic consumption plus export) until 2020, when the two are expected to draw level at about 2.2 percent [201]. It is not clear whether this scenario has been worked out under the condition that rain fed cultivation (45 per cent of total acreage) of HYLCs with current annual yield growth rate of 1.8 percent will have been replaced by irrigated cultivation with growth rates higher than 2 percent, or under the assumption that some other new technology (e.g. hybrid rice) will deliver higher productivity than the HYLCs.

Assuming that the IRRI projections will hold, and noting that the population growth rate, which is currently less than the rice output growth rate, is slowing down, one can reasonably conclude that India is not likely to face problems in meeting domestic demand for rice in the foreseeable future. The problem that presumably troubles the Indian authorities and trading firms is therefore not one of meeting future demand in domestic consumption, but the ability of the country to expand its current share of the export market. On the other hand, as all the main 'actors' in primary commodity trade the world over know too well, increasing production to be able to export more is a losing game. Over the last several decades, the trend rates in export prices of primary commodities have been falling and increased supply will lead to steeper falls (current dramatic examples being coffee and tea).

[197] Despite this, famine struck some of the poorest in a few parts of the country. For instance, Indian media reported starvation deaths among the tribal people in the state of Rajasthan. This was due, apparently, to the collusion between some officials and traders, who are alleged to have stolen the public system distribution's grain destined for the tribal regions.
[198] www.fas.usda.gov
[199] http://fciweb.nic.in
[200] The Hindu Business Line, Internet editions, Sept 16, 2002 and July 8, 2003
[201] The Financial Express, March 21, 2020, IRRI sees lower Asian rice exports in 2020, www.financialexpress.com

8.1.4 The failure of the hybrid rice strategy in India

One way of escaping the limits on productivity set by the inbred HYLCs of the "Green Revolution" (hereinafter called the 'inbreeds') is to cultivate the more productive hybrids. Rice is a self-pollinating plant involving single parental lines. Hybridisation consists in inducing cross-pollination between different parental lines, thus making it possible to transfer higher yield traits from one line into another. Although the possibility of creating rice hybrids was first sensed in the work done in the early 1950s at the Central Rice Research Institute in Cuttack in the State of Orissa in India, it lay unexplored until China in the early 1960s and IRRI, Japan and the USA in the 1970s, moved ahead purposefully to conduct research and innovate hybrids with 10 to 15 percent higher yields than the inbreeds[202].

In the event, hybrid cultivation did not take hold in Japan and the USA for several reasons: hybrids offered no advantages over inbreeds in quality, price and profit; they were more vulnerable than inbreeds to attacks by pests and diseases; and they required more labour input than the inbreeds did. With the exception of the labour factor, the same constraints would have applied in China too, had China been a market economy in the 1970s. But the "market constraints" did not apply in the context of the then centrally planned command economy of China, where the government's primary concern was to maximise the output in order to provide adequate supply of rice to the vast and growing population. The imposition of hybrid rice by the Chinese authorities on the Chinese farming communities, coupled with the reality that the supply of seeds and the purchasing of the produce were both in the hands of the state, resulted in more than half the total rice acreage (i.e. 16 out of the total 32 million hectares) being sown to hybrid rice, with yields averaging between 8 and 10 tons per hectare[203].

Faced with the levelling off the productivity of inbreeds at around 5.5 tons per hectare by the late 1980s, and impelled by the phenomenal hybrid rice success of the Chinese with yields of up to 10 tons per hectare, the Indian authorities decided in 1989 on a policy and a strategy to rapidly promote hybrid rice[204]. As a result, ICAR conferred the so-called 'mission mode' status to hybrid rice R&D and extension. It entailed the commitment of very large resources (financial, personnel and infrastructural) to an R&D network comprising twelve public-sector agricultural universities and research institutions[205]. Each institution in the network has assumed the responsibility for developing a specific variety of hybrid with certain specific traits and suited to certain agro-climatic conditions. IRRI has collaborated actively with the 'mission mode' project by providing germplasm and technical support. Since 1990, UNDP[206], the Asian Development Bank (ADB, based in Manila in the Philippines) and FAO have given financial and technical support[207]. Since 1998, ICAR's support to the "mission mode" project is being provided its National Agricultural Technology Project[208].

Following four years of R&D work (1989-93), the first hybrid variety was released for commercial cultivation in Andhra Pradesh in the spring of 1994. As of late 2003, twenty-four varieties have been released, of which thirteen are from the public-sector institutions and the rest eleven from the private sector companies[209]. A comparison of yields per hectare of inbreeds and hybrids, in 1997-98, in the states of Andhra Pradesh, Karnataka, West Bengal, Tamil Nadu and Orissa, reveals a mixed picture. In the first three states, the hybrids yielded more than the inbreeds, while in the last two the reverse was the case. Averaging over the five states, one finds that the hybrid and the inbred yields were,

[202] Janaiah, A. (2002) Hybrid Rice for Indian Farmers: Myths and Realities, Economic and Political Weekly, Mumbai, October 19, 2002, Vol 37, Number 42, pp 4319-4328
[203] Barker, R and Herdt, R. W. (1985), The Rice Economy of Asia, Resources for the Future, Washington D C; Lin, J. Y. (1991), The Household Responsibility System Reform and Adoption of Hybrid Rice in China, Journal of Development Economics, Vol 36, pp 353-72; Barwale, B. R. (ed) (1993), Hybrid Rice Food Security in India, Macmillan India, Chennai, India
[204] Janaiah, A. *op cit*
[205] The DRR in Hyderabad coordinates the network
[206] UNDP's assistance was for consultancies, fellowships, training abroad and research equipment
[207] During the period 1990-2000, these agencies have together contributed 8 million US dollars. UNDP's assistance was for consultancies, fellowships, training abroad and research equipment.
[208] See www.hybridriceindia.org
[209] www.hybridriceindia.org

respectively, around 7 and 6 tons per hectare[210]. The differences in performance can be attributed to the state-wise differences in the farmers' access to, and affordability of, fertilisers, pesticides and herbicides, and irrigation, as well as different cultivation practices. Further, the considerable variations in performance and yield of the varieties planted played a crucial role, since different varieties were released in different states. Farm size may not have been a major determinant, as the overwhelming majority of farmers in the five states are smallholders with average holdings of about a hectare.

Nearly a decade after the first commercial release in 1994, the total area planted to hybrid rice in India is estimated to be between 0.3[211] and 0.45[212] percent of the total rice acreage, i.e. between 130,000 and 200,000 hectares out of a total of 44 million hectares. (For the sake of comparison, we recall that in China the coverage is over 50 percent!). Clearly, therefore, the Indian strategy to promote hybrid rice has been a failure.

An important empirical study[213], based on a fairly large number of field surveys, was conducted in 2001 in the above-mentioned five states, to uncover the reasons for the failure. The surveys covered farmers, grain traders, millers, seed growers and traders, consumers, government officials, public sector researchers and private companies. The study identifies the following *main* reasons for the failure (the adjectives used, e.g. 'lack', 'poor', 'low', 'high', etc., are with respect to inbreeds):

- Very little consumer demand
- Consumers' negative experience and perceptions with respect to taste, smell, stickiness, etc
- Poor grain quality
- Low storage quality
- Lower market price
- Higher seed cost
- Lower net returns, lower profitability (measured in rupees per hectare)
- Lack of access to higher quality hybrid seeds
- Higher vulnerability to pests and diseases

The same study also points out that "the adoption of hybrid rice --- has been slowing down or even disappearing without a visible impact in India after 1996".

8.2 Research into transgenic rice in India

Research into transgenic rice has had a late start in India. One explanation offered by some scientists[214] is that the early and continued emphasis placed by ICAR and the rice research groups on developing rice varieties that are resistant to *abiotic stresses* like drought and salinity was not regarded until recently by GM-researchers as interesting and appropriate topics for a transgenic approach. Resistance to *biotic stresses* like attack by pests and diseases was considered to be the more relevant challenge for GM-research, as this would require the transfer of genes across species barriers, whereas abiotic stress could be handled by conventional, non-GM intra-species crossing and hybridisation.

Until 2001, there was hardly any public debate in India on transgenic rice. But things changed with the attempt to introduce into India the so-called "Golden Rice", developed by a team of researchers at the Swiss Federal Institute of Technology (ETH) in Zurich, over the period 1991-2000. "Golden Rice" has been genetically engineered to produce beta-carotene, a micronutrient, which on ingestion produces vitamin A in humans. The pro- and anti-GM groups in India are now locked in a public dispute about

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[210] Janaiah, A. *op cit* the tons per hectare figures for hybrids and inbreeds, were respectively as follows: Andhra Pradesh 8.8 and 7.2; Karnataka 8.3 and 7.0; West Bengal 7.8 and 5.1; Tamil Nadu 4.8 and 5.9; and Orissa 5.7 and 5.5. The hybrid yields in China range between 8 and 10 tons per hectare.
[211] Janaiah, A., *op cit*
[212] DRR, www.hybridriceindia.org
[213] Janaiah, A., *op cit*
[214] Our interviews

the merits or otherwise of "Golden Rice" and its relevance to overcoming vitamin A deficiency among the poor, in particular the children of the poorest households (see sub-section 7.2.5 below for a presentation of the salient features of the controversy).

The table below lists the ongoing main research work, which began in the early 1990s. All of it is in the public sector agricultural universities and research institutions. The traits tackled are resistance to insects (yellow stemborer), viral disease (sheath blight), drought and salinity, and nutritional improvement (protein enrichment). Progress has been slow and patchy. After nearly a decade of work, only a few of the transgenic varieties have reached the stage of limited field trials. General release and commercialisation are still distant prospects.

