# Science, Technology and Globalization Project Agricultural Biotechnology for Development – socioeconomic issues and institutional challenges\*

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# India's Experience with GM Crops: Socio-economic Impacts and Institutional Challenges

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### India's Experience with GM Crops: Socio-economic Impacts and Institutional Challenges

#### 1. Introduction

This paper examines the evidence on the impact of GM crops in India and what light, if any, it throws on the debates about the technology that continue to rage. For economists, the impacts that matter most are those on the economic welfare of growers, consumers and other agents in the seed market such as seed suppliers. However, these effects are in some sense "reduced form" impacts – the outcome of various processes including basic research, technology adaptation, biosafety regulatory procedures and its enforcement, seed pricing and competition in the seed market. Naturally, the government has a large presence in these activities and therefore, government policies and the institutional mechanisms devised to formulate and implement them are some of the "structural" factors that explain the reduced form impacts. The paper also considers the underlying institutional factors and their role and evolution in the spread of GM crops in India.

The Indian experience is limited to the three years since a GM crop was first approved (in 2002) for commercial release in India. The first approval related to three varieties of Bt cotton. In 2004 and 2005, the government granted permission for the release of several other varieties of Bt cotton. An unauthorized Bt cotton variety was discovered in farmers' fields at the end of 2001 and it continues to be used by growers particularly in the states of Gujarat and Punjab. Aside from Bt cotton, no other GM crop has been commercially released. With such a restricted history of GM crops, limited both

in time and the range of crops, the analysis in this paper should be seen as a reading of the initial trends.

#### 2. GM Crops and the Poor

Poverty is the pressing problem in developing countries. How can GM crops help? The Nuffield Council on Bioethics (2004) draws an analogy with the Green Revolution to delineate the circumstances in which GM crops could reduce poverty. Across much of Asia and Latin America, available farmland is pretty much exhausted. The expansion of non-farm employment opportunities in industry requires large investments in equipment and buildings as well as infrastructure. The limitation on land and the uncertain growth of nonfarm employment means that the most effective route to poverty reduction is through higher productivity and employment in agriculture. The Green Revolution created employment for landless agricultural workers, increased yields for small farmers and reduced prices of food staples for poor consumers. (I happen to agree with you and your points are solidly based on evidence. . However, this view is a highly contested one and many critics of the Green Revolution remain convinced even in face of evidence to the contrary that the GR was a disaster. They are mostly wrong but there were some downsides to the GR. For example, there were environmental impacts such as development of soil salinity from irrigation that had longer term consequences that undermined livelihoods. Without engaging in a lengthy analysis of these critics, a couple of sentences that would acknowledge some of the downside of the GR, and the lessons drawn from it would make your analysis more credible. Most proponents of biotechnology today call for a 'doubly green revolution', acknowledging the weaknesses

<u>of the first.</u>) However, as conventional plant breeding exhausts its possibilities, GM crops could revive the process of improving yields of food staples and of crops grown by the poor.

In India, the proportion of population that is poor has declined from above 50% in the mid-70s to about 35% by the end of the century. Ravallion and Datt (1996) found rural economic growth to have significant impacts in reducing urban and rural poverty while urban growth has little impact on rural poverty. In the rural sector, higher farm yields is the key variable that reduces poverty and increases wage earnings (Datt and Ravallion, 1998).

Not surprisingly, poverty has been seen to be highly correlated (inversely) with the level of agricultural earnings (Kijima and Lanjouw, 2003). As agricultural wages tends to be the reservation level of earnings for workers in other sectors, changes in agricultural wages is a good indicator of the changes in poverty. In India, agricultural earnings for illiterate workers increased by about 50% between 1983 and 1999 (Eswaran, Kotwal, Ramaswami and Wadhwa, 2005). In a simple two sector general equilibrium model, agricultural wages are determined by total factor productivity in agriculture as well as in the non-farm sector (Eswaran and Kotwal, 1993). So what has been the relative contributions of these two factors in explaining the earnings increase in India? Eswaran et. al (2005), find the contribution of the growth in productivity in the non-farm sector to be quite limited. The bulk of the increase in agricultural earnings seems to be because of growth in agricultural productivity. Similar results are reported

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<sup>&</sup>lt;sup>1</sup> These estimates are obtained by comparing the household budgets with the official poverty lines. Because of a change in survey design, official poverty estimates in 1999 are not strictly comparable to earlier poverty estimates. Various researchers have produced 'adjusted' estimates – the number reported in the text is on the higher side of the adjusted estimates.

by Kijima and Lanjouw (2004). They conclude that the expansion of non-farm sector has had limited impact on poverty reduction. However, nonfarm employment does play a role in putting pressure on the agricultural labour market and in raising agricultural wages. Clearly, though, this has not happened sufficiently for the nonfarm sector to be an important driver of poverty reduction.

This short review confirms the centrality of agricultural productivity growth in reducing poverty in India. While the nonfarm sector might become more important in the future, it seems very unlikely that it could be a primary source of employment especially for people with low education levels. The relevance of GM crops for the poor in India is therefore very much in line with what is envisioned in the report of the Nuffield Council on Bioethics.

However, this potential will not be realized automatically. The conditions under which it can work form the focus of this paper.

### 3. The Institutional Setting: The Seed Sector

Plant biotechnology products reach the farmer as seeds. The seed sector in India consists of a public and private sector. As befits its size, India has one of the largest public sector agricultural research establishments in the developing world with the Indian Council of Agricultural Research (ICAR) at its helm. Plant breeding in the food staples of rice and wheat forms the mainstay of the research program. The public sector is also involved in seed production and distribution through the National Seed Corporation, the State Farm Corporation of India and 13 State Seed Corporations. These corporations multiply and market varieties bred by the public sector institutions, i.e., the research institutes financed by the ICAR and the State Agricultural Universities.

