Globalisation and the International Governance of Modern Biotechnology

Regulating Biotechnology in India

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Research and Information System for the Non-Aligned and other Developing Countries (RIS)

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Introduction

Over more than a decade now, the prospects of Indian agriculture have often been linked to the developments in the area of biotechnology. This frontier technology has been seen as providing solutions to the more critical problems that the farm sector has been facing in recent decades. But even as solutions have been proposed, the technology itself has been questioned at various levels. The more serious of these questions have been raised about the possible impact of genetic engineering on human, animal and plant health, and more generally on the environment. The doubts about the safety of biotechnology, however, have been addressed at two levels. First, at the multilateral level, through the adoption of the Cartagena Protocol on Biosafety, and secondly, by adoption of national legislation to effectively take care of the biosafety concerns.

The present paper looks at the governance of biotechnology and its implications for Indian agriculture. For the past four decades, India's agricultural policy-making has focused almost exclusively on the issue of ensuring food security to the growing population of the country. This orientation in policy-making resulted in the adoption of the strategy to realise the objective of self-sufficiency in foodgrains production in the country. Consequently basic cereals have come to dominate the production structure of India's agriculture. Although in recent years, India has emerged as a net exporter of the major cereals, the objective of meeting the objective of food security continues to remain the cornerstone of Indian agriculture.[1]

This paper has been organised into the following sections. The first section indicates the priorities for the biotechnology sector in India. These priorities are counterpoised against the problem that Indian agriculture faces at the present juncture.

The second section deals with the state of the agri-biotech sector. The developments in this sector will be analysed in light of the structure of Indian agriculture.

The third section discusses the regulatory framework for transgenics that is currently in place. Besides bringing out its key features, this discussion also provides a critical assessment of the regulatory framework.

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[1] This has been evident from the stand India has taken in the negotiations on the review of the WTO Agreement on Agriculture. For details see WTO (2001).

The Policy Perspective

Biotechnology has been seen as contributing to the development of Indian agriculture. Although policy pronouncements by the Government in this regard have been relatively few, those that have been made need to be underlined.

One of the most significant statements about the role of biotechnology in furthering the fortunes of Indian agriculture was made in the National Agricultural Policy presented in the year 2000.[2] The National Agricultural Policy, which presented the blue-print for the agricultural sector for the next two decades, explored the options to ensure that growth of the sector is sustainable technologically, environmentally and economically. Biotechnology was seen as one of the alternatives for achieving this objective. The policy stated that the use of biotechnologies would be promoted for evolving plants that are drought resistant, pest resistant, consume less water, contain more nutrition, give higher yields and are environmentally safe.

The Department of Biotechnology (DBT) has complemented this initiative by policy makers in the agricultural sector by advancing their justification for the use of biotechnology for agricultural growth. According to DBT, the post-Green Revolution era has almost merged with the gene revolution for improving the productivity and quality of crops. The exploitation of heterosis vigour and the development of new hybrids including apomixis, genes for abiotic and biotic resistance, and development of planting material with desirable traits and genetic enhancement of all important cops will be the focus of the agricultural research agenda in the future. In addition to providing improved quality of plant material, biotechnology has been seen as contributing to integrated nutrient management and development of new biofertilisers and biopesticides, inputs that would be crucial from the point of view of realising the objectives of sustainable agriculture, soil fertility and clean environment. Biotechnology has thus been seen as a key input towards bringing a radical transformation of agricultural practices in India, one that involves a greater use of biological software on a large scale.

The above-mentioned objectives that the policy makers have set for biotechnology in the context of transforming Indian agriculture have been reflected in the research priorities set by the DBT in recent years. The Department has been promoting research to enhance food and agricultural production, quality and nutritional improvement and prevention of pre and post harvest losses.

These research efforts have, according to the DBT, provided significant leads in the areas of basic plant biotechnology and plant genome research, development of makers of high quality protein content and development of molecular methods for hybrid mustard and production of transgenic plants of tobacco with viral resistance.

The focus of agricultural biotechnology as is evident from the policy statements referred to above can be better understood in the context of the structure of Indian agriculture and the imperatives that it faces at the present juncture.

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[2] Government of India (2000). See also Government of India (2001).

The State of Indian Agriculture

Two key issues of Indian agriculture have been highlighted in the discussion below. The first is the nature of the product mix of the country's agriculture. The second issue is to understand the strength of Indian agriculture in relation to some of the major agricultural producers.

Indian agriculture has been dominated by food crops production. This stems from the basic orientation given to agricultural production by the policy makers, which has been to ensure self-sufficiency in foodgrains. Total area under foodgrains cultivation was nearly 65 per cent of the gross cropped area in 1997-98 (Annex, Table 1). Although in the subsequent period, the area under foodgrains cultivation has decreased somewhat, it nonetheless remains quite significant. Foodgrains production is in turn dominated by two of the major cereals, viz., rice and wheat. In 1997-98, these two cereals accounted for 75 per cent of the total foodgrains production in the country, which went up to over 77 per cent in 1999-2000 (Annex, Table 2). In terms of the area, rice and wheat accounted for nearly 58 per cent of the total area under foodgrains cultivation in 1999-2000. As compared to rice and wheat, maize occupies a relatively minor position in Indian agriculture, accounting for about 3 per cent of the gross cropped area in the late 1990s. Production of maize has also remained largely unchanged through the 1990s, mainly due to stagnating yields.

In sharp contrast, one of the most important non-food crops, viz. cotton does not count for much in terms of the total area under agricultural production. Although area under cotton production increased during the 1990s, even in 1996-97, the year in which the area under the crop had reached its peak, it was only about 4.5 per cent of the gross cropped area of the country.

The overwhelming domination by foodgrains in India's agricultural production can be justified on the grounds that net availability of foodgrains in per capita terms has been fluctuating around a declining trend in the country since the mid-1980s. This trend in per capita net availability cannot be ascribed simply to the changing consumption patterns since per capita GDP of the country has not experienced a dramatic change during the period referred to above. These figures therefore point to the fact that a country like India, in which poverty in absolute terms remains a major problem, ensuring food security to the population should be the key concern. That considerable efforts need to be put in this direction is evident from the fact that the yields of major crops in India have not only stagnated over a period of time but they are also considerably lower than those observed in some countries.

Behaviour of Yields in Major Food Crops

In the following discussion, the yield levels of five food crops in India have been compared since the mid-1980s. The crops included are rice, wheat, maize, pulses and rapeseed (Annex, Table 3)

In rice the yields have risen steadily but rather slowly over the period 1985 to 1999. In fact, it would not be unreasonable to conclude that yield rates of rice have reached a plateau after the mid-nineties. In 1985, the yield of rice was at 2329 kg/ha. This increased to 2929 kg/ha in 1999. However, in recent years, the growth rate of yield has declined. The yield increased by 12.8 per cent between 1985 and 1990, after which this rate declined to 1.9 per cent in the period 1990-95 and further to 5.2 per cent in the period 1995-99.

In case of wheat the yield increased by 13.4 per cent between 1985 and 1990 and further to 20.6 per cent between 1990 and 1995 but thereafter between the period 1995 and 1999 it declined to 0.9 per cent. The yield of wheat was 1870 kg/ha in 1985. It increased to 2559 kg/ha in 1995 and thereafter fluctuated. In 1999 the yield was 2583 kg/ha. Thus the peak was reached in 1997 after which the yields have declined.

Yield of maize, like that of wheat, reached its peak in 1997. Maize recorded a satisfactory growth rate in yield of about 33 per cent during the period 1985 and 1990. This rate however fell to –2.8 per cent during the period 1990-95, after which it became 0.9 per cent during 1995-99. Yield of maize increased from 1146 kg/ha in 1985 to 1524 kg/ha in 1990 but then it fell to 1481 kg/ha in 1995 and further to 1408 kg/ha in 1996. In 1997 the yield rose to 1746 kg/ha after which it kept falling till 1999.

In case of pulses taken as a whole the yields increased steadily from 519 kg/ha in 1995 to 628 kg/ha in 1995 after which it kept fluctuating till the latest year for which data has been provided. The yield increased by 7.7 per cent between 1985-90 and then by 12.3 per cent between 1990-95. This rate however declined significantly to 0.9 per cent during the period 1995-99. As in case of both wheat and maize, the yield of pulses in 1999 was nearly the same as in 1997, which suggests that no improvement in yield has taken place since 1997.

Yield of rapeseed grew steadily from 771 kg/ha in 1985 to 1017 kg/ha in 1997, which was the peak for the period considered here. Thereafter it fell to 668 kg/ha in 1998 and again increased to 875 kg/ha in 1999. The growth rate of yield during the period 1985-90 was 7.8 per cent. This increased to 13.7 per cent between 1990-95 and then became negative during the period 1995-99.

The brief trends in yields of some of the major food crops described above indicates that India's foodgrains production strategy needs to focus on ways to improve the yields for the crops included in the analysis. This needs to be the very first step that the country should take to improve agricultural productivity in the foreseeable future. The yield rates observed in case of India becomes even more stark when the figures are compared to those in select countries.

The following analysis seeks to compare the yield of two very important cereals, viz. rice and wheat, along with that of maize across countries over the years to throw light on the nature of improvements in yield that have taken place elsewhere.

Rice

India's rice yields do not compete favourably with the countries figuring in Table 4, (Annex). Not only were the Indian figures lower than those observed for Sri Lanka, but in the case of China registered yields were more than double than that of India. Countries like Argentina and Brazil, in whose agricultural production rice does not figure prominently, also registered yields that were higher than India had ever recorded. The only positive aspect for India has been that the rice yields have registered continuous increase between 1985 and 1999, albeit slowly, while for most of the countries appearing in Table 4, rice yields have fluctuated in the same period.