Table . The ongoing main research work

Institution	**Rice variety**	**Transgenes inserted and traits tackled**	**Stage reached, and tests and trials conducted**
Indian Agricultural Research Institute (IARI) at Pusa in Delhi	IRRI's IR-64 and Pusa Basmati 1	Bt-toxin genesCry1Ab, Cry1Ac. Resistance to yellow stem borer.	Limited field trials have been conducted
University of Delhi, South Campus	*Pusa Basmati I*	Cod A, COR 47. Resistance to abiotic stress.	Greenhouse (glasshouse) tests are continuing. Field trials are expected in 2004.
-ditto-		Heat shock protein gene (hsp 100). Resistance to drought.	Greenhouse (glasshouse) tests are continuing.
Jawaharlal Nehru University (JNU), New Delhi		Gene from the amaranthus plant. Protein enrichment.	Greenhouse tests are ongoing. Field trials are expected in 2004.
Bose Institute, Kolkata (Calcutta)		Bt-toxin gene. Resistance to yellow stemborer	Pre-greenhouse stage?
Madurai Kamaraj University, Madurai	*Pusa Basmati I*	Chitinase gene, Chi 11. Resistance to sheath blight (r*hizoctonia solani)*	Single copy transgene plants available in T2 generation
- ditto -	*IRRI's IR-50*	Pyrroline-5-carboxylate synthase. Resistance to salinity and drought.	Greenhouse tests conducted. By 2004, T3 generation seeds are expected to be ready for limited field trials
Tamil Nadu Agricultural University, Coimbatore	Indica rice	Chitinase gene X21 and TLP for leaf and sheath blight resistance. Bt-toxin Cry1 Ab and Ac, and Cry2A genes for insect resistance (stem borer, brown plant hopper and leaf roller). Virus and drought resistance.	Greenhouse tests have been conducted on all the transgenics mentioned. Now ready for limited field trials. T4 generation has been reached in the chitinase work.
Directorate of Rice Research (DRR), Hyderabad[215]		Resistance to insects (stemborer and brown plant hopper), gall midge, blast and bacterial leaf blight. Chitinase X21 for sheath blight resistance.	Greenhouse tests
Punjab Agricultural University, Ludhiana	Pusa Basmati 1	Chitinase X21 for sheath blight resistance.	T4 generation seeds developed. Ready for limited field trials
CPMB, Osmania University, Hyderabad		Snowdrop Lectin—GNA. Resistance to insects.	Ready for limited field trials

[215] According to a news item in the Deccan Herald of 4 August 2003, "Multiple disease-resistant rice in the offing", www.deccanherald.com

In addition to the substantial direct funding by the DBT, and the indirect infrastructural support by ICAR, the multi-faceted assistance provided by the Rockefeller Foundation through its International Program on Rice Biotechnology (IPRB) has been pivotal and decisive in establishing transgenic rice research in India.

The Rockefeller Foundation launched the IPRB in 1984 and ended it in 2000[216]. Support was provided to a number of advanced public-sector research institutions in 12 industrialised countries (high-income countries, HICs, in Rockefeller terminology), three IARCs in the CGIAR system[217], 73 public-sector universities and research institutions in 12 Asian developing countries[218] (low-income countries, LICs) and four institutions in Latin America. The strategy adopted was to focus the first half of the 17-year period on promoting basic research (i.e. into the fundamentals of the science of rice biotechnology) at the HIC institutions and IRRI, and the second half on transferring the know-how from, and the results of, the basic research to the LIC institutions. Periodic international meetings were held, which helped to develop collaborative research projects between the HIC institutions, the IARCs and the LIC institutions.

In addition to research, a major part of IPRB was devoted to the training of scientists from the HIC and LIC institutions to various levels (doctoral, post-doctoral, etc.)[219]. Over 400 scientists were provided training, most of them Asian, with China and India accounting for a big share (see below). The ‘trainees’ from the LICs were carefully matched with the ‘trainers’ in the HICs on the basis of shared research interests, as well as the present and future capacity needs of the trainees’ home institutions. Rockefeller financed the acquisition of some essential state-of the-art research equipment (including information technology) by participant institutions, the distribution of theses, reprints, books and patents’ information, and the publication and distribution of the newsletter "Rice Biotechnology Quarterly". All these activities were integral parts of a sustained effort by IPRB to build capacity in the participating LIC institutions in the field of rice biotechnology.

A major stage was reached in 1988, when the international effort resulted in a molecular genetic map of rice. The map and its DNA markers were disseminated worldwide. As of the early 1990s, *rice became the model plant for cereal genomic research*. Rice genome sequencing projects began in Japan and the US, which were then combined and expanded to include a range of other countries, to become the International Rice Genome Sequencing Project [220]. Within the framework of this project, India has successfully completed sequencing a part of chromosome 11.

China and India have been the major beneficiaries of the IPRB, together accounting for about 60 percent of the training grants and research project funds. Twenty-four institutions in India participated in the IPRB[221] and over 110 scientists from India with trained under various kinds of fellowships (doctoral, post-doctoral, career and short duration)[222]. The IPRB has also made a major contribution towards developing India’s *generic* capacity in plant molecular biology research, in particular in the

[216] For a summarised presentation and analysis of IPRB’s origin, development, functioning and output, see "The Rockefeller Foundation's International Program on Rice Biotechnology" by J.C.O'Toole, G.H.Toenniessen, T.Murashige, R.R.Harris and R.W.Herdt (20 pages), in Khush GS, Brar DS, Hardy B, editors. 2001. Rice genetics IV. Proceedings of the Fourth International Rice Genetics Symposium, 22-27 October 2000, Los Banõs, Philippines. Los Banös (Philippines): International Rice Research Institute. 488 pages. Available at www.rockmekong.org/pubs/lab-pubs/Ricebiotech.pdf

[217] IRRI in the Philippines, The International Centre for Tropical Agriculture (CIAT) in Colombia, and The West Africa Rice Development Association (WARDA) in the Ivory Coast

[218] Bangladesh, China, India, Indonesia, Malaysia, Nepal, Pakistan, Philippines, South Korea, Sri Lanka, Thailand and Vietnam

[219] IPRB’s total budget was about 105 million US dollars, with approximately 32 million spent on HIC institutions, 23 million on LIC institutions, 26 million on fellowships and training of both HIC and LIC scientists, 15 million on four international agricultural research centres doing both basic and applied rice research, 4 million on social science research and the rest 5 million on meetings and administration.

[220] J.C.O'Toole, et.al, op cit

[221] Eight conventional and six agricultural universities, and six, two and two, respectively, basic, agricultural and rice-specialist research institutions

[222] J.C.O'Toole, et.al, op cit

areas of GM- technology and marker assisted breeding in rice[223]. It has brought together plant molecular biologists and crop breeders who rarely interacted before.

With support from the Rockefeller foundation, DBT and ICAR, the Indian member institutions of the IPRB set up an Indian National Rice Biotechnology Network (INRBN) in 1989[224]. Its stated aims are to coordinate the work going on in India into transgenic rice, avoid duplication, share research facilities, promote inter-institutional exchange of information, literature, know-how and experience[225].

8.3 Transfer of technology and Intellectual Property Rights (IPR) Issues

The DNA sequences and constructs that are currently being used in transgenic rice research in India originate from foreign and international research institutions and private sector companies, which hold the IPR on the technology transferred to the Indian institutions[226]. This does not pose a problem as long as the transferred technology[227] is used strictly for R&D work. But the general release and commercialisation of the output of such R&D work (GM-products and processes) requires the approval of the IPR-holders, which means that the Indian institutions have to negotiate with the IPR-holders the terms and conditions under which commercialisation can take place, e.g. the royalty payments, licensing fees, export restrictions, etc.

At present, the IPR issues are simmering under the surface, as no Indian public-sector institution has yet managed to take any of its GM-crops from the ‘lab to the market’. However, several innovations are approaching that stage. Our interviews indicate that the government authorities and the R&D establishment are vaguely aware of the IPR hurdles lying in wait. But there is little sign of serious and coherent thinking, let alone forward planning, about how to tackle this dormant challenge come the day.

8.4 The entry of “Golden Rice” into India

Beta-carotene is a micronutrient that the human body converts to vitamin A. Clinical levels of vitamin A deficiency (VAD) can lead to xerophthalmia in children, which is a primary cause of childhood blindness, while sub-clinical levels increase the risk of children contracting infectious diseases like measles[228]. Beta-carotene occurs in a number of plants, some of which form part of the human diet.

A third of those affected by VAD live in those parts of Asia where rice is the main staple crop. In rice, beta-carotene occurs in the non-edible leaves of the plants, but not in the edible grain (called the endosperm). In 1990, Peter Bayer of the University of Freiburg in Germany and Ingo Potrykus of the Institute of Plant Sciences at the Swiss Federal Institute of Technology (ETH) jointly conceived the idea of genetically engineering beta-carotene into rice grain. Working together over a ten year period, they and their team at ETH succeeded in 2000 in developing a beta-carotene enriched GM-rice variety,

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[223] D. Pental, 1998, “*Plant Molecular Biology and Biotechnology in India*”, in Plant Molecular Biology Reporter, Issue Number 16

[224] INRBN is coordinated by the Directorate of Rice Research, Hyderabad.

[225] Our interviews uncovered some anxiety among scientists not involved in transgenic rice research that the strong attention being paid to GM-rice would drain resources away from non-GM work, in particular the development of non-GM hybrids.

[226] The same is true of several other GM-crops being developed in India. It is also worth noting that besides DNA sequences and constructs, India still relies heavily on imported enzymes and hormones that are essential for GM-R&D. The lack of indigenous manufacture of such inputs is a matter of great frustration to the Indian GM-R&D establishment, who chafe at the delays and problems that the import-dependence causes (our interviews).

[227] Acquired for the most part through the Rockefeller Foundation’s IPRB and the IRRI.

[228] It is estimated that in the developing world about 14 million children are affected by clinical VAD, while 250 million suffer from sub-clinical levels. See the Nuffield Council on Bioethics Draft Report of June 2003 on “The use of genetically modified crops in developing countries”, available at www.nuffieldbioethics.org

which has since been dubbed “Golden Rice”[229]. The genetic modification entailed the transferring of one bacterial gene and two daffodil genes into the endosperm[230].

The rice variety that the Swiss group worked on was the *japonica* TP 309, which grows in moderate climates. It has gone through greenhouse trials at ETH. The next stages contemplated by the Swiss team are to backcross the GM-japonica into selected local cultivars in selected developing countries in the tropical and sub-tropical belts, and to conduct field trials of the backcrossed varieties in the selected developing countries in compliance with the countries’ regulations, prior to general release and commercialisation. But the team discovered that this move requires the prior approval of the IPR holders of the GM-technologies employed in arriving at the “Golden Rice”. It meant having to obtain licenses covering about 70 patents held by 32 different owners[231].

In order to handle the complicated IPR negotiations, the Swiss group entered into a so-called” public-private partnership” with the transnational corporation Syngenta, which provided assistance in negotiating the deals successfully. In return, the Swiss team handed over to Syngenta the rights to the commercialisation of “Golden Rice”, under the *quid pro quo* that the GM-local cultivars incorporating the “Golden Rice” technology would be available free of charge to farmers and traders in developing countries whose profits from the sale of the crops were less than US$ 10,000 per year per farmer or trader[232].

The backcrossing work is now being undertaken in 14 public sector research institutions, which form the so-called “Golden Rice Network”, spread over Bangladesh, China, India, Indonesia, Vietnam, the Philippines and South Africa. Apparently, regulations concerning GM-crops in these countries are causing considerable problems in getting field trials started. Field trials are not expected to begin until 2007/2008[233].

According to a senior transgenic rice research scientist we have interviewed in India, the initial moves in the introduction of “Golden Rice” into India were as follows: At the final big meeting of the Rockefeller IPRB held in Phuket, Thailand, in 1999, Ingo Portrykos offered to make “Golden Rice” available to India, if India so wished. Both DBT and ICAR responded positively to the offer. DBT went ahead with the decision to import the gene construct and make it available for further work at four centres: Delhi University South Campus (DUSC), TNAU/CPMB, IARI Pusa Campus and DRR in Hyderabad. DUSC was authorised to obtain the gene construct and pass it on to the other three labs. It was agreed that DUSC and TNAU would conduct the transformation work, while IARI Pusa and DRR would do the backcrossing into local cultivars.