There are no firm estimates of the number of private seed firms. Estimates vary from 200 to 500. Private seed firms are heterogeneous with respect to size, research capacity and product segments. Plant breeding research is found in the larger firms. Unlike the public sector, where research is separate from seed production and marketing, these functions are integrated in the private firms. The other striking difference is in product types. Private sector research focuses largely on developing hybrids. As a result, it is unimportant in the crops dominated by open-pollinated varieties, which includes the major food staples of rice and wheat. On the other hand, the private sector is a major player in the hybrid seed markets of vegetables, sorghum, maize, cotton and pearl millet.

Till the early 1990s, the private seed industry was governed by regulations that restricted the entry of large business groups and foreign seed majors. After the removal of these restrictions because of economy wide reforms, the private sector plant breeding has grown rapidly. Pray, Ramaswami and Kelley (2001) estimate that private R&D investments in plant breeding tripled between 1988 and 1996. The same study concludes that about 50% of the observed increase in R&D was attributable to economic policy changes of the early 1990s. Public sector research has also fed into the success of private sector research. In sorghum and pearl millet, private plant breeders have made extensive use of advanced lines and other germplasm provided by the public sector (including the CGIAR system). In cotton, it was the state agricultural university in Gujarat that pioneered the development of hybrid cotton varieties that later disseminated to the private sector. The smaller private firms depend on the public sector in a more direct manner.

Their revenues are derived largely from sales of public bred open-pollinated varieties and hybrids.

#### 4. Institutional Setting: Biotechnology in the Public Sector

In 1986, the government of India set up the department of biotechnology (DBT) in the Ministry of Science and Technology giving biotechnology the same status as atomic energy and space exploration within its science portfolio. The department of biotechnology is situated outside the public sector agricultural research institutes and it funds plant biotechnology projects in the agricultural research institutes and outside it. Moreover, it occupies a central role in the regulatory apparatus (to be discussed later).

Thus, plant biotechnology has involved a wider range of expertise than could be found in traditional centres of plant breeding. This is a positive development in so far as it broke the long-standing institutional monopoly of public sector agricultural research and forced it to confront new expertise that was not wedded to the ICAR way of doing things. However, it also brought in a new concern. Because of the distance from the final users (i.e., the farmers), public sector agricultural research has to constantly seek to define its priorities and allocate resources accordingly. This problem could only be more acute for public sector plant research outside the specialized agricultural research institutions. The latter have the advantage, at least in principle, of links with allied plant disciplines (including traditional plant breeding) and with agricultural extension.

The DBT has supported research projects at different research institutes and agricultural universities throughout the country. It has also established specialized centres for plant biotechnology research. In terms of specific activities, a part of DBT

funds supports basic research in plant molecular biology and genomics. Rice genomics in particular has received attention in collaboration with the international genome sequencing programme. Other 'knowledge-building' types of work include tagging of quality traits in rice, wheat and mustard and molecular methods for heterosis breeding.

In 2003, 47 projects in the public sector aimed at developing transgenes in various crops. By far, the great majority of projects (numbering 33) intended to develop transgenes with resistance to insects or viruses or fungal infections. Out of these, 14 projects aimed at using a Bt gene to develop insect resistant varieties of cotton, potato, tobacco, rice, and vegetables. Other projects aimed at transgenes with male sterile and restorer lines for hybrid seed production (2), transgenes with delayed fruit ripening (3), nutritionally enhanced transgenes (2), transgenes that could withstand moisture stress or flooding (4) and transgenes that could supply edible vaccines (3). About half of the projects involved rice or vegetables. Other crops researched include chickpea, mustard/rapeseed, tobacco, cotton and blackgram.

India's public sector research programme has been criticized for spreading resources thin and for not orchestrating a concerted research effort with select crops and well-defined goals. In 2002/03, the annual DBT budget on crop biotechnology was only about \$3 million and the total spending planned for the 5 years starting from 2002 was no more than \$15 million (Sharma, Charak and Ramaniah, 2003). Further, not a single product from the public research system is in large-scale trials or close to commercialization. There are several factors that seem to be responsible. Firstly, expertise in plant biotechnology has remained limited within the traditional agricultural research institutions (Pental, 2005). There has not been an aggressive move to acquire

such expertise. Secondly, the development of transgenes for commercial use requires teams proficient in various disciplines such as agronomy, plant breeding, plant pathology, entomology and biotechnology. The public sector has failed to develop such coordinated approaches. Thirdly and this is related to the earlier point, the public sector has not incorporated regulatory know-how in the design of its research project (Pray, Bengali and Ramaswami (2005)). Research budgets do not explicitly budget for regulatory costs and delays in the regulatory process are common. A case in point is the work on insect resistance for *basmati* rice. *Basmati* rice is an exportable and has major markets in Europe and the Middle East. A regulatory advisor to the insect resistance project could have easily anticipated the regulatory difficulties.

Notwithstanding the lack of focus on commercialization apparent in existing public sector R&D, a consensus on public sector priorities in biotechnology is beginning to emerge. Grover and Pental (2003) surveyed the research priorities of agricultural scientists involved in crop improvement of each of 12 major field crops. Overall, breeding for biotic stresses, pests and pathogens are the major objectives for all crops. Almost all the major field crops suffer from major pests and pathogens including the crops grown in dryland areas.

For each specific crop, transgenic approaches were suggested for problems that were intractable by the use of conventional breeding techniques. For instance, in the case of rice, conventional plant breeding was regarded as adequate for providing resistance to blast, bacterial leaf blight, tungro virus, gall midge, brown plant hopper and whiteback plant hopper. However, germplasm resources for stem borer, leaf folder, sheath blight and sheath rot were inadequate and required transgenic techniques. Between the two

major cereal crops, rice receives higher priority for transgenic approaches as most of the biotic stresses in wheat can be dealt with conventional breeding technologies.