Wheat

Wheat yields recorded by India compare favourably with those observed for several countries included in Table 5 (Annex). Only China and the United States have recorded yields that have been higher than those recorded by India. For most countries, however, the wheat yields have peaked during the second half of the 1990s before declining in the closing years of the decade. India also follows this trend, with the highest yield being registered in 1997.

Maize

Maize yields in India have been among the lowest in the world. Among the countries included in Table 6 (Annex), only Sri Lanka has lower figures than India. As in the case of the other two food crops discussed above, China and the United States have consistently recorded the highest yields in maize among the countries included in Table 6. India's maize yields in 1999 were almost a third that of China and a fifth that of the United States. In fact during the 1990s, maize yields in India registered only a nominal increase, which does not compare favourably with most other countries included in Table 6.

The above analysis points to the need for a major transformation as far as Indian agriculture is concerned so as to make the sector meet the objectives that have been set by the policy makers. The imperative has increased given the threat of foreign competition that the domestic producers in India face in the era of open markets. This is an area where technological improvements brought about through the introduction of biotechnology can play a part. While the effect of structural impediments in depressing production and productivity of the country's agriculture cannot be ignored, technological solutions can make a contribution in reversing the trends. The success of the Green Revolution strategy in taking Indian agriculture to a substantially higher growth trajectory provides support to this argument.

Development of the Biotechnology Industry

India was one of the few developing countries which realised the importance of biotechnology much before it became an established industry even in the developed countries. It was in 1982 that the Indian government had established the National Biotechnology Promotion Board (NBTB), as a nodal agency for advancement of biotechnology in the country. Later in 1986-87, on recommendation of an expert group, NBTB was converted into Department of Biotechnology (DBT). Apart from supporting biotechnology research, this department was also given the responsibility for the development of biotechnology products under the Industries (Development & Regulations) Act of 1951. Research on biotechnology has also been supported by publicly funded institutions like the Indian Council for Agricultural Research (ICAR), Indian Council for Medical Research (ICMR), Department of Scientific and Industrial Research (DSIR), Council for Scientific and Industrial Research (CSIR).

In the years immediately after the DBT was set up, the state sector played a prominent role in the development of biotechnology in India with almost 90 per cent of the biotech R&D funds being invested by this sector, according to industry analysts. But with sweeping changes in the overall orientation of policy making since the early 1990s, which has seen withdrawal of the state from some sectors, the involvement of the private sector has increased. Over time, several large enterprises in the Indian industry, particularly in the areas of chemicals and pharmaceuticals, have increased their commitments to funding of biotechnological research. The full extent of private sector participation however remains unknown owing largely to the absence of an authentic database for the sector. Information about the size of the biotechnology industry and the areas it is focused on has therefore been obtained from some of the widely acceptable industry watchers.[3]

An Overview of the Growth of the Biotechnology Industry in India

The biotechnology industry in India is involved in the production of four broad product ranges. These are: (i) human and animal health products, (ii) agriculture, (iii) industrial products and (iv) other products.

Table 7 (Annex) provides the figure of consumption of biotechnology products in each of these four product groups.

In the absence of established data on production for the industry as a whole, the study relies on the data for consumption used as an indicator of the size of the industry as well as the market existing in India. Domestic consumption would roughly correspond to domestic production since India continues to be one of the more protected markets for most products. The large potential of biotechnology products that exists in the country is reflected by the rapid increases in consumption that is expected in the next five years.

Table 7 indicates the relative growth of consumption in the four products groups. The consumption of agriculture related products registered the most impressive increase in the period since 1992. This product group is expected to experience continued expansion in consumption till the middle of this decade, the period for which data is available. In contrast, the consumption of industrial biotechnology products is expected to register smaller increases in the next five years. As a result, by the year 2005, consumption of agri-biotech products is expected to be higher than those of industrial biotechnology.

The relative growth of the sectors indicated in Table 7 gets reflected in the changes in their respective shares of total consumption. Thus, while health care products are expected to be about 40% from the present 37% (1997), the share of agriculture may rise from 28% to nearly 33%. The share of other products would however be reduced from 35% to about 28%, although in monetary terms, there would be substantial rise in the consumption in these products as well.

A significant problem that the biotechnology industry in India faces at the present juncture is that the industry lacks even a basic database, which could help in analysing the potential that it holds. One of the limitations in establishing such a database could be that the industry itself is not properly defined in terms of the areas it encompasses. Thus,

[3] Included here are senior officials of the Department of Biotechnology.

both traditional plant breeding and genetic engineering are considered as a part of the biotechnology industry.

One of the few available studies that covers the biotechnology industry in a somewhat comprehensive manner suggests the future trends in the major segments of the industry.[4] This study indicates that in the Indian context, human and animal health products will grow substantially in areas of recombinant DNA products used in therapy. Among the conventional products, the production of antibiotics by fermentation will grow slowly but steadily. In agriculture, the major contribution is anticipated from the local production of increased quantities of hybrid seeds and high-yielding varieties. Genetically modified plants/seeds are expected to emerge during the next century and are likely to capture markets in specific sectors of the seed industry. There would also be an increase in the usage of bio-pesticides including botanical pesticides. Besides the increased use of hybrid seeds/varieties, the consumption of bio-pesticides, bio-fertilisers and plant growth promoters are also expected to increase.

The available projections are based on a number of factors. These include past consumption trends, the requirements of the public in the context of their unmet needs, the purchasing power of the people, the prices at which the products were offered, the quantum of the target population for specific products, the present technological base and the current capabilities of the country.

Agricultural Biotechnology

The likely scenario in relation to agricultural products based on biotechnology is presented in Table 8 (Annex).

The expected growth of consumption indicated by the rising number of seed varieties that are likely to be consumed by the middle of the present decade suggests that agriculture is going to be another important area for large future investment. The seed industry alone could invest over Rs. 1.5 billion in the next five years. Opportunities also exist for new investment in bio-fertilisers (over Rs. 200 million), biopesticides (about Rs. 300 million), pheromones, growth stimulants/promoters (over Rs. 500 million) and botanical pesticides.

The following sections will provide details of the developments in the seed industry, one of the major areas in which biotechnology was expected to play a critical role in India.

Trends in Agricultural Research

In past few years, agriculture in most of the developing countries has been witnessing the introduction of new products, emerging from the developments in the area of biotechnology. Biotechnology has held particular promise for these countries since it was maintained that the stagnating (in some cases declining) productivity levels seen in agriculture in developing countries could be reversed. In this context, advances in biotechnology offer an opportunity for growth and sustainable development of

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[4] Ghosh, (1999).

agriculture in these countries. Moreover, several international initiatives have been undertaken so as to enhance the access of this technology to the developing countries. The relevance of this technology for developing countries has to be seen in the light of the priorities that agro-biotech research has seen thus far. This will be dealt with below.

The emergence of the new technologies, biotechnology in particular, has, however, posed serious policy constraints for the developing countries. The international environment in which these technologies are being developed is considerably different from the one which saw the adoption of the high yielding varieties that heralded the advent of the Green Revolution more than three decades ago. The most significant difference is that unlike the Green Revolution varieties, which were primarily developed in the public-funded organisations, firms in the private sector are spearheading developments in biotechnology. Avramovic argues that this change in the respective involvement of the institutions has been caused by two factors: (i) declining public funding for research, and (ii) capital intensive nature of the R&D activity.[5] The decline, often in relative terms, of public funding for research has taken place essentially because of the fiscal crisis that the state has been going through in most developing countries.

The larger involvement of the private sector, however, portends to a major change in the structure of agricultural production in developing countries such as India (see Annex, Table 9), where enhancing the production of foodgrains was set as one of the principal objectives.[6] The direction of public sector research was in keeping with this objective: both food crops and commercial crops formed a part of the research agenda. But while public sector research took a balanced view, the private sector has shown a keen interest in the commercial crops, giving very little attention to the crops linked with the food security of a developing country. In fact, such crops are now being called ‘orphan crops', which are primarily consumed by small and marginal farmers and by the agricultural labourers. Further, as part of their globalisation efforts, many developing countries have been encouraging foreign investment in food processing industries, which has further taken away the focus of the R&D priorities from the primary crops to the commercial crops, a point that will be elaborated below. This approach towards R&D raises many questions regarding access to biotechnology which is appropriate to national needs. The issue of food security is inextricably linked to the growth of technology in this sector, and that agriculture continues to provide livelihoods to a majority of the population.

Private Sector R&D in Agriculture

Agricultural research in India has three distinct components. The first component of research is the development of the high yielding varieties, which have been popularised after the Green Revolution. The second component is production of hybrids, while the third is the production of genetically modified seeds.

The involvement of the private sector in R&D in the agricultural sector has traditionally been at a very low level. As in the case of most countries, India has seen an overwhelmingly large participation by government-funded organisations in agricultural research until the end of the 1990s. Production of the high yielding varieties, in

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[5] Avramovic (1996).
[6] Government of India (1974).

particular, was in the hands of the public sector organisations, which include the agricultural universities set up with state support.

The participation of the private sector was by only a few firms, which had started operating in the 1960s. These firms concentrated their efforts on developing superior hybrids. By 1980s, the number of private sector seed firms had gone up to just six, and by the end of the decade of the '80s, private sector seed firms were only 12.

One of the principal factors restricting private sector participation in the seed sector until the end of the 1980s was the restrictions imposed by the government on their expansion through the use of the licensing policy.[7] The provisions of the licensing policy as applicable to the production of hybrid seeds and agricultural biotechnology products were relaxed in 1987. Foreign firms and firms belonging to the monopoly houses, which were, till then, prevented from investing in the seed industry, were now given permission to do so.