A somewhat different version of events emerged from our interview with another senior researcher also closely involved in the entry of “Golden Rice” into India. According to this version, DRR had been given the primary responsibility to do the backcrossing and then disseminate the backcrossed varieties for further R&D to other rice research groups in the country. To this end, DRR secured financial support from the Swiss government under the ongoing “Indo-Swiss Collaboration Programme in Biotechnology” that DBT administers. But problems arose in deciding which local variety to backcross into. The central authorities in Delhi apparently insisted on IARI’s Pusa Basmati, but this was considered by DRR as being unsuitable for subsistence farmers in many parts of the country. Instead, DRR suggested the variety known as ‘Swarana’, arguing that it was more widely grown than the Pusa Basmati. This controversy, among other things, delayed the start of the backcrossing work at DRR until 2002.

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[229] This effort was funded by the Rockefeller Foundation (1991-2002), the Swiss Federal Institute of Technology (1993-1996), the European Union under a European Biotech Programme (1996-2000) and the Swiss Federal Office for Education and Science (1996-2000); see the Nuffield Draft Report, *op cit*

[230] Potrykus, Ingo, 2001, "Golden Rice and Beyond", in *Plant Physiology*, Vol.125, pp.1157-1161

[231] Potrykus, Ingo, 2001, *ibid*

[232] Nuffield Draft Report, *op cit*

[233] Nuffield Draft Report, *op cit*

Meanwhile, IARI at Pusa in Delhi has been given the go ahead by DBT to backcross the "Golden Rice" into its Pusa Basmati and distribute the backcrossed variety to other groups in the country for further work. At the same time, ICAR is facilitating some of the agricultural universities and research institutions that it funds in obtaining Golden-Rice-backcrossed varieties from IRRI in the Philippines for further backcrossing into Indian cultivars[234].

These moves and counter moves come as no surprise to those familiar with the rivalries between institutions based centrally in Delhi and those based in the various states. It is yet another example of the historically-entrenched difficulty of persuading public sector institutions in such a huge and heterogeneous country as India to agree on and implement a common strategy and to pull in the same direction.

8.5 The "Golden Rice" controversy

The argument advanced in support of "Golden Rice" by DBT, ICAR, the Ministry of Agriculture and the research institutions involved in the backcrossing work is that it will make a significant contribution towards combating vitamin A deficiency (VAD) among an estimated 12 million pre-school children (i.e. less than five years old) belonging to poor households[235]. It is claimed that government programmes to provide vitamin A supplements to the affected children are expensive and complicated. And it is asserted that conventional, non-GM methods of introducing or enhancing beta-carotene in other staple crops have been unsuccessful. These arguments have been vehemently challenged by GM-active CSOs[236] and treated with scepticism by some of the scientists working in agricultural universities on rice breeding[237]. Besides the Indian media, the controversy has surfaced in the Indian Parliament[238]. Three arguments are driving the controversy[239].

The first of these concerns the recommended daily intake (RDI) of vitamin A. FAO/WHO's RDI is 400micrograms for children between the ages of 1 and 3[240]. But Peter Bayer and Ingo Potrykus claim that 300 micrograms is adequate[241]. One hundred grams of "Golden Rice" produces approximately 160 micrograms of beta-carotene. Assuming a beta-carotene to vitamin A conversion rate of 1:1, Bayer and Potrykus conclude that 200 grams of "Golden Rice" per day provides 320 micrograms of vitamin A. But other researchers work with a conversion rate of 2:1, which implies only 80 micrograms of vitamin A for every 100 grams of rice, requiring a daily intake of 500 grams of rice to attain the FAO/WHO figure of 400 micrograms. There is as yet no agreed conversion rate and thus no agreement on the amount of vitamin A that "Golden Rice" can in principle provide.

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[234] Our interviews. Further, according to the news item in the Deccan Herald of 4 August 2003 cited in a footnote above, "the first batch of breeding lines, which India got from the International Rice Research Institute --- was found to have 'undesirable properties' ". The news item quotes the Director of the DRR as saying that "New materials are to come in a few months (from IRRI) as DBT has granted the permission. We will start the breeding process after examining the new material". www.deccanherald.com

[235] The estimate is from the survey conducted by the Indian National Nutrition Monitoring Bureau (NNMB)

[236] Using conventional, non-GM breeding techniques, researchers at the International Crops Research Institute for Semi Arid Tropics (ICRISAT) in Hyderabad, India, have produced a millet variety that contains high levels of beta-carotene. They intend to transfer this trait to other millet crops by using genetic marker techniques. See Jayaraman K (2002): Natural 'golden millet' rivals 'golden rice', on SciDevNet. Available: http://www.cdrive.co.za/ge_info/34.htm.

[237] Our interviews. See also the *Biotechnology and Development Monitor*, No.44/45, March 2001.pp.18-22: "Is this the way to solve malnutrition?" and the article in the national newspaper *The Hindu*, 5.12.2002, by Ramesh.V.Bhatt and S.Vasanthi, National Institute of Nutrition, Hyderabad: "Can golden rice eradicate Vitamin A deficiency?"

[238] Questions on transgenic rice in general and "Golden Rice" in particular were first raised in the Indian Parliament on 20.4.2001and 10.8.2001. Unstarred Q.No.3794, "Genetically modified rice and mustard for cultivation", answered in the *Rajya Sabha* (the Upper House of Parliament) on 20.4.2001 by Dr.Debendra Pradhan, Minister of State in the Ministry of Agriculture; Unstarred Q.No.2255, "Genetically engineered rice", answered in the *Rajya Sabha* by Shri.Bachi Singh Rawat, Minister of State for S&T on 10.8.2001. In their answers, the ministers advanced the above-mentioned arguments in support of "Golden Rice", and reassured Parliament that approval for its general release would be contingent on its passing the field trials successfully and complying with the national biosafety regulations.

[239] Greenpeace (2001) Vitamin A: Natural Sources vs. 'Golden Rice'. Available: http://archive.greenpeace.org/~geneng/reports/food/VitaAvs.PDF; Five Year Freeze (2002) Feeding or Fooling the World? London: Five Year Freeze; Koechlin F (2000) The 'Golden Rice' - a big illusion? Third World Network. Available: http://www.twnside.org.sg/title/rice.htm.

[240] Commonly used nutrition tables in Western Europe list the following RDIs of vitamin A: For children less than six months old. 420 micrograms; six months to three years, 400; four to six years, 500; and seven to ten years, 700. For males and females above ten years, 1000 and 800, respectively.

[241] Beyer P and Potrykus I How Much Vitamin A Rice Must One Eat? Available: http://www.agbioworld.org/biotech_info/topics/goldenrice/how_much.html.

The second argument is about the realism of assuming that children aged between one and five years can consume 500 grams of rice per day. Further, beta-carotene being only fat-soluble, the rice has to be eaten with a dish that contains enough edible fat for beta-carotene to be ingested (bio-available) and not be excreted undigested. The very poor in India (for instance, the households of the 12 million children affected by VAD) are entirely unlikely to be able to provide each child in the household with such quantity of rice. And the poor use edible oil (the only form of edible fat that they can possibly afford) very sparingly, its cost being prohibitive to them.

The third issue is about the primacy of political, economic and social factors over 'technological fixes'. In common with other technological solutions tried before, biotechnological interventions too cannot, *by themselves*, make an impact in overcoming nutritional deficiencies among the poor. For that to happen, there has to be significant improvement in the livelihoods and cash incomes of the poorest households, which can only come in the wake of more equitable political, economic and social interventions.

Reviewing the above arguments from the perspective of an effective way of overcoming the VAD that affects an estimated 12 million children in the poorest households today in India, we conclude that "Golden Rice" could, at best, make only a small contribution. We believe, rather, that the effective solution would be to enable the poor households to buy, or grow for self-consumption, certain green leafy vegetables and yellow vegetables that are rich in vitamin A[242]. The substantial costs involved in pursuing the "Golden Rice" route would be spent to better effect if the authorities were to implement appropriately designed campaigns to raise the awareness of the poor households to the micronutrient richness of some readily available and affordable vegetables, and the crucial importance of including them in the daily diet of children.

That said, as infants aged one or two years cannot really consume the requisite quantities of vegetables, their intake of Vitamin A and other micronutrients has to be ensured by other means. To discover what is likely to work, the authorities ought to study how the vast majority of the children <u>not</u> affected by VAD and other micronutrient deficiencies are in fact getting their daily intake. That will give them a lead on how to enable the households of the VAD-affected children to join the ranks of the majority.

Our analysis of the Indian situation indicates that the VAD-argument is not credible as a justification or motivation for promoting "Golden Rice" in India. We surmise that the central government authorities enthusiasm for "Golden Rice" is propelled by other un-stated factors. One of these could well be the determination not to bypass the opportunity to secure the technological know-how embedded in the "Golden Rice" for the public-sector research institutions working on transgenic crops. The introduction of "Golden Rice", in the teeth of the well argued opposition to it by activist CSOs and parts of the non-GM R&D establishment and the media, is likely to further erode public trust in the biotechnology promoting authorities and companies.

8.6 Conclusions

Research into transgenic rice in India began in the early 1990s with substantial financial support by DBT and the Rockefeller Foundation's International Program on Rice Biotechnology (IPRB), backed up ICAR's institutional and infrastructural support. The IRPB ended in 2000. Inclusion in the IPRB has been decisive for the initiation and growth of R&D work in transgenic rice, as well as for essential and broad based capacity building, in selected public sector institutions in India.

Most of the work is on achieving resistance to a few main insect pests and viral diseases, with six of the nine institutions listed in the table above involved in this. One of these six, and each of the other three, are tackling one of three other traits: drought resistance, salt tolerance and protein enrichment.

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[242] For example, 100 grams of carrots, spinach, yellow pumpkin and yellow and red capsicum (paprika, sweet pepper) provide, respectively, 1640, 620, 370 and 300 micrograms of vitamin A.

Despite the significant resources and time invested, progress has been slow in almost all the nine institutions and highly uneven as between them. Although all of them report having completed the laboratory and greenhouse stages, only a few have taken the next step of limited field trials. At the present rate of movement, it will take a few more years to start and complete the large-scale, multi-location field trials that the biosafety regulations stipulate. Thus, if and when the commercialisation of some transgenic varieties of rice takes place, the process of moving "from the laboratory to the market" will have taken about twenty years, which seems long by international standards.

The slow pace and uneven progress could well be the result of spreading the available resources (intellectual, financial and infrastructural) over a number of geographically widespread institutions. On the other hand, this dispersal is certainly beneficial to capacity building, and to the provision of opportunities for achievement, in different parts of this huge country. It is also politically unavoidable.