Improving water use efficiency and transgene approaches to abiotic stresses in general are also recognized as important. However, because of complex genetic mechanisms that govern abiotic stress tolerance, field deployment of abiotic stress-tolerant transgenics is still regarded as distant (Grover et. al, 2003). Research would need more funding support as well as collaboration between plant molecular biologists, crop physiologists and agronomists.

#### 5. Institutional Setting: Biotechnology in the Private Sector

Private sector investments in biotechnology have largely been in three crops – cotton, rice and vegetables – and a single trait – insect resistance through Bt genes. The exception to this was Bayer's research on developing genetically modified mustard that could be used to produce hybrid seed. Based on interviews with a large number of seed/biotech firms in 2003 and 2004, Pray, Bengali and Ramaswami (2005) found that the regulatory climate had induced private firms to shift research and technology transfer priorities away from rice, vegetables and mustard toward cotton.

Bayer's application for commercial release of its hybrid mustard went up to the last stage of regulatory approval when the regulators asked for additional tests and trials. Because of the continued costs and the uncertainty about whether this product will ever be approved and the potential market size for GM mustard, Bayer decided in 2003 not to continue trying to commercialize hybrid mustard in India. Bayer also scaled down their research on Bt vegetables.

Private rice biotech programs in India reached a peak about 5 years ago and have been declining due to both global and local factors. In the late 1990s Monsanto, Proagro (then owned by Aventis, now owned by Bayer), Syngenta, and MAHYCO were all working on insect resistant rice. Monsanto and Bayer Crop Sciences discontinued their India work on GM rice when they decided to stop working on GM rice worldwide. Syngenta stopped its rice biotech program in India a year or two ago, although it is watching golden rice to see if it finds a market. Now only MAHYCO and two biotech start up companies – Meta-Helix and Avesthagen – are conducting research on GM rice.

The trend in rice biotech research by local companies is less clear. MAHYCO continues to have a substantial biotech program on rice. Metahelix is working on developing synthetic Bt genes, identifying the role of different genes in the rice genome, and using this information in marker aided selection. Avesthagen is still doing some rice research, but it had to reduce all of its research because of financial problems in 2002. It was working on more efficient methods for producing hybrid rice, salt tolerance, and drought tolerance, but it has put the salt and drought tolerance on hold. As India is a centre for biodiversity in rice, there are special ecological concerns about GM rice. Further, two official policy documents have declared that biotech research in exportable crops should be low priority (Government of India, 2004 & 2005).

Cotton biotech research is on the other hand on the rise. No major company has dropped out and new companies are starting applied and basic biotech programs. Private sector cotton biotech research is led by the biotech multinationals. Monsanto is pushing the next generation of Bt technology - Bollgard II - through the Indian regulatory system. Syngenta has been working with their VIP gene for insect resistance. Bayer is just

starting their cotton biotech program. Ten of the main cotton seed companies have signed licenses to obtain Bollgard I and II from Monsanto and are conducting research to incorporate those genes into their cotton hybrids as well as pushing their early Bt hybrids through the regulatory system. Nath Seeds is experimenting with a Chinese Bt gene. Seven Indian companies—Nuziveedu Seeds, Ganga Kaveri, Prabhat Agri Biotech, Kaveri Seeds, Pravardhan, Nandi Seeds, Vikkis' Agrotech—have recently formed a consortium called Swarna Bharat Biotechnics Private Limited (SBBPL). It has entered into a memorandum of understanding with the National Botanical Research Institute (NBRI) to commercialize NBRI's Bt gene. Meta-Helix is working on commercializing their synthetic Bt gene in collaboration with Nuziveedu.

A recent development is the emergence of specialized research firms that supply contract research services in the area of biotechnology. Most of the contracts are with agricultural seed majors outside India; however, some work is being done as well for Indian seed companies. The customer provides the gene construct and the seed material that is to be genetically modified. The Indian lab genetically modifies the seed, germinates it in a greenhouse under controlled conditions for one or two generations and undertakes initial performance and safety testing.

#### 6. Institutional Setting: Biosafety Regulation

Indian regulatory institutions have three layers. At the bottom the institutional biosafety committees (IBCs) must be established in any institute using rDNA in their research. They contain scientists from the institute and also a member from Department of Biotechnology (DBT), which is part of the Ministry of Science. There are 230 plus

IBCs in India of which 70 deal with agricultural biotechnology. They can approve contained research at Institutes unless the research uses a particularly hazardous gene or technique. That type of research must be approved by the Review Committee on Genetic Manipulation (RCGM), which is the next layer of the system.

The RCGM is in the DBT and regulates agricultural biotech research up to the large-scale field trials. It requests food biosafety data and environmental impact data and agronomic data from applicants who wish to do research or conduct field trials. It gives permits to import GM material for research. It is primarily made up of scientists (including agricultural scientists) and can request people with specialized knowledge to review cases. It has a Monitoring-cum-Evaluation Committee (MEC) that monitors limited and large-scale field trials of GM crops.

The Genetic Engineering Approval Committee (GEAC) is under the Ministry of Environment and Forests. It is the agency that gives permits for commercial production of GM crops, large-scale field trials of GM crops, and the imports of GM commercial products. Although scientists are represented in the committee, bureaucrats representing different ministries dominate them.