Further encouragement to the growth of the private sector seed industry in India was given in 1988. Import of seeds of coarse cereals, pulses and oilseeds was allowed for a period of two years by firms established in India which had entered into collaboration with foreign firms for the production of seeds, provided that the foreign partners agreed to supply the parent-lines of the seeds to the Indian partners within two years from the date of import of the first commercial consignment. This policy excluded wheat and paddy mainly because of the strong presence of the public-funded organisations in the production of these two crops.

The import of seeds and/or planting material of fruits, vegetables, flowers and ornamental plants were freed from government control in 1989, in accordance with the provisions of Plants, Fruits and Seed Order of 1989.

The major involvement of the private sector in the seed industry has been through the production of hybrids. Development of genetically engineered seeds is at best in its early days (see further below). The developments in the two segments of the Indian seed industry are discussed below.

Involvement of the Private Sector in the Production of Hybrids

From the above discussion, it is quite clear that the period between 1987-89 laid the foundations for the development of a strong private sector seed industry in India during the 1990s. Sizeable growth of private sector participation was seen during this period. Table 10 (Annex) gives the details of private sector involvement in the major crops. The most recent data available with the seed industry relates to 1997 and 1998.

As was mentioned earlier, the involvement of the private sector was largely in the production of hybrids. The following discussion thus focuses on the developments in the Indian seed industry centering on the hybrids. The large involvement of private sector relative to the public sector in the hybrid segment was evidenced by the number of

[7] Until recently, India has followed the policy of regulating capacity in production units belonging to the private sector in keeping with the Industrial Licensing System that was adopted in 1951.

hybrids that it has succeeded in bringing to the market from the mid-1990s. Table 11 gives the details for the major crops in which the private sector has successfully marketed hybrid seeds.

A better indicator of the growth of the private sector in the seed industry in India is the increase in the share of this sector in the volume of seed sales. Table 12 compares the private sectors in the market for hybrid seeds. Table 12 shows that the share of the hybrids developed by the private sector has increased quite rapidly in several crops. In three of the six crops, almost the entire domestic production during 1996-97 was accounted for by the private sector firms. Maize and sunflower have in fact witnessed a supplanting of the public sector by the private sector.

The share of the private sector in the market for the same six crops as appearing in Table 11 in terms of value is given in Table 13.

As compared to the volume of production, the share of the private sector seed business in the total value of production of the major crops during 1996-97 has been somewhat higher. What is significant is that in a period of six years, the share of the private sector in the total production of the seed for the crops indicated in tables 12 and 13 has gone up from less than 50 per cent to 70 per cent. Table 9 (Annex) gives another estimate of the public-private participation in the domestic seed industry for all major crops taken as a whole.

The above discussion shows that private sector R&D was restricted to crops other than the two main cereals consumed in India, viz. rice and wheat. Rice is produced on nearly 42 million hectares and given this large market coupled with the fact that there is need to provide new varieties to improve productivity, private sector firms have begun making investments in R&D in developing rice hybrids.

Genetic Engineering and the Indian Seed Industry

These research efforts, according to the DBT, have provided significant leads in the areas of basic plant biotechnology and plant genome research, development of makers of high quality protein content and development of molecular methods for hybrid mustard and production of transgenic plants of tobacco with viral resistance.

The focus of agricultural biotechnology, as is evidenced from the policy statements referred to above, can be better understood in the context of the structure of Indian agriculture and the imperatives that it faces at the present juncture. The application of the gene technology can be brought about in three ways:

1. By selection of improved varieties through genome mapping to identify and propagate high yielding cultivars and utilisation of anther/pollen culture to speed up propagation of high yielding varieties.
2. Developing cultivars resistant to viruses, bacteria, fungi and pests tolerant to herbicides, salinity, drought, heat and water-logging, among other problems affecting production and productivity.

3. Improving the economic value of existing products: by delaying the ripening of fruits to improve their shelf life or by modifying cotton cultivars to improve their fibre qualities.

Of the applications that have been indicated above, imparting specific insect-pest resistance through the transfer of genes from *Bacillus thuringiensis* (*Bt*) into target plants is considered as one of the most advanced applications of biotechnology at present. These *Bt* genes that characterise different crystalline proteins are toxic to certain insect-pests. The *Bt* proteins selectively act on the insect-pests like caterpillars, beetles, flies and mosquitoes and are thus considered key to presenting crop losses due to pest infestation.
Proponents of biotechnology have argued that the use of *Bt* gene would have two major advantages. First, it would help provide an effective guard to the crops against the insect-pests and prevent major damage to the crops. Secondly, and more importantly, this manner of preventing crop losses would be safer and more cost effective than the conventional method of countering pest infestation using pesticides. By replacing the toxic pesticides, *Bt* gene can help protect the farmers, the consumers and, above all, the environment.

Genetic engineering in the Indian seeds industry is in its early days for most of the on-going research is presently limited to a few crops and to specific problems related to these crops. Some of the more significant attempts to genetically modify seeds are briefly mentioned below. One of the key problems that genetic engineering is trying to address is the excessive use of chemical pesticides and insecticides by the farmers on vegetables since most of the insects of these crops are developing resistance to these chemicals.

The joint venture of Maharashtra Hybrids (MAHYCO) Monsanto is testing a genetically modified cotton variety that is resistant to insects. Similarly, Rallis India is also working on various vegetable crops to introduce insect resistance based on the technology acquired from aboard (Annex, Table 14). Another leading company in India that is involved in the development of transgenics is ProAgro Seed Company Private Ltd., which is working on crops such as Indian mustard, cauliflower, cabbage, tomato and eggplant to introduce genes of insect resistance and male sterility. At present, in India there are no hybrids in *Brassica Juncea* and the yields have not been increasing for many years and all efforts to produce hybrids through natural male sterility systems have not been successful.

Besides the narrow scope of application in terms of the crops covered, as is evident from Tables 14 and 15, it can be argued that genetically engineered seeds do not have much of a future in India. The major cause for this is the fact that the attempts to introduce these seeds have come at a time when considerable debate is taking place globally on the likely adverse implications of the genetically modified organisms (GMOs) on the environment in general and plant, animal and human health in particular. The global concern has also triggered off some debate in India on the effectiveness of the regulatory mechanism in dealing with the GMOs. In this context, even the limited commercialisation of the genetically modified crops allowed by the regulatory authorities has been questioned.[8] Given the present state of debate, an early introduction of genetically modified seeds on a large scale in the market appears to be the least likely outcome.[9] This raises questions over the use of biotechnology on a scale significant enough to address issues concerning India's food security, which as was mentioned in an earlier section, could face difficult questions if the present productivity trends are allowed to continue. The real issue, however, is the extent to which growth of the biotechnology industry in India would be stymied as a result of the developments mentioned above, which could in turn affect the investments that the seed firms are likely to make in the future.

Regulatory Administration of Biotechnology in India

Biosafety policies in India are governed by the Environment (Protection) Act of 1986. In accordance with this Act, the Rules for the Manufacture, Use/Import/Export and storage of Hazardous Micro-Organisms/Genetically Engineered Organisms or Cells were notified in December 1989. The rules were made applicable to a set of specific cases, which include:

(a) Sale, offers for sale, storage for the purpose of sale, offers of any kind of handling over with or without a consideration,

(b) Exportation and importation of genetically engineered cells or organisms,

(c) Production, manufacturing, processing, storage, import, drawing off, packaging and repackaging of the genetically engineered products; and

(d) Production, manufacture, etc. of drugs and pharmaceuticals and food stuffs, distilleries, tanneries etc. which make use of micro-organisms/genetically engineered micro-organisms one way or another.

The Rules established the institutional structure for operationalising the biosafety policies in the country. A six-tier structure was put in place which had the following components: (i) Recombinant DNA Advisory Committee, (iii) Review Committee on Genetic Manipulation, (iii) Institutional Biosafety Committee, (iv) Genetic Engineering Approval Committee, (v) State Biotechnology Co-ordination Committee, and (vi) District Level Committee. These six bodies were designed to cover the entire decision-making involving research, use and application of biotechnology, as elaborated below. While the first of three Committees function directly under the Department of Biotechnology, the remaining three are linked to the Ministry of Environment and Forests.

Recombinant DNA Advisory Committee

The Recombinant DNA Advisory Committee (RDAC) has been mandated to review developments in biotechnology at national and international levels and to recommend suitable and appropriate safety regulations for India on recombinant research, use and applications. The RDAC, which functions under the Department of Biotechnology (DBT), has three broadly defined objectives. These are: (i) to evolve a long-term policy for research and development involving recombinant DNA; (ii) to formulate the safety guidelines for recombinant DNA research to be followed in India; and (iii) to recommend mechanisms for raising awareness among the personnel of the risks and

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[8] For details see further below

[9] This statement can be made on the basis of the on-going debate on the release of genetically modified mustard in India.

hazards involved in recombinant research. The RDAC is expected to meet at least twice a year.

Institutional Biosafety Committee

The Rules require every institution in India engaged in research involving genetic engineering and production of genetically engineered products to constitute an Institutional Biosafety Committee (IBSC). The IBSC is required to comprise at least six members including the Head of the Institution or his nominee. Two of the IBSC members are required to be from outside the Institution. Of the two external members, one would have to be nominated by the DBT and the other a scientist engaged in recombinant DNA research.