Looking at the six institutions working on resistance to the few main insect pests and diseases, one wonders whether there is considerable duplication in effort, al least at the level of the science, if not in the application of the science (i.e. the technology) to some site-specific local rice varieties. But the justification based on site-specificity cannot be invoked in those instances when the same rice variety (e.g. the Pusa Basmati) is being genetically transformed in institutions situated in very different agro-climatic and ecological zones, separated by two thousand kilometres.

In theory, the institutions working on similar problems are expected to coordinate and jointly plan their work, especially as they all belong to the national rice biotechnology network. But the network meets, apparently, once in two years. In our interviews, we could not elicit concrete examples of how the coordination was taking place, what the fruits of the coordination were and what synergies had been utilised. On the contrary, our interviews, for instance at the institutions involved in backcrossing Golden Rice into local cultivars, reveal that traditional patterns of rivalry among institutions are alive and well.

In vivid contrast to the Bt-cotton case, where it became (reluctantly?) involved only in the ultimate round of field trials, ICAR has been promoting R&D work in transgenic rice from the very start. This augurs well from the point of view of the nine institutions, for they are entirely dependent on ICAR's resources, infrastructure and institutional network, and crucially, on its system of All India Crop Trials, to have their innovations of transgenic rice varieties tested in the obligatory multi-locational and large-scale field trials.

It is too early to say whether the central biosafety regulating authority GEAC will be as thorough in enforcing the biosafety regulations with respect to the public sector institutions, as it was, and is, with regard to private sector companies (e.g. Monsanto-Mahyco in Bt-cotton and ProAgro in GM-mustard). Recent statements by certain highly placed biotechnology authorities, as well as researchers in a Delhi-based public sector institution, on putting protein-enriched potato and rice on to the market in the near future, when the process of their being tested in the obligatory large-scale field trials hasn't even begun, raises questions about the seriousness with which the concerned parties take the issue of environmental and health biosafety, let alone the agronomic (i.e. farm-level-economic) viability and socio-economic implications.

With the exception of the protein-enrichment traits, all the other traits being tackled by the research institutions are motivated by the central objectives of increasing the *net* yield of rice and the net monetary return to the farmer, per unit of land cultivated, and thus increasing the total rice production in the country. Net yields, and thus net monetary returns, at the farm level, are expected to increase significantly, through the elimination or reduction of attacks by insect pests and viral diseases, and the reductions in the use of pesticides. But it is impossible to predict such successful outcomes in advance of actual practice under the conditions that prevail at the farm, district and state levels. Rather, as the Bt-cotton case demonstrates, one can expect strongly conflicting claims.

The expectation of net return is premised on their being a ready domestic market for the transgenic produce. But that is far from being a foregone conclusion. As we have noted above in an earlier section, hybrid rice failed to take off for a number of reasons, chief among which were massive rejection by consumers who were put off by its culinary properties, and its non-competitive price and relatively inferior storage quality *vis à vis* the established conventional high yielding varieties of the Green Revolution.

The premise of a ready domestic market would hold with some degree of certainty, if there were supply shortages. But as we have pointed out in a sub-section above, the situation is exactly the opposite. For over two decades, the domestic supply of rice has substantially exceeded domestic demand [243], resulting in the piling up of huge stocks in the storage silos of the Food Corporation of India (FCI). And India's current export performance in rice is not dynamic enough to absorb the excess supply, especially in the face of competition by other major exporters like Thailand and Vietnam.

The question of potential export markets for GM-rice very problematic. The GM-labelling and -tracing rules that GM-food imports have to comply with in the EU, make it a virtual certainty that India will not be able to export transgenic rice to the EU. Further, the potential for the 'contamination' of conventional rice by GM-rice can seriously jeopardise current Indian exports of conventional rice to the EU. And there are clear signs that consumers and sellers in some other rice importing regions may be prompted by EU's stance into declining GM-foods altogether. It is for this reason that Thailand, the world's premier rice exporter, is maintaining its ban on the commercial cultivation of GM-crops, while simultaneously encouraging domestic R&D work on GM-crops. It is entirely on the cards that India may be compelled to do emulate Thailand in order to hang on to its export markets for rice and other food crops.

It is to be hoped that the intense and bitter public controversies that have raged in India between the government authorities, on the one hand, and activist civil society organisations (CSOs/NGOs) and parts of the media, on the other hand, on the introduction of Bt-cotton and Golden Rice, will prompt the authorities into becoming genuinely cooperative, transparent and inclusive in their dealings with the CSOs and the media. Without such a change in the current attitude and practice on the part of the authorities, transgenic rice will be embroiled in similar controversies.

[243] This does not mean that the rice needs of all households are being met. The poorest households have to make do with less than adequate intake of rice and wheat, because of insufficient cash income. Their 'need' does not translate into 'demand' which is what 'supply' is geared to respond to.

9. SUMMARY AND CONCLUSIONS

The concept of ‘agricultural biotechnology’ covers two main categories of activities, one of which is characterised by genetic modification using recombinant DNA techniques (GM-technology), while the other involves no GM-technology. The ‘non-GM’ label applies to many techniques involving tissue culture, molecular diagnostics and DNA-marker aided selection, and the ‘GM’ label to genetic modification / genetic engineering, genomics and bioinformatics. But these are not watertight compartments. The boundary between the two is hazy. For instance, the tools of genomics and bioinformatics are being utilised in marker- aided breeding.

Our study restricts itself to the task of analysing and assessing the efforts to introduce, develop and commercialise genetically modified crops (GM-crops) in India and the outcome of those efforts.

9.1 Potential benefits and risks associated with GM-crops

The potential benefits comprise increases in crop yields and crop productivity, and thus in farmers’ net income, reductions in the use of pesticides and herbicides and corresponding decrease in environmental pollution, and improvement in the nutritional content and storage characteristics of some staple foods.

The potential risks to human and animal health would arise from unexpected consequences of introducing the transgenes, such as the appearance of allergens, toxins and carcinogens in GM-food and GM-feed (livestock fodder). Ecological and other environmental risks could arise from cross-pollination between GM-crops and their indigenous wild relatives, potentially leading to loss of biodiversity, and the emergence and spread of pests, diseases and weeds that could acquire the same resistances as are engineered into the GM-crops. The socio-economic safety of small farmers and the peasantry may be put at risk by the potentially negative impact on their incomes and livelihoods by GM-crops technology and trade. Further, there are concerns about the impact on India of foreign companies’ and institutions’ GM-crops related intellectual property rights and associated world trade rules.

One could therefore advance the argument that the main aim of agricultural biotechnology policy and the biosafety regulatory system would be to try and maximise the potential benefits while minimising the potential risks.

9.2 Public sector effort in India

The Government of India has made large investments in the R&D of GM-crops. Public sector research into GM-crops in India began in the early 1990s, with DBT’s pro-active support and funding. Although by 2004 a very large number of public sector institutions could formally claim to have some ongoing work in agricultural biotechnology, it is only in twenty-two of them (spread over seventeen cities and towns) that active and focused research into GM-crops is being conducted. This effort is complemented by the work being carried out in two publicly funded international research centres in the country that, however, are *not* part of the Indian public sector.

A total of nineteen GM-crops are being developed in these twenty-four publicly funded institutions: rice, wheat, cotton, potato, banana, tomato, oilseed rape, mustard, coffee, tobacco, aubergine (called ‘brinjal’ or ‘eggplant’ in India), cabbage, cauliflower, melon, citrus fruit, mung bean (‘blackgram’), peanut (‘groundnut’), chickpea and pigeon pea. Of the twenty-four institutions, seven are tackling two or more crops.

Four kind of traits are being aimed at: (i) Resistance to attacks by insect pests and viral and fungal diseases (called “biotic” stresses in the technical literature), (ii) tolerance of the “abiotic” stresses of drought, water-logging and salinity, (iii) delayed ripening, increase in shelf-life and improved storage properties, and (iv) increase in protein and micronutrient (i.e. vitamin and mineral) content.

There is considerable institutional overlap and duplication in a few crops and traits. Our interviewees did not present any concrete example (past or present) of implemented coordination and division of work between the research groups working on the same crop and trait.

Rice is the most intensively researched crop, with fifteen institutions working on four varieties. The traits being transferred are resistance to insects and fungal and viral diseases, and tolerance of drought and salinity. The extensive effort in rice is the result of the participation of Indian institutions in the International Programme on Rice Biotechnology launched and supported by the Rockefeller Foundation. There is a national network of GM-rice researchers, which meets once in two years to share information and experience. We will return to transgenic rice (GM-rice) further below.

Four institutions are involved in tomato (focus on fungal disease), three each in cotton, mustard, potato and tobacco (focus on insect resistance), and two each in aubergine /brinjal, chickpea, melon, oilseed rape and pigeon pea. The remaining (banana, cabbage, cauliflower, citrus fruit, coffee, mung bean /blackgram, peanut/groundnut and wheat), are being addressed by just one institution each.

Transfer of GM-technology from the West has played a crucial role. With the single exception, so far, of the Amaranthus gene isolated and used by a research team in New Delhi (for protein addition in potato and rice), all the other transgenes (gene constructs) in use in GM-crop research in India originate from a few advanced public sector research institutions in some leading OECD countries, a couple of IARCs in the CGIAR-system and a few TNCs. Their transfer to India is subject to the intellectual property rights (IPR) of the transferring institutions and companies. Later on in the present Section we will indicate the implications of the foreign ownership of IPR for the potential commercialisation of public sector GM-crops.

9.3 The long road 'from the laboratory to the market' in the public sector

The transition of GM-crops 'from the laboratory to the market' involves five main stages: laboratory, greenhouse, contained field tests, large-scale field trials and approval by the biosafety and other regulatory authorities for general release, varietal tests and commercialisation. By late 2004, most of the nineteen crops had completed the laboratory and greenhouse stages. Six of them have been put through contained field tests: rice, tomato, cotton, potato, tobacco and melon. However, none has yet entered the stage of large-scale field trials. We advance an explanation for this in our discussion of the role of ICAR below.

If one assumes that one or several public sector institutions may embark on large-scale field trials of some their GM-crop innovations in 2005, the process of completing the trials including varietal testing and securing the approval of the biosafety regulatory authorities is likely to take several years. Our guess is therefore that it is unlikely for a 'public sector GM-crop' to enter the market before 2007. Thus, it will have taken more than fifteen years, at the earliest, for a 'public sector GM-crop' to have moved 'from the lab to the market'. This presumes, firstly, that civil society would be willing to accept the introduction of GM-food crops into the market, secondly that IPR negotiations can be successfully concluded fairly swiftly, and thirdly that the need to safeguard food exports to the European Union and other areas of the world, where there is strong consumer resistance to GM-food crops, will not indefinitely delay the commercialisation process.

It seems likely that many of the GM-crops being developed in the Indian public sector R&D institutions may not leave the lab at all, unless certain conditions are met. We will discuss what those are further below.