The main steps in the biosafety regulatory process for a new GM event (new gene inserted into one location on a specific variety's genome) is shown in column 1 of Table 1. Columns 2 and 3 have the data generated for regulators and which committees regulate each step. If little is known about the event or it is thought to be risky, then next level committee has to sign off on the experiment or trial. For example, the IBSC could not approve greenhouse experiments at its institute with risk category III events. The approval of RCGM would also be required. After the event in a specific variety proves

that it is safe for human health, the environment and agriculture, and will be economically beneficial for farmers, the GEAC approves it for commercial use. If an approved GM event is backcrossed into a new plant variety, the developers of the new variety do not have to produce new food safety and environmental data. However, they do have to put it through at least two years of agronomic trials to obtain GEAC clearance. Currently, privately marketed seed varieties have no registration requirement. The government is, however, considering new seed laws that would require mandatory registration. It is not yet clear whether the agronomic trials required for biotech commercialization would meet the registration requirements or whether registration would require separate trials.<sup>2</sup>

#### 7. How has regulation worked?

The experience with regulation can be seen with reference to the first product that was commercialized. The first event to be approved was a Bt gene from Monsanto that was inserted in three cotton hybrid cultivars (MECH 12, MECH 162, MECH 184) belonging to the Indian seed company MAHYCO. This event was commercialized by a joint venture called Monsanto MAHYCO Biotech (MMB), which is equally owned by the two partners. After backcrossing was done, the first biosafety tests were done in 1997. The approval for commercial release came five years later in 2002. The varieties

<sup>&</sup>lt;sup>2</sup> It seems that the GEAC does consider the registration trials as a partial but not a complete substitute for its set of agronomic trials. The approval for RCH 2 Bt (in 2004) from Rasi Seeds, the second firm to receive regulatory clearance after the Bt cotton hybrids of Monsanto-Mahyco, took 2 years. The non-Bt counterpart RCH2 is a notified hybrid and had already gone varietal testing. Mr. M. G. Ramaswami, the Managing Director of Raasi believes that the approval process for non-notified hybrids could take 3 years (Rao, 2005).

were approved for cultivation in southern, western and central India for a period of 3 years. The entire schedule of the regulatory process is shown in Table 2.

As one of the first GM products to go through the regulatory system, the MMB Bt cotton attracted media attention. Several Indian and international NGOs opposed the application and the regulatory process was repeatedly challenged. On the basis of environmental & biosafety tests and field trials, MMB sought commercial release in 2001. However, the regulator rejected this request and asked MMB to conduct field trials at 400 locations under the direct supervision of the ICAR. The cautious stand of the regulator and its involvement of the ICAR seemed to be aimed at deflecting the pressure from NGOs suspicious of the data generated from Mahyco experiments. According to newspaper reports, the scientist members of GEAC were in favour of approval but were outvoted by the bureaucrat members (Jain, 2001).

A fall out of this controversy is that for all subsequent product approvals, the regulator has required 2 years of field trials with the ICAR.<sup>3</sup> This decision has served its purpose of diffusing challenges to regulatory decisions. However, it has also highlighted the role of large-scale field trials in the regulatory process. The primary purpose of the large-scale trials is agronomic and economic evaluation of the candidate varieties. The implicit assumption is that farmers are unable to compare alternative varieties and they must therefore be protected from potentially disastrous choices. This point has come to the fore once again with the demand from NGOs to ban the approved MMB Bt hybrids because of their 'failure' in the field. NGOs claim that propaganda from MMB misleads farmers of the true merits of Bt varieties and therefore their studies, which 'demonstrate'

<sup>&</sup>lt;sup>3</sup> To diffuse NGO opposition, it is likely the GEAC will also standardise food safety and environmental tests by requiring that these tests be done by accredited institutes.

the failure of Bt cotton, justify a ban on the varieties and prevent farmers from accessing them. The initial approval of the MMB varieties expired in 2005 and the regulatory body GEAC met in April and May to consider the renewal of approval against the demand from NGOs to deny the renewal. While the regulatory authority renewed the approval for all the MMB hybrids in western and central India, the renewal was denied for one of the varieties in the states of Tamil Nadu and Karnataka and for all 3 varieties in Andhra Pradesh. Thus, the Indian regulator is not merely a guarantor of food and environmental safety of GM products but also of agronomic and economic performance of GM crops. The redefinition of their job is testimony to the pressures brought on them by opponents of GM crops.

The regulators have also had to cope with pressures from farmers. This crystallized in rather dramatic form when it was discovered in November 2001 that over 4500 ha in Gujarat were illegally planted and seeded with Bt cotton. Navbharat Seeds, a firm based in Ahmedabad, distributed the seed. By the time it was detected (on a complaint from Mahyco), the cotton was ready to be picked and harvested. Although initially the GEAC instructed that the crop be burnt, the state government found it expedient instead to procure the crop at a suitable price so that seeds could be separated and destroyed. Since then, the plantings of illegal Bt cotton has spread across Gujarat and to other parts of India, notably Punjab. In Gujarat, illegal Bt hybrids have driven out conventional hybrids and confined the approved MMB hybrids to a small group of farmers. The multiplication and distribution of the illegal seed occurs through an underground network of seed producers, small seed companies and their agents. It is the responsibility of the state government to prosecute violations of biosafety law. However,

in the face of strong farmer support to the illegal seeds, the state government has chosen to turn a blind eye to it. India's seed laws allow farmer-to-farmer exchange of seeds to be exempt from inspection and seed laws. This loophole has allowed the state government to claim ignorance of the extent of illegal plantings. For their part, illegal seed sales try to soften their challenge to the law by taking care to mask the seed sales as seed exchange. Thus, the illegal seeds are often sold loose in packets without a company seal and without a bill of purchase.