The IBSC has been identified as the point for interaction within an Institution for the implementation of safety guidelines adopted in 1990 as well as the revised guidelines for research in transgenic plants adopted in 1998. Any research project, which is likely to have biohazard potential as indicated by the guidelines, during the execution stage, or which involve the production of either microorganisms on biologically active molecules that could cause biohazard have to be notified to the IBSC. The IBSC has been empowered to allow genetic engineering activity on classified organisms only at places where such activity should be performed according to the guidelines. Each of the IBSCs is expected to carry out the following functions:

(i) Registration of the membership of the Committees with the Review Committee on Genetic Manipulation (RCGM)[10] of the DBT and submission of half-yearly reports on the on-going projects;
(ii) Review and clearance of project proposals that meet the requirements of the guidelines; and
(iii) Training of personnel and instituting health monitoring programme for them.

At the time when the RCGM formally started functioning in 1993, IBSCs had been established in about 49 institutions. By the second half of 1998, IBSCs had been set up in 124 institutions in India. In 2000-2001 the number of institutions having IBSCs had increased to 150 while other institutions, according to DBT, were being asked to take the requisite steps to set up these Committees.

Review Committee on Genetic Manipulation

The Review Committee on Genetic Manipulation (RCGM) is one of the key elements in the biosafety infrastructure that is in place in India. RCGM was established by the DBT in 1993 to monitor the safety related aspects of the on-going research projects and activities involving genetically modified organisms/hazardous microorganisms.

The RCGM includes representatives from the Indian Council of Medical Research (ICMR), the Indian Council of Agricultural Research (ICAR) and the Council of Scientific and Industrial Research (CSIR). These organisations are statutory bodies of

[10] Details of the functioning of this Committee are given below.

the Government of India engaged in research in identified areas. Besides, the RCGM includes experts who participate in the Committee meetings in their individual capacity.

In 1998, following the adoption of the revised guidelines for research in transgenic plants, the RCGM established a Monitoring-cum-Evaluation Committee (MEC) to monitor the impact of transgenic plants on the environment. Included in this Committee were seed technologists and plant breeders nominated by ICAR, a representative of the Ministry of Environment and Forests besides plant biotechnologists and plant ecologists nominated by the RCGM. The MEC was mandated to undertake field visits at the experimental sites where transgenic plants were being tested and provide data relating to the trials that could be used for evaluating the environmental risks emanating from transgenic plants. This Committee was expected to advise the RCGM on the risks and benefits arising out of the use of transgenic plants whose trials it would be monitoring.

Field trials were to be done for at least one year with a minimum of four replications and ten locations in the agro-ecological zone in which the plants were to be grown. The MEC was authorised to recommend those transgenics, which were found to be environmentally viable by the RCGM, to the Genetic Engineering Approval Committee under the Ministry of Environment and Forests for consideration for release into the environment.

The RCGM was established on the basis of the 1990 guidelines for research on transgenic plants. The guidelines were amended first in 1994 and subsequently in 1998. The RCGM was assigned the following functions in the 1990 guidelines:

(i) To establish procedural guidelines for regulating activities involving genetically engineered organisms in research, production and application related to environmental safety;
(ii) To review the reports in all approved on-going research projects involving high risk and controlled field experiments in order to ensure that safeguards were maintained in keeping with the guidelines;
(iii) To recommend the type of containment facilities and special containment conditions that were required to be followed for experimental trials and other experiments;
(iv) To advise the customs authorities on import of biologically active material, genetically engineered substances or products, and on excisable items to Central Revenue and Excise;
(v) To assist the Department of Industrial Development and Financial Institutions for clearance of applications for setting up industries based on genetically modified organisms;
(vi) To assist the Bureau of Industrial Standards to evolve standards for biologics produced by recombinant DNA technology; and
(vii) To advise on intellectual property rights with respect to recombinant DNA technology.

The RCGM was clearly conceived of as a regulatory authority that was to link up all the different activities that involve the use, production and application of genetic engineering as a technology. The regulatory functions of the RCGM were strengthened further in the revised guidelines for research in transgenic plants and guidelines for toxicity and allergenicity evaluation of transgenic seeds, plants and plant parts adopted in 1998. At the same time, however, RCGM was sought to be re-positioned as a facilitator in the efforts to effectively develop biotechnology in the country.

Introducing at least two additional dimensions strengthened the regulatory role. First, the revised guidelines provided a new classification of risks associated with experiments involving transgenic plants. Among the major changes that were effected in this respect was that it was made mandatory for all projects involving recombinant DNA technologies to at least inform the IBSC of the details involved. This was a departure from the 1990 guidelines, which exempted projects that were generally considered as safe to humans, animals and plants from giving any intimation to the RCGM about the activities involved. The second major change in respect of classification of Category III risk which included transgenics that can cause alterations in the biosphere. All open field experiments of transgenic plants, howsoever organised, have been included in Category III risk. Thus, even when experiments are conducted under reasonably contained conditions by taking all the precautions to prevent the escape of transgenic plants or their parts that have propagating traits, as for example, seeds. Secondly, the RCGM, assumed the powers to direct the applicants to generate data pertaining to (a) toxicity allergenicity and any other relevant data on transgenic material; (b) long term environmental safety; and (c) economic advantages of the transgenics over the existing varieties.

The facilitating role of RCGM towards promoting research in genetic engineering involving plants was seen on two counts. These were:

(i) RCGM could issue clearances for import/export of seeds and plant parts and other material required for conducting research; and
(ii) RCGM could authorise limited field trials in multi-locations in the country. The design of the trial experiments could be provided either by the RCGM or it could approve the protection designed by the applicants.

These guidelines adopted in 1998 underlined the detailed procedures for conducting contained field experiments using transgenic plants. The contained field experiments are to be conducted in a manner that can arrest the escape of transgenic plants or plant parts, including seeds, into the open environment. In addition, these experiments are also designed to create a reasonably effective barrier to prevent the escape of pollen from the transgenic plants into the environment.

RCGM monitors research on transgenic organisms in the laboratory and in the contained open environment and fields. In the case of transgenic plants, experiments are conducted in contained green houses to generate vital safety information before decisions are taken to conduct contained open field trials. Through these trials, RCGM tries to obtain information on environmental safety, including human and animal food safety issues for all kinds of transgenics. The nature of information sought by the RCGM is summarised in Table 16 (Annex).

Genetic Engineering Approval Committee

The Genetic Engineering Approval Committee (GEAC) was constituted under the Ministry of Environment and Forests (MOEF) for approval of activities involving large-scale use of hazardous microorganisms and recombinants in research and industrial production. The GEAC was also identified as the agency responsible for approval of proposals relating to the release of genetically modified organisms and products into the environment, including experimental field trials. With its focus on the protection of the environment, the GEAC was mandated to monitor the following activities:

(i) Import, export, transport, manufacture, processing, selling of any micro organism or genetically engineered substances or cells including food stuffs and additives;
(ii) Discharge of genetically engineered organisms/cells from laboratories, hospitals etc, into the environment;
(iii) Large scale use of genetically engineered organisms in industrial production and applications; and
(iv) Deliberate release of genetically modified organisms.

The membership of GEAC covered the widest spectrum of Government agencies. Four Ministries/Departments were represented on the Committees. These were: Ministry of Industrial Development and Departments of Science and Technology, Ocean Development and Biotechnology. Other members of GEAC were representatives from ICAR, ICMR, CSIR, Central Pollution Board and Health Services, the last named being under the Ministry of Health and Family Welfare. Among the other members of GEAC were the Plant Protection Adviser and three experts in the relevant fields.

More recently, the objectives of GEAC have been fine-tuned. According to these revised set of objectives, GEAC was expected to issue clearances from the point of view of environmental safety on a case-by-case basis for:

(i) Activities involving large scale use of hazardous micro-organisms and recombinants in research and industrial production from an environmental angle;
(ii) Proposals relating to the release of genetically engineered organisms and products into the environment including field trials;
(iii) Production, sale, import or use of substances and products including food stuffs and additives including processing aids containing or consisting of genetically engineered organisms or cells or micro-organisms;
(iv) Import, export, transport, manufacture, process, use or sale of any hazardous micro-organisms or genetically engineered organisms/ substances or cells; and
(v) Scale up or pilot operations for facilities using genetically engineered organisms/micro-organisms.

Alongside the fine-tuning of its objectives, the membership of GEAC was expanded by involving a number of additional ministries. The Ministries of Commerce and Industry, Food Processing Industries, Health and Family Welfare and External Affairs and the Department of Agriculture were included in the GEAC.

State Biotechnology Coordination Committee

The State Biotechnology Coordination Committees (SBCCs) were conceived in keeping with the federal structure of state polity that India has developed. These Committees assume further significance in the context of the sharing of responsibilities between central government and the state in the crucial area of agriculture, which, according to the Indian constitution, is to be managed entirely by the state government.

The SBCCs were given the powers to inspect, investigate and take punitive action in case of violations of statutory provisions under the Environment (Protection) Act, 1986. More specifically those Committees were assigned the following functions:

(i) Review and control safety measures adopted while handling large scale use of genetically modified organisms in research, developmental and industrial production activities;

(ii) Monitor large scale release of genetically engineered products with the environment, and oversee field applications and experimental field trials; and

(iii) Provide information/data to RCGM upon surveillance of approved projects, and in case of environmental releases, with respect to safety, risks and accidents.

The members of the SBCCs included representatives from the state Ministries of Environment, Health, Agriculture, Industry and Forests. The State Pollution Control Board and microbiologists from the state were the other prominent members.

District Level Committee

The Rules of the Environment (Protection) Act provides for the establishment of the District Level Committees (DLCs) wherever necessary to monitor the safety regulations in installations engaged in the use of genetically modified organisms. The DLC could impact any installations engaged in activities involving genetically modified organisms and identify the sources of risks associated with such installations and coordinate activities with a view to meeting any emergency. The DLC was expected to submit regular reports to the relevant SBCC and GEAC. As in the case of the other Committees, the members of the DLC were government officials who were involved in the areas of agriculture, pollution control and health.