9.4 Private sector effort in India

One of the major consequences of the ‘Green Revolution’ in India (that ‘took off’ in the 1970s) was the strong growth in private sector seed companies, which bred and marketed the high yielding varieties of rice and wheat. But, by and large, the private sector companies did not, and still do not, do their own basic research work for creating their own improved seeds. They have relied, and continue to relay, on the public sector institutions to develop and disseminate new crop technologies. That being the case, public sector R&D institutions will be indispensable for the development and dissemination of GM-local crops of relevance and importance to small farmers.

Of the total of ten private sector companies that were actively working on GM-crops in India in 2004, five are joint-ventures or subsidiaries of transnational corporations based in the USA, Switzerland, Germany and India, while the other five are wholly Indian owned smaller companies. Their ‘R&D’ work consists essentially in ‘backcrossing’ the genetically engineered traits from imported or locally obtained GM-crop seeds into selected local varieties of the crop through standard breeding techniques. They then aim at securing the approval of the Indian biotechnology and biosafety regulatory authorities (GEAC) for conducting large-scale field trials and thence to the marketing of the GM-hybrids.

As of 2004, the private sector was working on eleven crops: cotton, rice, mustard, maize, tomato, pigeon pea, aubergine (brinjal), cauliflower, cabbage, chilli and paprika (bell pepper). Only biotic stresses are being tackled, i.e. resistance to attacks by insects and diseases. Of these, cotton is attracting the most attention with six companies working on it, followed by tomato (3 companies), mustard (2), rice (2) and maize (2). There is an overlap, and thus latent competition, between the private companies’ and the public sector institutions’ efforts in these crops, except so far in maize, chilli and paprika (bell pepper).

Private sector efforts at introducing GM-crops into India began in 1995, when the seed company Mahyco obtained RCGM’s approval to import Bt-cotton seeds from Monsanto in the USA for backcrossing into selected Indian cultivars. So began the practice by Indian companies of importing readymade GM-crop technology from North America and Western Europe for backcrossing into Indian cultivars and breeding hybrids resistant to biotic stresses. A new practice was added in 2004, when another company, Swarna Bharat Biotechnics, obtained Bt-cotton technology on license from the Indian public sector institution NBRI in Lucknow, which in turn had imported the original transgene (gene construct) from the West.

The first, and the only GM-crop, that has been approved so far for general release and marketing in India by GEAC is the Bt-cotton developed by the private sector. Three Bt-cotton hybrid varieties belonging to the India-USA joint venture Mahyco-Monsanto were approved in March/April 2002 and the first *legal* harvests of Bt-cotton reached the market in late 2002. Under license from Mahyco-Monsanto, the Indian company, Rasi Seeds, bred further varieties of this Bt-cotton, which were approved by GEAC for general release and marketing in March 2004.

It was expected that the GM-mustard developed by ProAgro/PGS- India (a subsidiary of the German TNC Bayer) was next in line for approval, but a final decision by GEAC has been shelved, apparently indefinitely, for reasons that are not quite transparent. One credible theory is that the fierce controversy surrounding Bt-cotton has made the authorities very cautious, in particular about approving a GM-*food* crop.

In 2001, i.e. a year before Mahyco-Monsanto got its go ahead, one of the five smaller Indian companies (Navbharat Seeds) put on sale some Bt-cotton hybrids which it claimed were its own, without however obtaining GEAC’s approval. This was clearly illegal. It then transpired that the transgenes inserted into the Navbharat hybrids were the same as the ones in the Mahyco-Monsanto hybrids. The central government authorities have lodged a case against Navbharat in a high court, whose ruling is still being awaited. The harvest from Navbharat’s illegal seeds reached the market late in 2001. Since then, illegal Bt-cotton varieties have proliferated and have been openly marketed in all the major cotton growing areas of the country.

Several reasons account for this:

- The illegal seeds are sold at approximately one-third the price of the legal ones;

- In electoral and economic terms, the cotton farmers are a force to reckon with, and state governments would not want to antagonise them by clamping down on the supply of cheap seeds; and

- Even assuming that the authorities at the central and state government levels do want to move decisively against this illegal practice, there just is not the enforcement capacity at the *local* level to deal with the greatly fragmented and heterogeneous configuration of retailers and buyers of seeds.

With no sign in the offing that this state of affairs will change, it is safe to predict that the same illegal practice will affect other GM-crops, if and when they become available to seed breeders.

Unlike the public sector institutions, the private sector companies have the resources and the infrastructure to undertake the legally obligatory large-scale, multi-location field trials that would test the biosafety of their GM-crops. Some of the companies, in particular the subsidiaries of the TNCs, have conducted and are conducting the field trials. Others have filed applications with GEAC for its approval to start the trials. However, it is uncertain as to whether and when GEAC will reach a verdict on the crops that have already undergone the trials. Given the intensity and the impact of the Bt-cotton controversy, it will take a while for some clarity to emerge about the intentions of the authorities on other crops. The reader is referred to our conclusions below on the implications of the Bt-cotton case.

9.5. The role of the Indian government in promoting GM-crops and the outcome of its support so far

The Department of Biotechnology (DBT) of the Government of India (GoI) has been the predominant funder and promoter of public sector R&D in GM-crops, ever since this effort began in the early 1990s. It is the focal point in the administrative structure of GoI for the planning, execution, promotion and coordination of public sector activities and programmes in all the four major sectors of biotechnology: medical/pharmaceutical, agricultural, industrial and environmental. It has had, and continues to have, great influence in shaping the biotechnology and biosafety policies of GoI and in determining the levels of funding made available by GoI for the promotion of biotechnology.

The lion’s share of DBT’s grants goes to the medical/pharmaceutical sector, with the agricultural sector coming a distant second, while the industrial and environmental sectors’ shares remain relatively marginal.

We would have liked to explore in detail, the growth, pattern and outcome of GoI funding of GM-crops R&D. However, the non-availability of disaggregated data makes it impossible to embark on a time-series and comparative analysis of the links between funding levels and achievement of results, by category (GM and non-GM), crop and institution. From our interviews with selected senior officials in DBT and senior scientists in GM-active institutions, we surmise that the support by DBT to the *GM-categories of agricultural biotechnology* has over the years amounted to only a very small fraction of DBT’s total budget (less than five percent), although the absolute magnitude of the grants to individual GM-active institutions may be impressively large. The validity of this hypothesis can only be tested if and when DBT releases the disaggregated figures.

DBT's overarching policy has been, and continues to be, to promote public sector R&D on as wide a front as possible. It is the outcome of the strong conviction shared by public sector scientists and top government officials that India should establish R&D activity in all the subject-areas that are being pursued in biotechnologically leading countries in the OECD region, in all the four sectors of biotechnology (medical/pharmaceutical, agricultural, industrial and environmental). This 'wide front' policy has been, and is, being implemented through three interconnected 'down-stream' policies:

- to build R&D *capacity* in a number of institutions spread over the country;

- to let the transfer of GM-technology from selected institutions and companies in North America and Western Europe determine the specific GM-routes taken by Indian researchers;

- to promote research collaboration between selected Indian and foreign public sector institutions. The strongest collaboration, in terms of number of projects, funding and duration, has been with Switzerland.

A strong, if largely tacit, factor in shaping India's biotechnology ambitions is the determination not to be 'overtaken' by China, which too has invested massively in biotechnology, as in other areas of advanced science and technology. This view emerged in our interviews with some senior scientists. It is an argument that has also surfaced in the Indian media.

The two main outcomes of DBT's policies and investments are, firstly, the creation of R&D infrastructure in about twenty public sector institutions (laboratory equipment, greenhouse and other testing facilities, routines and resources for obtaining research and other supplies, and library and information technology facilities) and the training of several hundred R&D personnel to advanced levels (doctorate, post-doctoral and specialist project). Further, the predominant emphasis on capacity building has led to a growing accumulation of projects covering a wide variety of crops and traits. The ensuing lack of concentration partly explains why, after nearly fifteen years of effort, *no public sector GM-crop has yet reached the stage of commercialisation.*

Another important reason for the total absence thus far of commercialisation of public sector GM-crops is the lack of sufficient support to public sector R&D institutions for conducting large scale field tests and dissemination of GM-technology. We take up this issue in the sections below on the role of ICAR and the transition from the lab to the market.

9.6 The emerging role of ICAR in the area of GM-crops

The Indian Council for Agricultural Research (ICAR) of the Government of India is emerging as the second most important government agency, after DBT, in promoting agricultural biotechnology. Until the end of 2003, ICAR's support to the R&D of GM-crops was indirect and implicit in the sense that the agricultural research personnel and infrastructure it funds in various parts of the country have been involved in DBT funded projects. In December 2003, ICAR made its commitment explicit by announcing the allocation of 400 million rupees to the R&D of about a dozen GM-crops, aimed at incorporating traits to resist both biotic and abiotic stresses. This announcement was followed up in October 2004 by the statement that ICAR will be investing about Rs. 320 million to build up Indian R&D capacity in the functional genomics of rice.

Since the crops and traits that ICAR's funding is aimed at are the same as the ones that DBT has been supporting for nearly fifteen years, ICAR's plans raise three important questions that remain to be answered: Is the funding meant to back up ongoing DBT-funded activities in selected ICAR-affiliated institutions, or is it for starting activities in other institutions belonging to the ICAR family that have so far not received DBT support, or both? How will ICAR ensure that there is no duplication of effort? Will ICAR intervene actively to promote coordination and cooperation between the numerous R&D groups funded, and if so, how?

Going by past and current practice, one wonders whether the traditional tendency towards duplication, and the traditional reluctance to coordinate and cooperate meaningfully, will prove too strong to counteract.

Further below, we take up the issue of ICAR's indispensable future role in facilitating the large-scale field trials of public sector GM-local crops and their transition from the lab to the market

9.7. The biosafety regulatory regime and structure

The Indian biosafety regulations are modelled on the biosafety guidelines first developed and implemented in some of the leading OECD countries. They cover the health safety of humans and livestock, environmental safety (ecology and biodiversity) and economic impact. Health and environment safety aspects dominate the regulations, while socio-economic issues are only briefly touched upon. They have been legislated under the Environment Protection Act and are mandatory for all Indian institutions and companies that deal in genetically modified organisms (GMOs). As with the regulations in force in the European Union (EU), they are based on the precautionary principle, and are applied on a case-by-case basis, using a step-by-step approach.

GMOs cannot be imported without the explicit permission of the regulatory authorities. The same regulations apply to both locally developed and imported GMOs.

Extensive and detailed requirements have been laid out for conducting tests and trials, which are different for greenhouse and contained field tests and large-scale field trials.

The regulations classify activities involving GMOs into *four risk categories,* provide lists of bacterial, fungal, parasitic and viral agents that fall into each category, and specify the roles of the institution and the company, the IBSC and the RCGM *vis à vis* the risk categories:

- Category I comprises *routine* recombinant DNA experiments conducted inside a laboratory;
- Category II consists of both laboratory and greenhouse experiments involving transgenes that combat biotic stresses through resistance to herbicides and pesticides;
- Categories III and IV comprise experiments and field trials where the escape of transgenic traits into the open environment could cause significant alterations in the ecosystem.