The discovery of the illegal plantings in late 2001 and the complicity of the state government probably reassured the GEAC that it was correct to approve the MMB hybrids in 2002. The GEAC also faces direct pressures from farmer representatives including chief ministers of agriculturally prosperous states like Punjab (Jain, 2002). The initial approvals of the MMB varieties did not extend to Punjab. Worried by the illegal plantings, Punjab government officials pressed the regulators for approval of varieties for their region. The regulator seems to have responded to the need to combat the spread of illegal seed. Since 2004, it has approved several other Bt hybrids all of which spent just 2 years in the regulatory process. The entire list of approvals is given in Table 3. While some of the newly approved hybrids are from MMB, most of them are from other seed companies who licensed the Cry 1 AC gene from MMB. The regulator seemed to use this fact to considerably abridge the food safety and environmental tests and to largely base their approval on large-scale field trials for agronomic and economic performance. As of yet, the regulator has not approved a cotton hybrid with a Bt gene other than Cry 1 Ac. Such approvals are expected in 2006.

#### 8. Compliance Costs

A normative view of biotech regulation is that it is a process of risk assessment based on rigorous science. However, as the Indian experience attests, biotech regulation is an intensely political process and is contested at many levels – by bureaucratic wrangling (between scientists and bureaucrats, between biotech scientists commanding expertise in the lab and agricultural scientists commanding expertise of field conditions), by NGOs and civil society organizations who use the occasion to debate and question the direction of agricultural technology and forms of corporate control and by farmers who simply want a product that could make their lives simpler and better.<sup>4</sup>

Subject as it is to so many pressures, the regulatory process is subject to delays and is not entirely predictable. For biotech suppliers, this will show up as higher compliance costs. Pray, Bengali and Ramaswami (2005), survey the compliance costs of 4 products that went through the regulatory system or are still under regulation. These were the first Bt cotton hybrids of MMB, the GM hybrid mustard of Bayer, Bt eggplant and high-protein potato from public sector research institutions.

MMB's costs are laid out in Table 4. The total pre-approval cost is between U.S. \$1.6 and 1.8 million (depending on whether the 400 field trials in 2001/2 were really necessary or not), which is a substantial sum. The numbers for hybrid mustard are not as complete, primarily because of changes in owners of the technology but also because the technology has not been approved for commercial use. This program was started by the Indian seed company Proagro in collaboration with the Belgium biotech company PGS. The multinational seed company Aventis purchased both of these companies and then in

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<sup>&</sup>lt;sup>4</sup> For a more complete discussion about how the regulatory process (including its enforcement) is challenged at various levels, see Scoones (2003). Scoones also talks of the dynamics between the centralised regulator and the priorities of state level officials.

2001, Bayer, the German chemical company, purchased Aventis. Bayer was able to provide the data on costs in broad regulatory categories, and estimates of the costs that they would have had to pay if they continued with this program.

The genes that were used to produce hybrid mustard have been used in canola to produce hybrid canola cultivars in Canada and the U.S. They have cleared the biosafety regulations in those countries. However, the use of these genes in mustard have not been commercialized anywhere in the world. Therefore, Bayer and its predecessors decided that they would not commercialize it in India unless they conducted research to show India's neighbors and trading partners that this particular genetic event was safe. Newspaper reports quote former officials of Proagro that they spent Rs. 50 million (about US\$ 1 million) over 8 years by December 2002 (Editorial, Times of India 2002). In addition to this amount that was spent primarily on foods safety, environmental and agronomic research in India, between US \$ 3 and 4 million was spent in the U.S. and Europe to ensure that it met the international food safety and environmental requirements. These costs are shown in the top section of Table 5. After spending between \$4 and \$5 million on meeting regulatory requirements in India and elsewhere, GEAC required another set of trials which are listed with their expected cost in the bottom section of Table 3. Because of the continued costs and the uncertainty about whether this product will ever be approved and the potential market size for GM mustard, Bayer officials in India informed us in December 2003 that they decided not to continue trying to commercialize hybrid mustard in India.

In contrast to the high costs estimated by the private sector, most public sector scientists felt that costs were not a major constraint on their research or

commercialization efforts. They felt that the years lost in the regulatory process is the main problem. One of the few institutes that have long experience with the biosafety process is the National Research Center for Biotechnology at the Indian Agricultural Research Institute (IARI). Their vegetable program has had Bt varieties in the regulatory system for a number of years. They started Bt research 8 years ago in 1996. They developed a Bt eggplant using a Cry1Ab gene that controls 70 percent of the fruit borer attack. They had agronomic trials in a controlled environment in 1998/99, 1999/2000, and 2000/2001. In 2003 they were permitted to conduct field trials in five locations -Delhi, Karnal, Pune, Tamil Nadu Agricultural University and the Indian Institute of Horticultural Research. The cost of controlled environment trials and field trials so far has been about \$10,000 (see Table 6). If they were required to do two more years of field trials in 10 locations, this would add another \$10,000. They asked for and received estimates of the cost of meeting the food safety requirements in 2003. They received cost estimates from three institutes—National Institute of Nutrition, Central Food Technology Research Institute, and Institute of Toxicology, Lucknow - to provide the information requested by the regulators. The estimates ranged from Rs 1 to 1.5 million (\$22,000 to 33,000) for everything needed (Personal communication IARI scientists, New Delhi, December 2003). Thus with this food safety data and two more years of field trials the total cost would come to \$53,000. This is a large sum for the Indian research system, but IARI has grant money to cover it.

IARI's problem is delays in obtaining regulatory approval and the time that it takes scientist to shepherd their applications through the regulatory process. For example, they had Bt eggplant ready for the multilocation testing in 10 places in 2001/2

but were not granted permission. They earliest they could hope to get permission was for the 2004/5 crop year – three years later. The testing of new Bt rice varieties from IARI have already been delayed by two years in December 2003 due to slow responses from the regulatory committees at the central government and state levels.