The Committees that form the regulatory administration of biotechnology in India have clearly marked out functional areas as was elaborated above. However, the manner of their functioning does leave some room for doubting, at least on two counts, whether or not the tasks assigned to them are effectively accomplished. First, the nature of intervention of the State Biotechnology Coordination Committees and the District Level Committees in the regulatory process is not clear and this arises from the absence of the requisite information. In other words, although a decentralised structure has been provided for carrying out the regulatory functions, no real attempt seems to have been made to make it respond to the problem at hand. The second issue, which is related to the first, is the low level of transparency that the regulatory administration maintains. This was quite in evidence in the process leading up to the approval for commercial exploitation of the first genetically modified crop in India. The details of this case are provided in the following sections.

Status of Regulatory Approvals

In the earlier discussion it was indicated that a number of publicly funded institutions and private sector companies have been involved in the development of transgenics involving a range of crops. Most of these crops are commercial crops, which include a range of vegetables, cotton, tobacco and mustard. These crops are in various stages of development and field-testing, after having received the necessary approval of the RCGM. The genetic modifications that have been carried out in a vast majority of these crops are intended to introduce pest resistance. Yet another focus of the genetic transformations has been the production of higher value hybrid crops such as mustard.

Although development of transgenics has taken off in the country encompassing the private and the public sector, no transgenic crop has yet been granted unrestricted approval for commercial application. Contained field trials have been taking place in case of tobacco, mustard, tomato, brinjal (egg plant) and cotton. Of these crops, transgenic cotton being developed by MAHYCO which is resistant to cotton bollworm is the only one to have received approval for limited commercialisation by the GEAC.

The case of transgenic cotton has become the testing ground for regulatory mechanism for genetically modified crops in India. A critical evaluation of this case is presented in the following discussion.

Evaluation of the Regulatory Mechanism: The Case of Transgenic Cotton

The case under discussion involves the transgenic cotton developed by MAHYCO Monsanto Enterprises, an associate of Monsanto Enterprises Pvt. Ltd., which in turn is a 100% subsidiary of Monsanto Inc, USA. The cotton variety being field-tested contained the *Bt* gene aimed at protecting the crop against bollworm. The regulatory administrators had allowed MAHYCO to carry out field trials of the *Bt* cotton to evaluate the behaviour of the cotton variety in different agro-climatic conditions.

In 1995, the Department of Biotechnology had permitted MAHYCO to import 100 grams of cotton seed containing *Bt* Cry 1Ac gene. The company backcrossed the imported variety into Indian lines for six generations and saved seeds in each generation for the next set of experiments in the contained green house. After at least four back crossings, the subsequent generations were shelved to generate stable levies for developing hybrids. The experiments conducted in the field were with hybrids developed from lines generated after four backcrosses and two shelved generations. These genetically modified hybrids were granted permission for field evaluation along with *Bt* hybrids.

First trials of *Bt* cotton began in 1996. These were followed by multi-locational trials on limited scale on plots of 200 square metres that were carried out during 1997 in five states of the country. These were the Southern Indian states of Andhra Pradesh, Karnataka and Tamil Nadu, the Northern state of Haryana and the Western state of

Maharashtra. In 1998, the field trials were extended to four more states, two from Central India, viz., Madhya Pradesh and Rajasthan, and one each from the North and the West of the country, Punjab and Gujarat respectively. In all these states, trials were conducted in 40 locations in a slightly larger area. 11 additional sites were brought under field trials in the following cropping year. Between 1996 and 1999, thus, trials of *Bt* cotton were taking place in nine states of the country covering all but the eastern region of India. According to the DBT, the field trials conducted during all these years showed no differences in the risks from the use of *Bt* cotton plants to the environment.

In July 2000, the Genetic Engineering Approval Committee (GEAC) of the Ministry of Environment and Forests (MOEF) approved large-scale field trials of *Bt* cotton to the Monsanto affiliate Maharashtra Hybrid Seed Company (MAHYCO) for seed production and demonstration and generating environmental safety data for crops under various agro-climate conditions. MAHYCO was to undertake open field trials in 85 hectares and seed production in 150 hectares. One of the more important decisions that was taken alongside this was that the Indian Council of Agricultural Research (ICAR) system, which included agricultural universities besides the public-funded research institutions, would be fully involved in the monitoring of seed production. The decision to involve the ICAR system was taken even as the Central Institute for Cotton Research, one of the publicly funded agricultural research institutes, had unveiled the plans of putting its own variant of *Bt* cotton in the market by the year 2002.

During 2000–2001, field trials involving three varieties of *Bt* cotton were extended beyond experimental fields to two research stations under Indian Council of Agricultural Research (ICAR) in the three southern states of Andhra Pradesh, Karnataka and Tamil Nadu. These field trials, according to DBT, did not show the time potential in terms of yield, which has been ascribed to the fact of late sowing of the crop. Alongside, the field trials in the ICAR research stations, trials were also carried out by MAHYCO, on the company's private land and in the farmers' field in the five states of Maharashtra, Andhra Pradesh, Karnataka, Tamil Nadu and Madhya Pradesh. These two sets of trials indicated that *Bt* cotton plants used in the trials performed much better in terms of increased yield and reduced consumption of pesticides, as compared to the non-transgenic varieties. It was felt, however, that the late sowing of the crops did not result in the expected performance of the hybrids in these cases as well. The GEAC therefore considered it necessary to conduct the large-scale field trials for another year in order to access the real agronomic benefits of *Bt* cotton.

In March 2002, the GEAC approved commercial cultivation of three *Bt* cotton varieties developed by MAHYCO, viz. *Bt* MECH 162, *Bt* MECH 184 and *Bt* MECH 12 for three years subject to the fulfilment of a number of conditions.[11] These include:

(i) Every field where *Bt* cotton is planted shall be fully surrounded by a belt of land called 'refuge' in which the same non-*Bt* cotton variety shall be sown. The size of the refuge belt should be such as to take at least five rows of non-*Bt* cotton or shall be 20 per cent of total sown area whichever is more.

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[11] ENVIRO NEWS (2002)

(ii) To facilitate this, each packet of seeds of the approved varieties should also contain a separate packet of the seeds of the same non-*Bt* cotton variety, which is sufficient for planting in the refuge defined above.

(iii) Each packet should be appropriately labelled indicating the contents and the description of the *Bt* hybrid including the name of the transgenes, the GEAC approval reference, physical and genetic purity of the seeds. The packet should also contain detailed directions for use including sowing pattern, pest management, suitability of agro-climatic conditions etc., in vernacular language.

(iv) MAHYCO will enter into agreements with their dealers/agents that will specify the requirements from dealers/agents to provide details about the sale of seeds, acreage cultivated, and state/regions where *Bt* cotton is sown.

(v) MAHYCO will prepare annual reports by 31st March each year on the use of *Bt* cotton hybrid varieties by dealers, acreage and locality (state and region) and submit the same in electronic form to GEAC, if asked for by the GEAC.

(vi) MAHYCO will develop plans for *Bt* based Integrated Pest Management and include this information in the seed packet.

(vii) MAHYCO will monitor annually the susceptibility of bollworms to *Bt* gene vis-à-vis baseline susceptibility data and submit data relating to resistance development, if any, to GEAC.

(viii) Monitoring of susceptibility of bollworms to the *Bt* gene will also be undertaken by an agency identified by the Ministry of Environment and Forests at the applicant's cost.

(ix) MAHYCO will undertake an awareness and education programme, *inter alia* through development and distribution of educational material on *Bt* cotton, for farmers, dealers' and others.

(x) MAHYCO will also continue to undertake studies on possible impacts on non-target insects and crops, and report back to GEAC annually.

(xi) The label on each packet of seeds, and the instruction manual inside the packet should contain all relevant information.

(xii) MAHYCO will deposit 100 g seed each of approved hybrids as well as their parental lines with the National Bureau of Plant Genetic Resources (NBPGR).

(xiii) MAHYCO will develop and deposit with the NBPGR, the DNA fingerprints of the approved varieties.

(xiv) MAHYCO will also provide to the NBPGR, the testing procedures for identifying transgenic traits in the approved varieties by DNA and protein methods.

The conditions accompanying the approval granted by the GEAC indicated that commercial use of *Bt* cotton in India would remain under close scrutiny, at least in the foreseeable future. This was reinforced by the fact that the GEAC did not grant approval to another variety of cotton, viz. *Bt* MECH 195, which has been developed for use in the Northern region of the country.

Evaluation of the Regulatory Mechanism employed in case of *Bt* Cotton

The attempts made by MAHYCO to introduce genetically modified varieties of cotton in India have remained at the focus of considerable controversy ever since the open field trials were taken up in multi-location sites in 1998. Critics have questioned the functioning of the regulatory administration on several counts. These criticisms have grown after it was discovered that the standing cotton crop in the state of Gujarat contained Cry 1Ac gene, the safety aspects of the use of which were being tested through the field trials described earlier. Navbharat Seeds Pvt. Ltd., a locally based seed company, supplied the seeds from which this cotton crop was obtained.