Through the biosafety regulations, GoI established a three-tier regulatory structure at the central level in New Delhi comprising three committees:

- The *Review Committee on Genetic Manipulation (RCGM)* under the Ministry of Science and Technology (MoST);
- The *Genetic Engineering Approval Committee (GEAC)* under the Ministry of Environment and Forestry (MoEF);
- The *Monitoring and Evaluation Committee (MEC)* under DBT/MoST;

DBT provides the secretariat for RCGM and MEC, and the MoEF for GEAC. The GoI also issued directives on the setting up a de-centralised structure consisting of institutional biosafety committees (IBSCs) and state and district level committees (SBCCs and DLCs).

The biosafety regulations indicate in broad terms the composition and responsibilities of all these six bodies. DBT is represented on all of them except the SBCCs and DLCs. IBSCs have been established in all institutions (public and private) that deal with GMOs. But, even as late as of 2004, only three states (out of a total of twenty-five states and several 'union territories' that make up the Indian Union) had created SBCCs, while DLCs have not been set up anywhere.

RCGM's mandate is to assess and decide on the applications submitted by institutions and companies for conducting R&D work, greenhouse tests and contained field tests *on plots of less than one acre in size (0.4 hectare)*. Institutions and companies wishing to proceed beyond these stages towards general release and commercialisation of GM-crops must conduct large-scale and multi-location field trials that are mandatory under the biosafety regulations. GEAC enters into the picture at this stage.

GEAC has the sole responsibility and power to authorise large-scale and multi-location field trials, to asses the ‘output’ of the trials and on the basis of that assessment to approve, reject or put on hold the applicant’s request for general release of the GM-crop for commercial planting, imposing conditions (if need be) under which the general release can take place. GEAC may request ICAR to check and validate the ´output’ of the field trials submitted by the applicant, if necessary by conducting its own field trials.

MEC monitors the small-scale contained field tests (RCGM’s ambit) and the open larger-scale field trials (GEAC’s sphere), and submits its reports to RCGM, which are then made available by DBT to GEAC. MEC’s monitoring work and reports are expected to cover all the main aspects of biosafety, i.e. the impact of the GM-crop on the environment (ecology and biodiversity), the agronomy (crop production science and farm-level economy), the health of humans and livestock and the livelihoods of the farming community.

RCGM, GEAC and MEC are made up of representatives of (i) DBT, MoST, MoEF, MoA, as well as the ministries of health, industry, commerce (trade), and law and justice, (ii) the central government funded national research councils dealing with science, technology, agriculture, health and industry, and (iii) some selected public sector R&D institutions from the four sectors of biotechnology (medical/pharmaceutical, agricultural, industrial and environmental).

A striking feature of the composition of RCGM, GEAC and MEC is the *absence* of the representatives of other crucial stakeholders, e.g. civil society organisations (CSOs, including NGOs), private sector companies and institutions, and the central government funded Indian Council for Social Science Research (ICSSR). While the regulations do explicitly say that the RCGM, the GEAC, the SBCCs and the DLCs may co-opt other members/experts as necessary, they neither explicitly include nor exclude representatives of CSOs /NGOs and the private sector. In practice, however, these non-governmental stakeholders have been excluded.

9.8. Implementing the biosafety regulations

The composition, structure and functioning of RCGM, GEAC and MEC, and the manner in which they have implemented their mandates and responsibilities, have come in for strong and sustained criticism by important stakeholders in the biotechnology arena. That critique is presented further below.

The rules pertaining to risk categories I and II (see above) reveal that a great deal of the responsibility for ensuring biosafety has been devolved by the central authorities on to the institutions and companies and their IBSCs. In effect, therefore, a major part of the regulatory system has been decentralised and dispersed. This raises the critical question of biosafety accountability of the institutions and IBSCs vis à vis the local environment and local population, and of the accountability of the central regulatory authorities as the bearers of ultimate responsibility. Our research reveals that neither the various stakeholders nor the general public know whether there is a system of biosafety accountability and how it operates.

It is too early to say whether GEAC will be as thorough in enforcing the biosafety regulations with respect to the public sector institutions, as it was, and is, with regard to private sector companies (e.g. Monsanto-Mahyco in Bt-cotton and ProAgro in GM-mustard). Recent statements by certain highly placed biotechnology authorities, as well as researchers in a Delhi-based public sector institution, on putting protein-enriched potato and rice on to the market in the near future, when the process of their being tested in the obligatory large-scale field trials hasn’t even begun, raises questions about the seriousness with which the concerned parties take the issue of environmental and health biosafety, let alone the agronomic (i.e. farm-level-economic) viability and the wider socio-economic implications of GM-crops.

There are serious shortcomings in the implementation of the regulations, which are partly due to a lack of appropriate mobilisation of existing capacity. India has adequate capacity in terms of competence, expertise, infrastructure and resources, in the relevant government ministries and public sector R&D institutions. But this capacity has not been sufficiently mobilised into the “right shape” (i.e. teams, structures and instruments), the “right orientation” through purpose-made specialist training, and the “right interaction” through appropriate and efficient modes of intra- and inter-institutional communication, coordination and consultation.

The processes and deliberations that take place within the biosafety regulatory structure are not in the public domain. Our own experience, during the course of the field research undertaken for the present study, corroborates that of others that it is impossible to find out what criteria were (and are being) *actually* used by the regulatory authorities in their risk assessment and what issues were (and are being) debated within the committees. This lack of transparency is clearly counter-productive to the proclaimed intention of the authorities to promote public trust in the biotechnology and biosafety systems and to gain the public’s acceptance for GM-crops.

9.9 The role of civil society: Raising public concerns about, and campaigning for public participation in, the biotechnology and biosafety regulatory regimes

The term ‘civil society organisation (CSO)’ denotes several kinds of institutions: voluntary, non-governmental, non-state (a term of Indian usage) and community based. It is thus wider than, and includes, the more commonly used concept of NGOs (non-governmental organisations). In the context of the present study, CSOs comprise farmers’, consumers’ and environmental organisations and the private sector media, but not the public sector organisations (e.g. universities, R&D institutions, etc.) and private sector companies, which dealt with as separate categories.

About fifteen CSOs are actively involved in agricultural biotechnology and biosafety issues, but not exclusively so. Most of them also address wider themes such as sustainable agriculture, sustainable development, the economic and social conditions of the poor, the empowerment of women, a range of farmers’ and consumers’ interests, etc. Some of the CSOs either actively involve or have ready access to senior scientists, retired top civil servants and leading “grassroots” activists.

The CSOs that have a stake in the biotechnology arena can be divided roughly into three groups: Pro-GM, anti-GM and GM-concerned. The ‘pros’ concentrate on extolling the potential benefits of GM-crops, the ‘antis’ focus sharply on the potential risks and the ‘concerned’ are ‘agnostic’ in the sense that they are prepared to accept those GM-crops that pass rigorous biosafety tests, that can be shown to benefit small farmers and the consumers at large and that do not lead to TNC-control of Indian agriculture. While farmers’ organisations and private sector media can be found in both the pro and the anti camps, the environmental and consumers’ organisations tend to be exclusively anti-GM or GM-concerned.

About half a dozen leading English language newspapers with all-India coverage have acted as the main platform for the CSOs to put across their views, inform the public about their activities and mobilise support for their campaigns (not least from members of the central parliament and state legislatures). In addition, the newspapers have carried news reports and feature articles by their own correspondents on the unfolding scene of claims and counter claims. Several of the more prolific correspondents tend to reproduce the pro-GM group’s narratives, often ‘hyping’ them up, in particular those put out by the government agencies, the public sector R&D establishment and the private sector companies.

Despite several years of campaigns, advocacy and legal challenges, the anti-GM and GM-concerned CSOs do not seem to have succeeded in obliging the authorities to alter any of their key decisions or reform their decision-making processes. But the public interest lawsuits, the publicity in the press, the street demonstrations and the militant action that have preceded and followed the commercialisation of GM-cotton have made the authorities much more cautious in their attitude towards and response to the applications by companies (in particular, the subsidiaries of TNCs) for conducting field trials and marketing other GM-crops. One can reasonably argue that the non-approval so far (late 2004) of any other GM-crop for marketing is due as much to the pressure maintained by the CSOs as to other factors.

The biotechnology and biosafety authorities are strongly convinced of the appropriateness of the regime and the structure they have set up and the correctness of their functioning. That being the case, they should have no hesitation in opening up the processes and deliberations within the structure to public scrutiny, in particular by CSOs. They should seriously consider putting into the public domain all the information that they have received from the applicants, and how the applications have been (and are being) processed, pointing out what the potential benefits and risks are that they have assessed and how, and what balance they have struck between benefits and risks in arriving at their decisions. There is no better or surer way of gaining public credibility.

The U. K. provides a good example of such an open approach. The British government commissioned a group of independent public sector research institutions to conduct large-scale field trials of GM maize (fodder), oilseed rape and sugar beet that transnational corporations had submitted for approval for commercial cultivation. After a three-year period of farm scale evaluations (FSEs), the research group published its findings in October 2003, putting all the details of the FSEs into the public domain on the internet and through the Philosophical Transactions Of the Royal Society: Biological Sciences. (According to a report on the BBC, the FSEs are the ‘largest scientific experiment of their kind on GM crops anywhere in the world’.) At the initiative of the U. K. government, the FSE findings were subjected to a public hearing and debate. It was only after this public process was completed, that the U.K. government, acting on the recommendations of the Advisory Committee on Releases to the Environment (ACRE), decided to approve the GM-maize but not the other two GM crops.

9.10 Stakeholders’ critique of the biotechnology and biosafety authorities

The biotechnology and biosafety authorities have come in for sustained criticism by sections of the research community, private sector companies and the CSOs. We summarise below their views, perceptions and demands, as they emerged in the interviews we conducted and from our examination of a large number of reports in the leading nation-wide English language newspapers.

9.10.1 Views from public sector research community

There are markedly different experiences and perceptions among public sector institutions on the levels of funding made available for agro-biotechnology R&D. The centrally funded national laboratories and research institutions (belonging to the DBT, DST, CSIR and other research councils) say they have adequate funds. This is in sharp contrast to the state agricultural universities, whose GM-active scientists complain of funding shortages. They say that the grants made just about cover the salaries of the research personnel, with little left over for investment in research equipment and supplies and other components of the research infrastructure.

At a wider level, scientists who are involved in conventional (non-GM) crop research complain that, in contrast to the recent decades, their work is now less favoured, leading to a skewing of new research proposals to include biotechnology components, to make them more attractive to the central funding bodies.

9.10.2 Views from private sector companies and public sector R&D establishment

- The biosafety guidelines and regulations are very cumbersome, stringent and time consuming. A literal compliance would be too difficult to achieve. Of particular concern are the problems posed by the requirement to test for potential toxic effects on livestock of feed and forage derived from GM-crops, not least due to the difficulties in obtaining permission by the relevant authorities to conduct the tests and the impact of the campaigns by animal rights activists.