When a project has the full support of the Department of Biotechnology both the time and the cost of the regulatory process can be small. The high protein potato research at the Center for Plant Genomics Research in New Delhi was often used by the previous head of the Department of Biotechnology as an example of the consumer benefits from GM technology. The lead scientists on this project, Dr. Niranjan Chakraborty, reported in early 2004 that their costs of meeting regulatory requirements have been negligible – some costs of the allergenicity/ toxicity and the costs of labor and fertilizer for three years of field trials. The agricultural institutes that conducted the tests absorbed all other costs. They still had not submitted their data to the GEAC to get approval for wide-scale testing of the technology. So there will be more costs at the next level and at least two more years of testing, but at the moment the total costs and the time required has been limited.

In addition to these estimates five private companies – Monsanto, MAHYCO, Avesthagen, Meta-Helix and Nunhems (Bayer) provided us with their estimates of the future costs of meeting biosafety regulations. They vary widely based on the type of crop – food vs. non- food; whether the gene had been already approved by regulators in India, whether it has been approved the elsewhere (i.e. U.S. or Europe); and whether the tests could all be completed in India or not. In addition there may be some differences because some companies may wish to do more research than is required by Indian

regulators because they may wish to document certain qualities of the crops other than those required in India.

For new GM varieties with approved events or those with events that have not been approved, the cost estimates of different companies are shown in Table 7. As mentioned above, if the plant variety containing a specific event has been approved for commercial use by the GEAC and then is backcrossed into another variety, the GEAC requires two to three years of agronomic trials before the new variety is approved for commercialization. If the number of biosafety trials are 15 the first season and 40 the next two season and each ICAR trial costs about \$1000, the costs could be almost \$100,000.

The least expensive new events will be in crops that are non-food crops like cotton and events like Monsanto's Cry1Ac Bt gene in a Delta Pineland variety that has been in commercial use in the U.S. Much basic information and the results of many field trials and toxicity/allergenicity tests are available from the U.S. and elsewhere. U.S. and European companies now spend from \$5 to 10 million for each new gene to put together a package of information for regulators and their customers. The companies will also have purified protein ready for tests where needed. They bring this package to each new country in which they introduce the gene, and then do whatever addition tests are required. These new tests at least take into account differences in the way the crop is consumed and local nutritional issues and specific agricultural and environmental conditions. There may also be specific requirements based on ethical or political values of a country (e.g. India requires that new varieties be tested for the presence of the "Terminator" genes which is prohibited in India).

No food crops have yet been approved for use in India. Companies speculate that a food crop such as maize or soybean will require much more testing and time to be approved than cotton, even if the specific event has been approved and used extensively in the U.S., Argentina, and South Africa. These costs were estimated in the \$500,000 to one million dollar level. Non-food and food crops which have not been approved elsewhere and events that have not been approved, will require more tests because they can not rely on dossiers of information developed elsewhere. RCGM may require tests that necessitate the production of purified protein to be used in animal studies. Production of purified protein can add another \$500,000 to the cost. There also may be increased environmental/agricultural research required if India is a center of biodiversity for a crop such as it is for rice. Finally, for events not approved elsewhere, companies like Bayer with hybrid mustard, may see the need to do extra research on food safety and environmental impacts and do some of the trials in the U.S. or Europe to give their customers (both in India and abroad) assurance about the safety of these genes. Additional studies will probably also be needed if the material is going to be registered in neighboring countries to avoid creating difficulties with the export position. There is also the risk that seeds will be transported to neighboring countries for growing. To avoid blame for not anticipating on that impact, the company started seeking approval for the transformation events in other countries even though the target market is India The extra tests and research that is done in the U.S. or Europe are the reason for the \$4,000,000 estimate.

Why are the private companies' estimates so high relative to the costs of the public sector? In fact, except for salaries, there is no reason for public sector costs to be

any lower than private sector costs. While the private sector might have an incentive to exaggerate its costs in order to lobby for lower costs in the future, public sector costs seem to be substantially underestimated. The reasons for this are complex and are related to the way research programmes are managed in the public sector. Public sector research programmes do not budget separately for compliance. Salary costs are not included because they are paid for from a general budget. Biosafety tests are often done by other public sector research institutes that charge the public sector scientists nominal amounts rather than fees that are related to their costs. For these reasons, it would seem that the compliance costs reported by the private sector are more accurate than that reported by public sector scientists as a substantial part of their costs are not borne by their research program.

In the future we would expect the gap between private and public sector compliance costs to narrow. As the public sector moves more products through the biosafety process, it seems unlikely that they would continue to remain insulated from the regulatory costs. Government labs will begin charging commercial rates for biosafety testing for public sector as well. As internationally certified domestic testing facilities become available, the private sector will be able to avoid the expense of doing tests outside the country. The most detailed data that we have – for MAHYCO's Bt cotton and Bayer's hybrid mustard - were the first products through the system. As a result there was a lot of learning by doing and future products may not cost as much (although they could cost more if regulation becomes more stringent and more tests are required). Note, however, that once the public sector stops receiving hidden subsidies for doing the

regulatory costs, it will be very hard hit by compliance costs since public sector research funding is only in the region of \$3 million.

#### 9. The Surplus from Bt Cotton and its Distribution

The all India area under cotton is fluctuates around nine million hectares (22million acres) of which the share of hybrids is estimated to be about 50%. Table 8 displays the area under Bt cotton hybrids since 2000. By the end of 2004/2005, it is estimated that Bt cotton is grown on 3 million acres, which is about 15% of the total cotton area and 30% of the area under cotton hybrids. Of this, illegal Bt varieties occupy nearly 2 million acres. As the cotton growing areas are specialized into hybrid regions and variety regions and since that division has been changing only slowly, it is reasonable to assume that Bt cotton hybrids have replaced other hybrids.