The critics have made the following points in respect of the *Bt* field trials:

1. The clearance given by the RCGM to carry out the field trials in 1998 was illegal since the GEAC and not the RCGM should have given the approval for open field trials.
2. Post-harvest management and safety involving the field experiments was grossly inadequate. Farmers had sold their genetically engineered cotton in the open markets. In some states, farmers had replanted their trial fields with crops like wheat, turmeric and groundnut.
3. The ICAR, one of the major actors in the regulatory mechanism, had commented that the data available from the field trials are not adequate to put all doubts about the safety of *Bt* cotton to rest.
4. The case of Navbharat Seeds Pvt Ltd selling transgenic cotton seeds epitomises the ineffectiveness of the regulatory mechanism. That a private seeds company could be selling seeds that were planted in as much as 11,000 hectares of farm land since 1998 before being detected indicates that lack of control of the regulators over the process of introducing transgenic crops in the country.

Further questions about the regulatory process can be raised in light of the conditional approval given by the GEAC for commercial exploitation of *Bt* cotton. The more obvious of these concerns is the limited period for which MAHYCO has been granted permission to market the *Bt* cotton seeds. While this step taken by the GEAC is indicative of the fact that it was yet unsure of the possible long term impacts of *Bt* cotton despite the protracted field trials, little thought was given to the larger implications of commercial use of *Bt* cotton, including their use in the regions that did not receive permission to use these genetically modified varieties of cotton. In other words, the Committee did not dwell on establishing mechanisms to prevent leakages of the genetically modified cotton seeds into the regions of the country which have not received the approval for using *Bt* cotton on commercial scale.

Another significant issue that needs to be raised in this context is the extent to which non-*Bt* varieties can be prevented from getting contaminated through the strict adherence to the guidelines introduced by the GEAC for commercially using *Bt* cotton. According to the recently announced National Seeds Policy, the Ministry of Agriculture and the State Departments of Agriculture are expected to monitor the performance of transgenic varieties for 3 to 5 years, and for which the necessary infrastructure for testing and evaluation would be developed. In other words, the regulatory administration would be strengthened but only after the *Bt* cotton has begun to be commercially exploited.

What should also be pointed out in light of the above is that the regulatory administration for agri-biotech in India is virtually de-linked from the Seeds Act of 1966, which, as has been mentioned in its preamble is an "Act to provide for regulating the quality of certain seeds for sale, and for matters connected therewith". The Seeds Act provides for a mechanism for seed certification besides providing an institutional mechanism for ensuring that the provisions of the legislation are adhered to. This Act is being amended.

Perceptions on the Regulatory Administration

Several questions were asked of the decision to introduce *Bt* cotton in the country. The first was that approval for the field trials did not have the requisite level of transparency. The second was that the claims pertaining to the advantages of using this variety of cotton, particularly on the grounds that it offered an environmentally safer alternative to the pesticide-intensive cotton cultivation were not quite justified. And finally, the cost of adoption of *Bt* cotton could be prohibitive for the small farmers. Even though all these questions were raised, the campaign against the field trials of *Bt* cotton was built essentially around the point about transparency of the regulatory mechanism.

Two of the more pertinent questions have been the following. One, the six-committee structure that constitutes the regulatory administration described above is largely non-functional since only two of the Committees seem to have any role to play. These are the Review Committee on Genetic Manipulation (RCGM) of the DBT and the Genetic Engineering Approval Committee (GEAC) of the MOEF. The functions of the sub-federal committees remain largely undefined. The second question was related to the framing of rules of the committees that have a role in regulatory administration of GMOs.

The latter dimension seems to have acquired more prominence in the controversy centering on *Bt* field trials. The regulatory procedure followed by the RCGM has been questioned on two grounds. The first is that the field trials had been approved by the RCGM after the farmers chosen for this purpose sowed the Monsanto seeds on their fields. The second issue was regarding the approvals of field trials granted on 40 locations in nine states in the country, which brings into question the role of the sub-federal Committees.

A further issue that was raised in the context of the functioning of RCGM was the change in the rules of the Committee, which have taken place since August 1998. The significance of this factor lies in the fact that it was precisely during this phase that the *Bt* cotton field trials were in progress.

The lack of transparency in granting clearance to the field trials of *Bt* cotton was the single most important factor that caused the farmers in the southern states of the country to protest against the field trials. The apprehensions of the farmers were two-fold. First, corporate giants like Monsanto would be able to capture the seed market in India leaving the small farmers at their mercy. And second, the farmers would not be able to re-use the seeds of one years harvest in the next. The latter point made by the farmers' organisations made several of the proponents of genetically engineered seeds argue that the campaigns had spread misinformation since the objective of promoting biotechnology was primarily to increase the viability of Indian farmers.

Misinformation or otherwise, the campaigns managed to put sufficient pressure on the government not to push for an early introduction of *Bt* cotton in the market. However, what changed the balance of forces to a significant extent was the explicit support for biotechnology offered by three southern Indian states, Karnataka, Andhra Pradesh and Tamil Nadu, the first two of which had witnessed the farmers' protests during 1998 and 1999. These states began announcing their biotechnology policies from the year 2000 and this provided the necessary fillip to the federal government to fulfil its unfinished task of completing the *Bt* cotton field trials. The support for biotechnology by these states has larger significance in the Indian context. The Constitution of India, which delegates powers between the Central government and the states, has included agriculture in the list of issues to be exclusively managed by the states.

An important constituency that started asserting itself at this stage was the domestic biotechnology industry. After spending years in the shadow of the corporate giants like Monsanto, this section of the industry started evolving its own co-ordinated strategy for establishing biotechnology in India. The beginnings of this process was made in April 2001 and interestingly, the central character was to be agriculture.

But some twists in the tail did remain despite what appeared to be smooth sailing for genetically engineered seeds. The users of the genetically engineered seeds did not appear too convinced. This came in the form of a comment made in the Indian Parliament by the Ministry of Agriculture in December 2000 that a final decision on the use of genetically modified seeds had not been taken. It is in this context that the decision taken by the GEAC to go in for repeat trials of *Bt* cotton for another cropping season assumes significance. A contributory factor in this regard would have been the campaigns run by the civil society organisations. At the same time, however, it must be pointed out that these campaigns have at best caught the imagination of a few and it would require considerable co-ordinated efforts by the organisations involved in the campaigns to have their concerns heard.

The case of introduction of *Bt* cotton in India depicts quite well the complex nature of the processes that are involved in key decision making areas of the government. Unlike in the past when vital decisions were implemented first before the implications were analysed, the present times are witnessing a more active involvement of the different stakeholders before the hammer falls on any particular issue. Many would insist that the lack of transparency still pervades but these are changing times.

By Way of Conclusions

The regulatory administration for biotechnology in India, as is captured from the developments in the agri-biotech sector over the past several years described in this paper, has suffered from the inability to set its own terms. This was despite the fact that India has been one of the first countries in the developing world to set up a mechanism for making a risk assessment of biotech products before their commercial exploitation. The setting up of the regulatory administration was even more remarkable since it took place even before the global community formally launched into the process of developing the Biosafety Protocol.

The push for the increased use of transgenic varieties by the commercial interests, represented predominantly by the transnational corporations in the seed industry, has set the tone for the regulators. As a result, the more critical issues, which relate to the ability of the system to regulate the use of transgenics in an agricultural system that is largely unorganised, have not been addressed. Thus, after years of field trials, when the commercial use of transgenic cotton was finally approved, the regulatory authority imposed conditions for monitoring their performance for which the available infrastructure would be seriously tested. The *Bt* cotton case proves the point once again that in developing countries there is a yawning gap between the policies and their implementation, particularly when the policies have to be developed in response to pressures that are not home grown.

The doubts over the regulatory administration of biotechnology raises questions about the large scale use of biotechnology for addressing the problems facing Indian agriculture, including its ability to meet food security concerns. This comes at a time when the industry seems to have reached the threshold of releasing genetically modified seeds covering a range of food crops on a commercial scale, the case of genetically modified mustard developed by ProAgro Seed Company Private Ltd. being a case in point. ProAgro's genetically modified mustard was considered for commercial release by the GEAC in early November 2002, and as was seen in case of *Bt* cotton, the decision was deferred, thus adding a few more questions about the regulatory administration of biotechnology in India.

Annex

Table 1: Area under Cultivation of Major Crops in India

(Million hectares)
Source: FAO

Year	Wheat	Rice	Maize	All Foodgrains	Cotton	Gross Cropped Area
1990-91	24.17	42.69	5.90	127.84	7.44	185.74
1991-92	23.25	42.65	5.86	121.87	7.66	182.24
1992-93	24.59	41.78	5.96	123.15	7.54	185.70
1993-94	25.15	42.54	6.00	122.75	7.32	186.58
1994-95	25.70	42.81	6.14	123.86	7.87	188.05
1995-96	25.01	42.84	5.98	121.02	9.04	187.47
1996-97	25.89	43.43	6.26	123.58	9.12	189.59
1997-98	26.70	43.45	6.32	123.85	8.87	190.76

Table 2: Production of Major Crops

Source: FAO

Year	Wheat	Rice	Maize	All Foodgrains	Cotton
1990-91	55.14	74.29	8.96	176.39	9.84
1991-92	55.69	74.69	8.06	168.38	9.71
1992-93	57.21	72.86	9.99	179.48	11.40
1993-94	59.84	80.30	9.60	184.26	10.74
1994-95	65.77	81.81	8.88	191.50	11.89
1995-96	62.10	76.98	9.53	180.42	12.86
1996-97	69.35	81.74	10.77	199.44	14.23
1997-98	66.35	82.53	10.82	192.26	10.85

Table 3: Yield of Different Crops in India (in kg/ha) in Different Years

Source: FAO

Crops	**Years**						
	1985	**1990**	**1995**	**1996**	**1997**	**1998**	**1999**
Rice	2329	2628	2784	2811	2888	2894	2929
Wheat	1870	2121	2559	2493	2679	2485	2583
Maize	1146	1524	1481	1408	1746	1745	1667
Pulses	519	559	628	602	635	572	634
Rape Seed	771	831	945	952	1017	668	875