- The transgenes that have been cleared by the regulatory authorities as being safe in the context of a given crop (e.g. the Bt-genes in Bt-cotton) should be "deregulated" and be exempt henceforth from the regulations, when used in other crops, i.e. the case-by-case approach should be interpreted as applying to transgenes and "transgenic events" and not to individual crops. In other words, GEAC should restrict itself to assessing the biosafety of transgenes (gene constructs), but not of each hybrid into which the transgene is inserted.

- The regulations should be made less stringent for GM-crops whose transgenes are derived from "closely related plant species".

- The smaller and less well-endowed companies want access to an increased number of public sector risk assessment facilities (e.g. national laboratories and agricultural universities) spread over country.

- GEAC does not have the scientific expertise to perform the tasks it is mandated to. Like its chairperson, the more influential of its members are top civil servants with administrative abilities and experience but not scientific ones.

- GEAC does not meet often enough to be able to deal expeditiously with the applications, which, in combination with its slow and inefficient way of working, leads to great delays in processing the applications.

- The present three-tier regulatory structure should be replaced by a 'single window' agency with a mandate that stretches from R&D to commercialisation;

- The several Acts of parliament whose provisions have to be met prior to a GM-crop being approved for general release and commercialisation, should be harmonised, and a single agency ('single window') should be created with the mandate to ensure that the provisions are met. At present, the applying institution has to make its way through each ministry that administers its specific Act.

9.10.3 Views from Civil Society Organisations (CSOs)

- The representatives of civil society have been deliberately excluded from participating in the biotechnology and biosafety *policy and regulatory system* (i.e. in the RCGM, GEAC, MEC and the various top-level policy-making and policy-implementing committees set up by DBT). This *policy and regulatory system* has not even acknowledged, let alone responded to, the queries, letters and submissions sent to them by the CSOs.

- The applications processed by the system, the proceedings and minutes relating to the processing, and the written 'output' (e.g. data, information, reports, etc.) from the field trials, have not been put into the public domain, despite repeated requests.

- The system has neither imposed penalties and nor taken punitive action against the institutions and companies that have failed to comply with the biosafety regulations.

- The system is not transparent and lacks public accountability.

9.11.Initiative to reform the biotechnology and biosafety policy and regulatory system

The strong and persistent critique by major stakeholders outside the government of the current biotechnology and biosafety policy and regulatory systems prompted (some would say compelled) the GoI into setting up three high-level taskforces for reviewing the current regimes and making recommendations for reform. The first of two of these are on, respectively, agricultural biotechnology (chaired by Dr. M. S. Swaminathan) and medical/bio-medical//pharmaceutical biotechnology (chaired by Dr. R. A. Mashelkar, the Director General of CSIR).

The Swaminathan task force submitted its report to the Minister of Agriculture in June 2004. It makes far-reaching recommendations, the most of striking of which are that

- an autonomous Agricultural Biotechnology Regulatory Authority (ABRA) be set up,
- and pending the creation of an ABRA, (i) the GEAC should be split into two separate wings, one dealing with transgenic crops and the other with transgenic medical and pharmaceutical products, (ii) GEAC's role be limited to 'environmental clearance', and the authority for deciding on the commercial release of GM-crops transferred to ICAR and MoA, (iii) the RGCM should be authorised to grant approvals for open field testing for biosafety, while ICAR and the applicant company should be asked to conduct large-scale field trials, and (iv) the post-release monitoring of GM-crops be done by MoA and ICAR.

The third and latest is the Taskforce on New Biotechnology Policy, set up in late October 2004, under the chairmanship of the Secretary of DBT, Dr M. K. Bhan. Besides Dr Swaminathan and Dr Mashelkar, the Bhan taskforce includes a number of top civil servants and representatives of the public sector R&D establishment, private sector industry and India's leading GM-concerned CSO, the Gene Campaign. It has been directed by GoI to make recommendations, *inter alia*, "on setting up of sub-committees in different sub-sectors (of biotechnology) and their roadmaps ---- for the next 10 years, --- on modifications to the existing laws and procedures --- (concerning) regulation of transgenic products, --- and on incentives for promotion of trade and investment in biotechnology". One expects the reports by the Swaminathan and Mashelkar Taskforces to have significant impact on the deliberations of the Bhan Taskforce.

It is telling that none of these taskforces have been charged with the task of coming up with recommendations on how to promote public trust and credibility in the biotechnology and biosafety systems and on instituting channels and measures for communicating to civil society the processes and deliberations that take place in the regulatory structures.

9.12 Stages of and conditions for the transition from the lab to the market

Despite large investments and many years of effort, most of the GM-crops being developed in public sector R&D institutions in India have not advanced beyond the greenhouse stage, with only a few going one step further into limited and contained field tests. The only GM-crop that has successfully completed the mandatory large-scale, multi-location field trials and been approved for commercialisation is the GM-cotton developed by the private sector USA-India joint-venture Monsanto-Mahyco and its private sector licensee Rasi seed company. Obviously, the public sector institutions are facing obstacles that are specific to their particular situation.

Public sector R&D institutions have to successfully complete *two major stages* in taking their GM-crop innovations from the lab to the market. *First*, they have to conduct the large-scale, multi-location and multi-season field trials that are obligatory under the national biosafety regulations and present the outcome of the trials to GEAC, on the basis of which GEAC would decide whether or not to approve a given GM-crop for general release and commercialisation. Second, they have to negotiate with seed production and marketing firms (in the private and public sectors) the terms and conditions of technology transfer agreements, under which the firms would be willing to take over the innovations and produce and market the GM-crop seeds (planting material). *This second stage* involves also the potentially contentious issue of intellectual property rights of foreign owners of the GM-technology that almost all Indian work on GM-crops is currently based on.

9.12.1 The shortfall in resources in public sector institutions

We think that one of the main reasons for the inability of the public sector R&D institutions to emulate the momentum of the private sector companies in moving from the lab to the market lies in their lack of resources (financial, infrastructural and staffing) to conduct large- scale, multi-location field trials, including the breeding of sufficient magnitudes of GM-seeds to that end. In terms of access to such resources, the private sector companies are much better placed than the public sector institutions. The "resource barrier" cannot probably be overcome without a serious commitment by ICAR to put its well- established, well-functioning, nation-wide system of "All India Crop Trials" at the disposal of the GM-active public sector R&D institutions, irrespective of whether or not they come under ICAR's aegis (ICAR's financing umbrella). Another possible route to try is public-private partnership.

Assuming that a GM-crop has been approved for general release and marketing by GEAC, the actual transition from the lab to the market depends upon several crucial factors and instruments:

- technology demonstration and dissemination,
- "entrepreneurial bridges" between the R&D institutions, and the seed producing and marketing firms,
- economic viability at the small farm level,
- consumer acceptance and
- market competitiveness.

As of late 2004, no public sector R&D institution had yet embarked on the stage of large-scale, multi-location field trials and therefore the prospect of a public sector GM-crop innovation being commercialised remains a distant one. Thus, it is too early to say whether the above factors and instruments would be in place when the time comes for setting forth on the post-GEAC approval stage of the transition. In principle, however, that ought to be the case, because they were in evidence in the highly successful transition from the lab to the market of *non-GM tissue culture* innovations from a few public sector labs to the private sector in the 1980s and 1990s.

9.12. 2 In-country transfer of technology to market actors and the question of intellectual property rights

As in the medical/pharmaceutical sectors, the food and feed crops sector at the global level is characterised by a massive concentration of technology, patents and IPR-covered genetic material in the hands of half a dozen agro-chemical transnational corporations (TNCs). Thus, access to the state-of-the-art biotechnology and its products is strictly regulated. As pointed out above, almost all current GM-crop work in public sector R&D institutions in India is being conducted on the basis of the GM-techniques patented either by the TNCs or by some advanced research institutions in the OECD region. The Government of India (as represented by DBT, MoA, MoC, etc.) and the public sector institutions would therefore have to negotiate with the TNCs and foreign research institutions affordable terms and conditions for using patented GM-technologies (processes) and GM-products, *including the conditions that will govern the Indian public sector institutions' own IPRs vis-à-vis the Indian market actors (the so-called "freedom to operate" clauses*). These negotiations presume the existence of IPR-focused policies, as well as institutional capacities and strategies, within GoI, of which we found no readily available evidence either in the public domain or through our interviews with selected officials.

In principle, the IPR-agreements with the TNCs and foreign research institutions would affect the approach adopted by the Indian public sector R&D institutions in their own IPR-negotiations with the local market actors. It is too early to say how this will work out in practice. In any case, in such negotiations, the institutions would have to be sensitive to a variety of responses by the indigenous local market actors when confronted by the institutions' IPR demands, which are determined by the actors' heterogeneity, differential access to resources and differing motivations in entering the GM-crops arena. In order to initiate and successfully conclude such negotiations, and to administer and manage the ensuing agreements, the R&D institutions would need recourse to capacities in a variety of fields in the social sciences, management and legal disciplines. Since the R&D institutions are unlikely to have all the required capacities within their own walls, they would have to access the capacities from a range of institutions that lie outside the GM-arena. However, it is important for R&D institutions to have IPR-policies in place, backed up by in-house IPR-units with the relevant expertise to provide advice to the scientific and managerial personnel as they negotiate with the IPR-holders. GoI needs to facilitate this process. For instance, universities in the United States have established in-house IPR-offices, a move that is afoot in Western Europe as well.

GoI has deployed some policy measures and instruments to steer R&D institutions towards establishing linkages with, and working on problems of practical importance to, local market actors, e.g. tax breaks, reduced customs duties on imports of R&D inputs, ready access to training and service infrastructure. Again, it is too early to say how relevant and effective these will prove to be in the case of GM-crops. One has to await the start of the transition process. It is anybody's guess as to when that is likely to happen.

9.13 Biosafety regulatory regime in action: What the Bt-cotton case reveals

Bt-Cotton is the first, and so far (as of early 2005) the only GM-crop to be commercialised in India. Our research into the various stages of this process leads to some serious questions about the structure and implementation of India's biosafety regulatory regime, and the roles played by the main stakeholders in the government, the private sector, the public sector R&D establishment and civil society.

In March/April 2002, GEAC approved three Bt-cotton hybrids developed by Monsanto-Mahyco for commercial release. One assumes that GEAC would have ensured the environmental (ecology and biodiversity), livestock health (cotton seed is used as livestock feed by Indian farmers) and socio-economic safety of the hybrids by extensive and rigorous *monitoring* of Monsanto-Mahyco's large-scale, multi-location field trials in five states whose outcome was the decisive input into the approval process. However, our field research conducted in a district of Karnataka revealed that the MEC-directed monitoring process was cursory and very narrowly focussed. The monitoring restricted itself to measuring the Bt and non-Bt cotton yields, the bollworm-load and -migration on the trial plots, and the frequency and magnitude of pesticide spraying. We found no evidence of any monitoring of a range of other features and indicators that the three broad areas of safety mentioned above dictate. To check whether these omissions were limited to the district we studied or were common to all the field trials monitored in the five states, one needs to examine the monitors' reports, as well as Monsanto-Mahyco's field trial reports, submitted to GEAC. But GEAC has declined to put these reports into the public domain, despite repeated calls by CSOs and sections of the media. Until this is done, serious doubts will remain over the approval process.