The impact of MMB Bt cotton on crop yield and farmers' income has been hotly contested in India. Especially for the opponents of GM crops, the performance of MMB hybrids has amounted to a referendum on GM crops. As a result, many farm "surveys" have been carried out – by the media, NGOs and industry. It is impossible to evaluate the worth of each of these studies. Here in this paper, I consider the findings reported in major academic and policy journals. All of these papers have a simple design. They compare the performance of Bt cotton with a check variety in terms of yields and input use. And after assuming certain prices for the output and input, the studies estimate the change in farm income because of Bt cotton. Although the procedure seems deceptively simple, there are pitfalls in its execution. Firstly, the survey design must be such that the selection of growers is truly random and not biased (towards region or any other grower

characteristic). Secondly, we must be sure that we have correctly identified the counterfactual. In the absence of Bt cotton, what would the adopters do? Would they be growing the check variety? Thirdly, a comparison of adopters and nonadopters must control for differences in observable and unobservable characteristics. The easiest way to control for this would be to compare Bt and non Bt plots of the same farmer and this is what is done in a few studies. This would work whenever there are large number of partial adopters.

Table 9 compares the difference between group means of Bt adopters and non Bt adopters across five different studies. Of these Bennet et. al (2004), and Sahai and Rehman (2004) have results for the years 2002 and 2003 – thus we have comparisons from 7 surveys across the years 2001 to 2003. The surveys also differ in terms of sample size, the states that are surveyed and whether they control for individual grower characteristics. Among these results, the Sahai and Rehman (2004) study stands out as an outlier. It is the only study that shows a worse performance for Bt cotton compared to other commonly grown hybrids. Otherwise, all the other studies agree on a common picture despite vast differences in methodologies. The net returns to the grower (relative to the non-Bt alternative) ranges from Rs. 3400 to Rs. 8800 per acre. The increase in percentage terms varies from 49% (Bennet et. al for the year 2002) to 480% (Qaim (2003) for the year 2001). The Qaim study uses data from MMB field trials in 2001. The Bambawale et. al analysis uses an experimental setting to compare Bt cotton hybrids with non Bt cotton hybrids under similar production practices. All the other studies use data from farmers growing Bt cotton under normal field conditions. It is difficult to explain the poor performance of Bt cotton in the Sahai and Rehman analysis and how it can be

reconciled with the rapid adoption of Bt cotton overall. Naik et. al (2005) suggest that performance of Bt cotton has not been uniform across states and its advantage over non-Bt cotton has been non-existent in Andhra Pradesh – the state from which Sahai and Rehman draw their analysis.

Taking a conservative view of the performance of Bt cotton, suppose the returns from it relative to non-Bt alternatives is Rs. 2161 per acre – the lowest figure in Table 9 (except for Sahai and Rehman). We can interpret it as the average all India figure. From the Bennet et. al and the Naik studies, we see that the cost of Bt seed for 1 acre is Rs. 1550 and that of non-Bt seed is Rs. 500. The net surplus to the seed industry from Bt cotton is therefore Rs. 1050 per acre. Hence, the total surplus per acre generated by Bt cotton is the sum of grower returns and seed industry profits, which works out to Rs. 3211 per acre. The share of the seed industry is 33% and the remainder 67% remains with the grower. Table 9 suggests that 67% is a lower bound to the share of the grower in the surplus. In terms of aggregate gains, applying the gains to growers to the current diffusion level (of 1 million acres of legal Bt) means an increase in aggregate gains by over Rs. 2 billion rupees. As a proportion of overall farmer income from hybrid cotton, the gains amount to 7%.

The above calculations assume that the additional supply due to Bt cotton does not affect prices. As Bt cotton diffuses, it would reduce cotton prices. Consumers will benefit and producer gains will not be as much as compared to the case when prices remain unchanged. However, the sum of consumer and producer benefits will continue to add up to a 67%. The exact division of gains between these two groups of agents depends on the elasticity of demand for cotton.

#### 10. Market Structure Issues

In the conventional hybrid cotton seed market as many as ten firms account for a market share of 60-80% and of these only two firms are fully owned multinationals (Syngenta and ProAgro owned by Bayer). Another one, Mahyco, has an equity and technical alliance with Monsanto. The others are owned by domestic investors. Ankur and Raasi Seeds are two of the larger cotton seed firms with a turnover between \$20 to \$30 million. The remainder market share is held by a large number of small firms. The hybrid cotton seed market is therefore competitive and no single firms is dominant.

Bt cotton has, however, thrown the market in turmoil. Till 2004, MMB hybrids were the only Bt hybrids that has received biosafety authorization. MMB therefore had monopoly power and used it to charge farmers Rs. 1600 for a packet of seed (for one acre), which is much higher than the pricing of conventional private bred hybrids (at Rs. 300-Rs. 500).

MMB would have gained even more from their ownership of Bt technology but for the illegal Bt varieties. These have captured the hybrid cotton areas in Gujarat and made inroads in other states as well. Indeed, more area is under the illegal varieties than the legal varieties. The illegal seed is cheaper selling for a price between Rs. 800 and Rs. 1200 but seems to perform just as well. The success of MMB hybrids and the even more rapid diffusion of illegal Bt has had a major impact on the other firms in the business. For instance, in Gujarat, the market leader Vikram Seeds till 2002 lost its entire market share to Bt cotton. The sales of public bred hybrids have also been adversely affected. Faced with the possibility of losing market shares overnight (as happened to Vikram

Seeds in Gujarat), there is a scramble among the major seed firms to obtain Bt technology for cotton. Many of the leading firms have licensed the technology from MMB. MMB has reportedly sold licensed the technology to at least 10 firms in India and is charging licensees a one time fee of \$100,000 to \$200,000 plus a 70 percent royalty on sales. Despite the competition from illegal Bt, the rate of return to MMB's investment in regulatory costs is estimated to be 38% (Pray, Bengali and Ramaswami, 2005).