Table 4: Yield of Rice Across Countries in Different Years (in kg/ha)
Source: FAO

Country	Years						
	1985	**1990**	**1995**	**1996**	**1997**	**1998**	**1999**
India	2329	2628	2784	2811	2888	2894	2929
Sri Lanka	3071	3064	2136	2801	3245	3247	3247
China	5253	5716	6022	6062	6311	6353	6321
United States	6068	6200	6301	6860	6610	6354	6622
Australia	6857	8093	8544	6788	7650	9507	10071
Argentina	3599	3671	5033	5047	5370	4841	5609
Brazil	1898	1880	2565	2558	2601	2523	3092

Table 5: Yield of Wheat Across Countries in Different Years (in kg/ha)
Source: FAO

Country	Years						
	1985	**1990**	**1995**	**1996**	**1997**	**1998**	**1999**
India	1870	2121	2559	2493	2679	2485	2583
China	2937	3194	3542	3759	4102	3685	3969
United States	2519	2656	2408	2442	2655	2903	2872
Australia	1378	1634	1772	2136	1842	1880	1828
Argentina	1617	1900	1918	2303	2631	2316	2500
Brazil	1614	1154	1544	1800	1621	1568	1945

Table 6: Yield of Maize Across Countries in Different Years (in kg/ha)
Source: FAO

Country	Years						
	1985	**1990**	**1995**	**1996**	**1997**	**1998**	**1999**
India	1146	1524	1481	1408	1746	1745	1667
Sri Lanka	915	1035	969	1069	996	1137	1137
China	3607	4523	4918	5173	4390	5269	4880
United States	7407	7438	7121	7975	7952	8438	8398
Australia	2833	4182	4826	5197	5940	6316	5500
Argentina	3563	3018	4522	4010	4556	6077	5254
Brazil	1866	1874	2599	2393	2553	2781	2768

Table 7: Consumption Trends of Biotech Products in India (1995-2005)
(Rs. Million)
Source: Ghosh P.K. (1999), Table 1.

Sectors	Actual Consumption		Estimated Consumption	
	1992	1997	2000	2005
Human and Animal Health Products	13750 (73%)	26370 (37%)	35320 (38%)	57480 (39%)
Agriculture	680 (3%)	20270 (28%)	28880 (31%)	47680 (33%)
Industrial Products	4290 (23%)	24470 (34%)	28500 (30%)	36470 (25%)
Other Biotech Products	20	430 (1%)	1300 (1%)	3970 (3%)
Total	18740	71540	94000	145670

(Figures in brackets are percentage shares of the total in the respective years)

Table 8: Consumption Estimates of Selected Biotechnology based Products in Agricultural Sector
Source: Ghosh, P.K. (1999), Table 2.

Product Category and Products with measuring units	Actual Consumption	Estimated Consumption	
	1997	2000	2005
Agriculture (figs in '000 tonnes)			
Wheat	207 (VAR)	220(VAR) 2(HYV)	250(VAR) 5(HYV)
Rice	155(VAR)	165(VAR) 1.6(HYV)	191(VAR) 2(HYV)
Sorghum	21(HYV) 21(VAR)	22.3(HYV 22.3(VAR	26(HYV) 26(VAR)
Pearl Millet	20(VAR)	21.2(VAR	24.6(VAR
Maize/Corn	5.2(HYV) 10.4(VAR)	5.5(HYV) 11.0(VAR	5.0(HYV) 12(VAR) 2(GMS)
Pulses (mainly peas and grams)		45.1(VAR	51(VAR)
Groundnut	42.5 (VAR)	82.8(VAR	95.6(VAR
Mustard/Rapeseed	78 (VAR) 8.3 (VAR)	8.8(VAR)	10(VAR) 2(GMS)
Soyabeans	31 (VAR)	32.9(VAR	38(VAR) 2(GMS)
Sunflower		6.6(VAR)	7.7(VAR)
Cotton	6.2(VAR) 12.4 (HYV) 13.5(VAR)	13.2(HYV 14.3(VAR	7.5(HYV) 14(VAR) 10(GMS)
Bio-fertilisers (Tonnes)			
Rhizobium		5500	6700
Azospirillum	5000	3500	5800
Azotobacter	3470	2200	2400
Bio-pesticides	2000		
Growth promoters / stimulants	40	120	200
Gibberillic acid (kgs.)	7000	15000	30000

Note: HYV: High yielding hybrids; VAR: Varieties; GMS: Genetically modified seeds

Table 9: Structure of the India Seed Industry
(Rs. Million)
Source: Seed Association of India

Sector	1993-94	1996-97
Private Sector	6,000	19,850
Public Sector	4,000	5,750
Total	10,000	25,600

Table 10: Private Sector Firms engaged in Crop Improvement Programme (1987-1998)
Source: Seed Association of India

Crop	No. of Firms with Crop Improvement Programmes		
	1987-88	1993-94	1997-98
Pearl Millet	12	23	25
Sorghum	10	12	15
Maize	6	15	20
Paddy	-	3	3
Sunflower	10	30	20
Cotton	9	21	34
Hybrid Rice	-	4	6

Table 11: Private and public bred hybrids marketed during 1995 and 1998
Source: Seed Association of India

Crops	Number of Hybrids in Market				No. of Private hybrids grown on 2% plus area
	1995		1998		
	Private	Public	Private	Public	
Pearl Millet	50	4	60	6	14
Sorghum	22	4	41	5	6
Maize	57	3	67	3	12
Sunflower	47	5	35	6	10
Cotton	73	15	150	15	19
Hybrid Rice	4	4	12	4	-

Table 12: Growth Trends in Use of Hybrids (1991-98) in Selected Crops ***(Qty. in tons.)***
Source: Seed Association of India

Crops	1990-91				1996-98			
	Public bred hybrids	Hybrids bred by Private Sector	Total	Private-bred as % of public bred	Public bred hybrids	Hybrids bred by the Private Sector	Total	Private-bred as % of public-bred
Pearl Millet	24,000	6,000	30,000	20	10,000	11,000	21,000	52
Sorghum	7,000	7,000	14,000	50	5,000	11,200	16,200	69
Maize	12,000	6,000	18,000	33	2,000	18,000	20,000	90
Sunflower	500	4,500	5,000	90	200	7,800	8,000	98
Sudan-sorghum	-	6,000	6,000	100	-	12,000	12,000	100
Cotton	4,000	1,500	5,500	27	5,000	5,000	10,000	50

Table 13: Growth Trends in Terms of Value of Research Hybrids 1991-1997 ***(Million Rupees)***
Source: Seed Association of India

Crop	1990-91				1996-98			
	Publicly bred hybrids	Hybrids bred by Private Sector	Total	Private-bred as % of public-bred	Public bred hybrids	Hybrids bred by Private Sector	Total	Private-bred as % of public-bred
Pearl Millet	432	174	606	29	350	495	845	58
Sorghum	126	217	343	63	110	504	614	82
Maize	108	84	192	44	40	540	580	93
Sunflower	20	360	380	95	14	1170	1184	99
Sudan-sorghum	-	72	72	100	-	180	180	100
Cotton	640	225	865	26	1250	1250	2500	50
Total	1326	1132	2458	46	1764	4139	5903	70

Note: 1$ was equivalent approx to Rs 23 in 1991 and Rs 36 in 1997.

Table 14: Transgenic Research and Applications: Development in Indian Context
Source: Seed Association of India

Company/Crop	Goal
MAHYCO-Monsanto	
Cotton	Insect Resistance
Soybean	Herbicide Resistant
Hotpepper	Insect Resistance
Bell Pepper	Insect Resistance
Tomato	Insect Resistance
ProAgro Seed Company Private Ltd.	
Indian Mustard	Crop Hybridization System
Tomato	Insect Resistance
Cauliflower	Insect Resistance
Cabbage	Insect Resistance
Eggplant	Insect Resistance

Table 15: Developments in Indian Transgenic Research and Applications
Source: Department of Biotechnology, Government of India

Institute	Plants/crops used for transformation	Transgenes inserted	Aim of the project and progress made
Central Tobacco Research Institute, Rajahmundari	Tobacco	*Bt* toxin gene Cry 1 A(b) and Cry IC	To generate plants resistant to H. armigera and S. litura. One round contained field trial completed. Further evaluation under progress
Bose Institute, Calcutta	Rice	*Bt* toxin genes	To generate plants resistant to lepidopteran pests. Ready for undertaking Green House testing
Tamilnadu Agricultural University, Coimbatore	Rice	Reporter genes like hph or gus A and GNA gene	To study extent of transformation in the green house
Delhi University, South Campus New Delhi	Mustard/rape seed	Bar, Barnase Barstar Market gene remover (crelox)	Plant transformations completed and ready for green house experiments. Plants with marker genes as well as without market genes made
	Rice	Selectable marker genes (hygromycin resistance and gus) Abiotic stress tolerant genes (codA. Cor47 hsp1)	Transformations completed with marker genes as well as with abiotic stress tolerant genes.
	Cotton	Cry 1 A© gene	Transformation completed.
	Wheat	Abiotic stress tolerant gene (hva 1)	Transformation completed.
		Insect resistance (Pin II)	Transformation completed.
	Brinjal	Abiotic stress tolerant genes (adc. Mtl D. imt I)	Transformation completed.
		Fungal resistance (glucanase)	Transformation completed.
	Tomato	CTX-B	Transformation completed.
Indian Agricultural Research Institute Sub-Station, Shillong	Rice	*Bt* Toxin gene	To impart lepidopteran resistance, transformations in progress
Central Potato Research Institute, Shimla	Potato	*Bt* toxin Gene	To generate plants resistant to lepidopteran pests. Ready to undertake Contained Field trials.
ProAgro Seed Company Private Ltd., New Delhi	Brassica/ Mustard	Barstar/Barnase, Bar	To develop better hybrid cultivars suitable for local conditions; over 15 locations contained field trails completed. Further contained open-field research trials in progress at multi-locations in 2000-2001.