The exclusion from GEAC, RCGM, MEC, and the field monitoring teams of independent representatives of the social science research community and the CSOs causes grave concern. Any process of biosafety scrutiny that wants to be taken seriously by the broad public must necessarily include such representation. This exclusion is compounded by the fact that RCGM and GEAC in practice (although perhaps not in a formal sense) handed the tasks of setting up the monitoring teams and the directing of the teams' work to Monsanto-Mahyco. Needless to say, this has undercut the credibility and legitimacy of the monitoring and approval processes.

The biosafety regulations call for the close involvement of state and district level biosafety committees (SBCCs and DLCs) in the monitoring of the field trials and subsequent commercialisation of GM-crops. Approval to conduct field trials of Bt-cotton should have been contingent on this provision being met. This clearly has not happened. As of early 2005, SBCCs and DLCs had not been set up in twenty-two out of the twenty-five states of India, and in the three states (Andhra Pradesh, Himachal Pradesh and Karnataka) in which SBCCs have been created, they have remained, by and large, as paper exercises. On what legal basis did RCGM and GEAC feel secure enough to ignore this aspect in giving the go ahead to Mahyco-Monsanto? Are not the state governments themselves also legally remiss in not abiding by this provision?

As the Navbharat illegal seeds episode has demonstrated, the biosafety regulatory authorities have no effective means of keeping themselves informed of what is going on in the various states in the GM-arena and of taking direct punitive action against parties that flout the biosafety regulations. The Navbharat case has exposed the profound limitations in the functioning of the current biosafety regulatory regime.

The universities of agricultural sciences (UAS) have missed very valuable opportunities for acquiring some hands-on experience of the 'lab to the market' process by not actively lobbying DBT, ICAR and the state governments for the right to be closely involved in the designing and execution of the Mahyco-Monsanto and RASI field trials. The UASs, after all, have standing and ready access to extensive and well-endowed field trial and extension infrastructure (including staff), thanks to the generous and long-term support by ICAR and the Departments of Agriculture of the state governments.

Given the deeply sceptical attitude of the public sector R&D establishment and the GM-activist CSOs to the private sector actors in GM-agriculture, one would have expected Mahyco-Monsanto and RASI to have put into the public domain all the steps they have taken in getting their seeds approved, in particular all the data and information they have submitted to RCGM and GEAC. In addition, it would have been in their own long-term interest to actively maintain a continuing process of dialogue and discussion, on the basis of transparent sharing of information, with these two stakeholder groups. On the contrary, the private sector actors have chosen to ignore the public stakeholders, and when forced by parts of the media to address the public stakeholders' legitimate concerns, have responded with palliative public relations exercises. No wonder that this tactic has generated a severe backlash.

It is surprising that the central and state governments did not commission biosafety studies, and long-term monitoring studies, by Indian research institutions, into the potential build-up of Bt-resistant insects and on strategies to deal with that near-certain contingency. More generally, the Bt-cotton case has revealed severe shortcomings in the state of biosafety research in India, not only in the environmental and health areas, but also in the socio-economic fields. The authorities need to ensure that Indian institutions acquire sufficient capacity to conduct biosafety and monitoring research in all affected disciplines (environmental, health and socio-economic).

9.14 Biotechnology policy regime in action: What the transgenic rice case reveals

In terms of the efforts made and the resources invested (research personnel, financial and infrastructural), transgenic rice is far ahead of all the other GM-crops being developed in India. Research into GM-rice in India began in the early 1990s with substantial support by DBT and by the Rockefeller Foundation's International Program on Rice Biotechnology (IPRB), backed up ICAR's institutional and infrastructural support. The IRPB ended in 2000. Inclusion in the IPRB has been decisive for the initiation and growth of R&D work in transgenic rice, as well as for R&D capacity building, in selected public sector institutions in India. Most of the effort is on trying to build in traits that confer resistance to attacks by a few main insect pests and viral diseases, but some work is also underway on improving drought and salt tolerance and on increasing the protein content.

Despite the significant resources and time invested, progress has been slow in almost all the nine public sector institutions undertaking the GM-rice work. Although all the nine report having completed the laboratory and greenhouse stages, only a few have been able to take the next step of contained field tests. At the present rate of progress, it will take several years from 2005 before the large-scale, multi-location field trials of the first batch of GM-rice innovations can be completed. Thus, if and when the commercialisation of some transgenic varieties of rice takes place, the process of moving “from the laboratory to the market” will have taken about twenty years, which seems long by international standards.

The slow pace and uneven progress is probably due to the spreading of the available resources over a number of geographically widespread institutions. On the other hand, this dispersal is certainly beneficial to capacity building, and to the provision of opportunities for future achievement, in different parts of this huge country. It is also politically unavoidable.

Looking at the six institutions working on insect and disease resistance, one wonders whether there is considerable duplication in effort at the level of the fundamental GM-science, if not in the application of the fundamental GM-science (i.e. the technology) to some site-specific local rice varieties. But the justification for duplication of the applied science and technology work based on the site-specificity work is hard to comprehend in those instances where the same rice variety (e.g. the Pusa Basmati) is being subjected to fundamental GM-science investigations in institutions located in very different agro-climatic and ecological zones.

In theory, the biotechnology policy and funding authorities expect institutions working on similar problems to coordinate and jointly plan their work, especially as they all belong to the national rice biotechnology network. But the practice belies the theory. The network meets, apparently, once in two years. In our interviews, we could not elicit concrete examples of how the coordination was taking place, what the fruits of the coordination were and what synergies had been utilised. On the contrary, our interviews reveal that traditional patterns of non-cooperation and rivalry are alive and well.

In vivid contrast to the Bt-cotton case, where it became involved only in the ultimate round of field trials at the behest of GEAC, ICAR has been promoting R&D work in transgenic rice from the very start. This augurs well from the point of view of the nine institutions working on GM-rice, for they are entirely dependent on ICAR’s resources, infrastructure and institutional network, and crucially, on its system of All India Crop Trials, to have their innovations of transgenic rice varieties tested in the legally mandatory large-scale, multi-location field trials.

With the exception of the protein-enrichment traits, all the other traits being tackled by the research institutions are motivated by the central objectives of increasing the *net* yield of rice and the net monetary return to the farmer, per unit of land cultivated, and thus increasing the total rice production in the country. Net yields, and thus net monetary returns, at the farm level, are expected to increase significantly, through the elimination or reduction of attacks by insect pests and viral diseases, and the reductions in the use of pesticides. But it is impossible to predict such successful outcomes in advance of actual practice under the conditions that prevail at the farm, district and state levels. Rather, as the Bt-cotton case demonstrates, one can expect strongly conflicting claims.

The expectation of net return is premised on their being a ready domestic market for the transgenic produce. But that is far from being a foregone conclusion. The fate of the *non-GM hybrid rice* ought give pause for thought. It failed to take off for a number of reasons, chief among which were the massive rejection by consumers who were put off by its culinary properties and its non-competitive price and the relatively inferior storage quality *vis à vis* the established conventional high yielding varieties of the Green Revolution.

The premise of a ready domestic market would hold with some degree of certainty, if there were supply shortages. But the situation is exactly the opposite. For over two decades the domestic supply of rice has substantially exceeded domestic demand, resulting in the piling up of huge stocks in the storage silos of the Food Corporation of India. And India's current export performance in rice is not dynamic enough to absorb the excess supply, especially in the face of competition by other major exporters like Thailand and Vietnam.

The question of potential export markets for GM-rice is very problematic. The GM-labelling and -tracing rules that GM-food imports have to comply with in the EU make it a virtual certainty that India will not be able to export transgenic rice to the EU. Further, the potential for the 'contamination' of conventional rice by GM-rice can seriously jeopardise current Indian exports of conventional rice to the EU. And there are clear signs that consumers and sellers in some other rice importing regions may be prompted by EU's stance into declining GM-foods altogether. It is for this reason that Thailand, the world's premier rice exporter, is maintaining its ban on the commercial cultivation of GM-crops, while simultaneously encouraging domestic R&D work on GM-crops. It is entirely on the cards that India may be compelled to emulate Thailand in order to hang on to its export markets for rice and other food crops.

IPR issues will be particularly contentious in the rice case. Almost all the research on GM-rice in India is based on transgenes (gene constructs) obtained from foreign companies and institutions. With rice being the world's leading cereal and with great export profits at stake, one can foresee the IPR-holders insisting on agreements that may prove very expensive and restrictive to Indian institutions and the Indian government.

It is to be hoped that the intense and bitter public controversies that have raged in India between the government authorities, on the one hand, and activist civil society organisations (CSOs/NGOs) and parts of the media, on the other hand, on the introduction of Bt-cotton and Golden Rice, will prompt the authorities into becoming genuinely cooperative, transparent and inclusive in their dealings with the CSOs and the media. Without such a change in the current attitude and practice on the part of the authorities, transgenic rice will be embroiled in similar controversies.

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SEI is an independent, international research institute specializing in sustainable development and environment issues. It works at local, national, regional and global policy levels. The SEI research programmes aim to clarify the requirements, strategies and policies for a transition to sustainability. These goals are linked to the principles advocated in Agenda 21 and the Conventions such as Climate Change, Ozone Layer Protection and Biological Diversity. SEI along with its predecessor, the Beijer Institute, has been engaged in major environment and development issues for a quarter of a century.

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Stockholm Environment Institute

SEI-HQ
Director: J. Rockström
Box 2142
S-103 14 Stockholm
Sweden
Tel+46 8 412 1400
Fax+46 8 723 0348
E-mail postmaster@sei.se
www.sei.se

SEI-Boston
Director: P. Raskin
11 Arlington Street
Boston, MA 02116-3411
USA
Tel+1 617 266 8090
Fax+1 617 266 8303
E-mail seib@tellus.org
www.seib.org

SEI-Tallinn
Director: V. Lahtvee
Lai 34, Box 160
EE-10502, Tallinn
Estonia
Tel+372 6 276 100
Fax+372 6 276 101
E-mail seit@seit.ee
www.seit.ee

SEI-York
Director: J.C.I. Kuylenstierna
University of York
Heslington, York YO10 5DD
UK
Tel+44 1904 43 2897
Fax+44 1904 43 2898
E-mail seiy@york.ac.uk
www.seiy.org

SEI-Asia
Director: T. Banuri
c/o UNEP RRC.AP
Asian Institute of Technology
P.O. Box 4, Klong Luang
Pathumthani 12120, **Thailand**
Tel+66 (0) 2 524 6495, 524 5369
Fax+66 (0) 2 516 2125, 524 6233
www.sei.se/asia

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