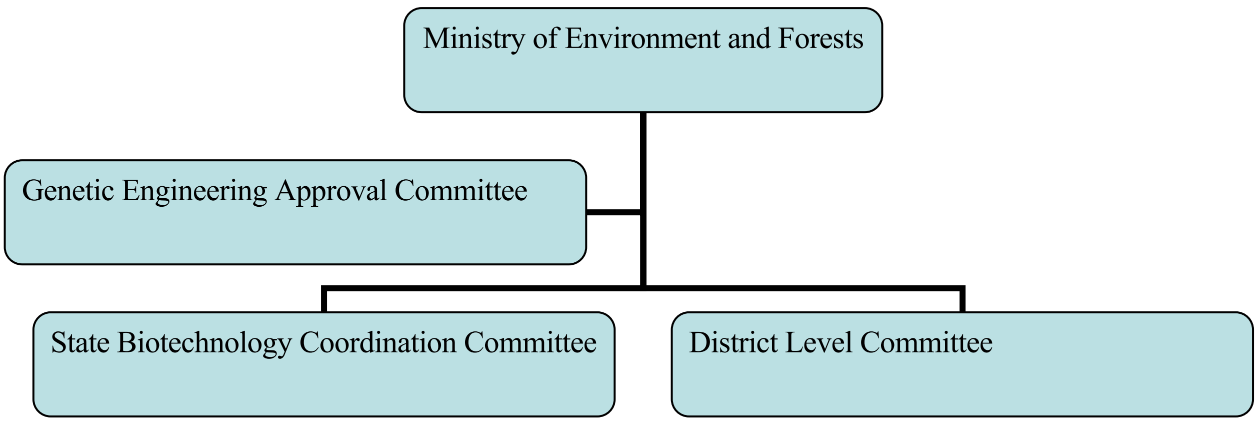
	Tomato	Cry 1 A Ib)	To develop plants resistant to lepidopteran pests; glass house experiments and one season contained field experiment completed. Further experiment in progress.
	Brinjal	Cry 1A (b)	To develop plants resistant to lepidopteran pests; glass house experiments in progress.
	Cauliflower	Barbase, Barstar and Bar	To develop hybrid cultivars for local use; glass house experiment in progress
	Cauliflower	Cry I H/Cry 9C	To develop resistance to pests; glass house experiment in progress.
	Cabbage	Cry I H/Cry 9C	To develop resistance to pests; glass house experiment in progress.
M/s MAHYCO Mumbai	Cotton	Cry IA©	To develop resistance agaisnt lepidopteran pests: Multi-centric field trials in over 51 locations completed and further large scale field trails in progress.
M/s Rallis India Ltd. Bangalore	Chilli	Snowdrop (Galanthus nivalis) Lectin gene	Resistance against lepidopteran, coleopteran & homopteran pests: transformation experiments in progress.
	Bell Pepper	Snowdrop (Galanthus nivalis) Lectin gene	Resistance against lepidopteran, coleopteran & homopteran pests: transformation experiments in progress.
	Tomato	Snowdrop (Galanthus nivalis) Lectin gene	Resistance against lepidopteran, coleopteran & homopteran pests: transformation experiments in progress.
Indian Agricultural Research Institute, New Delhi	Brinjal/Tomato/ Cauliflower	*Bt* gene	To impart lepidopteran pest resistance, transformation completed, green house trials completed and one season field evaluation completed for brinjal and Tomato.
	Mustard/Rapeseed	Arabidopsis annexin gene	Transformation completed, Green house trial completed, ready for field trials for moisture stress resistance.
	Indian rice	*Bt* gene	Transformation completed and contained green house trial in progress
Jawaharlal Nehru University, New Delhi	Potato	Gene expressing for seed protein containing lysine obtained from seeds of amaranthus plants (Ama-I gene)	Transformation completed and transgenic potato under evaluation in the contained open environment.
Indo-American Hybrid Seeds. Bangalore	Tomato	Lead curl virus protein genes, chitinase and alfalfa gluconase gene and combinations	Transformation completed, green house tests completed and ready for contained open field experiments.

Table 16: Summary of the Biosafety information sought from GMO trials by RCGM
Source: Department of Biotechnology, Government of India

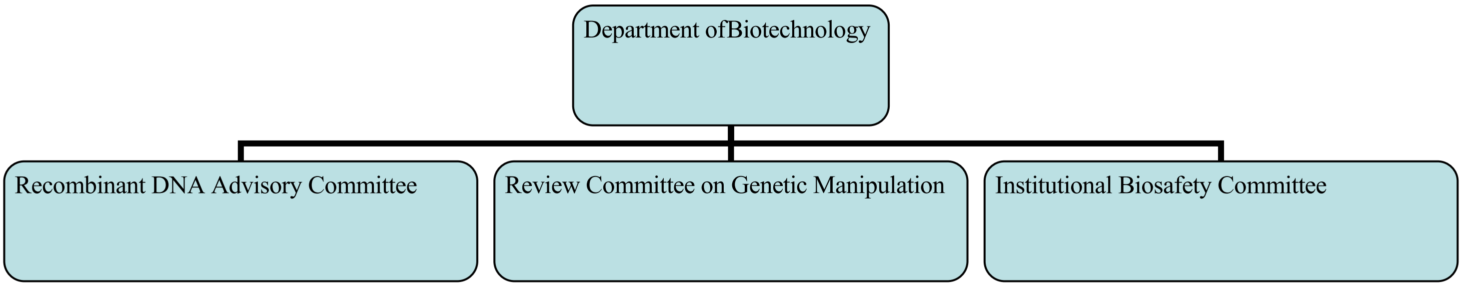
Particulars	Information Sought
Rationale for the development	Economic, agronomic and other benefits, and rational of development
Details of the molecular biology of GMOs (Micro-organisms, plants and animals)	• Description of the host organisms (micro-organisms, cell lines, plants, animals etc.) • Source and sequence of transgene • Sequential block diagram of all trans-nucleic acid stretches inserted· • Cloning strategy· • Characteristics of expression vectors· • Characteristics of inserted genes with details of sequences • Characteristics of promoters • Genetic analysis including copy number of inserts, stability, level of expression of transgenes, biochemistry of expressed gene products etc. • Transformation/cloning methods and propagation strategy.
Laboratory, Green House Trials (for plants) and contained enclosure trials (for animals)	• Back-crossing methods for plants • Seed setting characteristics of plants • Germination rates of seeds • Phenotypic characteristics of transgenics • Organism challenge tests where ever applicable • Effects of chemical herbicides for all herbicide resistant plants • Growth characteristics and general health of animals, measured through specific scientific parameters • Toxicity and allergenicity implications to human if any during handling of GMOs
Field trials in open environment	• For GM Plants, comparison of germination rates and phenotypic characteristics, using non-transgenic as controls. • Study of gene flow of plants • Possibility of weed formation for GM plants • Invasiveness studies of plants and animals compared to non-transgenics used as controls • Possibility of transfer of transgenes to near relatives through out crossing/cross-fertilisation • Implications of out crossing/cross-fertilisation • Comparative evaluation of susceptibility to diseases and pests for plants and animals

	• For human food/ animal feed, elaborate determination of composition and assessment of quality of transformed plants/ fruits/seeds as well as animals as the case may be, with appropriate controls. Compositional analysis shall include near equivalence studies of all the major ingredients in GMOs so as to assess substantial equivalence with reference to non-transgenics. Change in the levels of allergens, toxicants if any, beyond acceptable limits is a matter of food safety concern and such substances are unsuitable for commercial release. • Toxicity and allergenicity implications of transformed GMOs. This include microorganisms, plants/fruits/seeds as well as animals; lab animal studies for food /feed safety evaluation is a requisite. • Handling procedures for allergenic substances. • Agronomic evaluation for GM plants • Economic evaluation for GM animals

Structure of the Regulatory Administration of Biotechnology in India – I



Structure of the Regulatory Administration of Biotechnology in India – II



References:

Avramovic, Mila (1996), *An Affordable Development? Biotechnology, Economics and the Implications for the Third World*, Zed Books, London and New Jersey.

Dhar, Biswajit (2001), Perceptions on the Adoption of Biotechnology in India, *Biotechnology and Development Monitor*, No. 47.

Down to Earth (2000), The newcomer: Transgenic cotton is poised to enter the Indian market, 9(2).

ENVIRO NEWS (2002), vol. 6, April-June, http://envfor.nic.in/news/aprjun02.

Ghosh, P.K. (1999), Consultancy and its Relevance to Biotechnology in India, *RITES Journal*, Inaugural Special Number.

Government of India (2000), Ministry of Agriculture and Cooperation, National Agriculture Policy, New Delhi.

Government of India (1974), Planning Commission, Draft Fifth Five Year Plan 1974-79, New Delhi.

Government of India (2001), Working Group on Agricultural Research and Education for the Xth Five Year Plan (2002-2007), New Delhi.

Seed Association of India (1998), *Crop Improvement Research in Private Sector in India*, New Delhi.

WTO (2001), Committee on Agriculture, Proposals by India in the areas of: (i) Food Security, (ii) Market Access, (iii) Domestic Support, and (iv) Export Competition, G/AG/NG/W/102, Geneva.