Bt cotton, therefore, has disrupted the competitive structure of the cotton seed market. At this moment, MMB has a decisive technological edge over the other firms. However, despite the seed premium charged by MMB, the farmers have, as we have seen, gained from the new technology although they would gained even more from a competitive market. In the longer run, however, the market for Bt technology is likely to be more contested. As mentioned in section 5, cotton biotech research is on the upswing and pest resistant products are expected from Syngenta and Bayer among the multinationals. In addition, research work is going on developing Bt genes in Indian institutions and in adapting the Chinese Bt gene.

#### 11. Revisiting the impact of GM crops on the Poor

The hope is that GM crops would revitalize crop productivity, increase the incomes of small farmers and landless workers and reduce poverty. The logic for this was seen in section 2. How realistic is this possibility? And what would be needed to make it work?

In this paper we have seen that the private sector in India has a strong presence in the distribution and marketing of seeds and also in developing new varieties in certain crops. The diffusion of Bt cotton has been the handiwork of private agents. The legal Bt was backed by large firms with technical and marketing prowess. The unofficial Bt has spread on the strength of a network of skilled seed producers, small companies and their agents. The demand for both these seeds has been strong because of their considerable advantages relative to conventional hybrids in protecting yields from pest losses. Thus, the lesson is that if farmers perceive gains from using certain type of seeds, the private sector has enough capabilities to supply them. The constraint to the adoption of beneficial GM crops does not arise from distribution.

What is of concern, however, is appropriability. The private sector activity is confined to hybrid seed. Although India has plant breeder's rights, it is unlikely to stimulate any private sector interest in open pollinated varieties because the rights protection does not apply to seed saved or exchanged by farmers. For poverty impacts, crop productivity must rise in the major food staples, i.e., in the open pollinated crops of rice and wheat. Hence governments need to solve the appropriability problem.

Conventionally, what has been done is to invest the responsibility of public goods type research with the public sector. The public sector played this role in the case of the Green Revolution.

The public sector in India is not yet well equipped to play a similar role in GM crops. Several difficulties will have to be overcome. First, is the scale of funding. It is too low (especially in relation to potential benefits) at present to support initiatives on a large scale. Second, the funds need to be deployed in a focused and sustained manner. Third and this is possibly a more structural problem than the earlier ones is the lack of relevant expertise within the public agricultural research sector. Public private

partnerships have been proposed in this context. In India, there has been no instance of this kind although the official biotech policy does talk about it. This issue is not unique to biotech seeds; it arises also in the development and supply of drugs that attack the third world diseases. In that context, various solutions have been proposed including government guarantee for procurement and purchase of drugs and vaccines. Fourth, most of the public sector is not yet in tune with regulatory demands.

Intellectual property rights could well be a constraining factor in the future. However, it has not been a critical factor constraining public sector R&D because of the absence of IPRs till recently. India has a new patent law to comply with WTO obligations. As part of the law, India has to provide patent protection to biotechnology innovations. Although it is still very early to know whether Indian patents on biotech innovations will be broad or narrow, India may well keep in public domain the key elements of genomics and the basic biotech tools. It is CGIAR research that is more hampered by materials transfer agreements.

As regards regulation, India is on a learning curve. The initial products paid the price of being the first ones and suffered delays and costs. Later products should encounter a more streamlined process. However, the regulatory process will continue to reflect pressures from anti-GM voices as well as from pro-Gm voices. The resulting uncertainty is one form of regulatory cost as well. If regulatory costs remain large, private sector will focus only on hybrids with large markets. A GM technology plus regulation creates formidable entry barriers and gives the owner of GM technology protection from competition. The owner of Bt technology has earned non-competitive profits in India. However, the growers are still better off.

A pressing issue in regulation is enforcement of biosafety regulations on growing practices. A completely legalistic approach cannot possibly succeed in small scale agriculture. The limited evidence from the diffusion of illegal Bt indicates that noncompliance was driven by the price (too high) and performance (just adequate) of the legal seed. Policy makers must then strive to increase the legal offerings and keep the markets for seeds competitive. Regulation on the other hand restricts entry. The willingness of farmers to buy illegal seed that is not backed by a bill or formal guarantees underlines the low value that farmers place on formal approvals and the rights that it gives them. This will have to change for greater compliance.

Table 1. Regulation of Research and Commercialization of GM Plants

|                                  | TS                                             | XXII            |
|----------------------------------|------------------------------------------------|-----------------|
| Steps in GM plant                | Data generated at this step                    | Who approves –  |
| commercialization                | (more can be requested if needed)              |                 |
| process                          |                                                |                 |
| 1. Lab & Greenhouse              | Rationale for development of GM plant          | IBSC risk       |
| Experiments                      | Cloning strategy                               | category I & II |
|                                  | Characteristics of expression vectors,         | RCGM risk       |
|                                  | inserted genes, promoters                      | category III    |
|                                  | Transformation/cloning method                  |                 |
|                                  | Genetic analysis of transgene                  |                 |
|                                  | Biochemistry of expressed gene                 |                 |
|                                  | Compositional analysis                         |                 |
|                                  | Description of host plant, geographical        |                 |
|                                  | distribution in country of origin,             |                 |
|                                  | Back crossing duration, seed setting           |                 |
|                                  | characteristics, Germination rates,            |                 |
|                                  | phenotypic characteristics, target gene        |                 |
|                                  | efficacy tests                                 |                 |
|                                  | Observations about implications of             |                 |
|                                  | toxicity & allergenicity                       |                 |
| 2 Contained onen                 |                                                | IBSC/RCGM       |
| 2. Contained open field trials & | Germination rates & phenotypic characteristics | IBSC/RCGIVI     |
|                                  |                                                |                 |
| generation of biosafety          | Studies of gene flow, invasiveness, weed       |                 |
| data                             | formation.                                     |                 |
|                                  | Implications of outcrossing                    |                 |
|                                  | Susceptibility to diseases & pests,            |                 |
|                                  | Toxicity & allergenicity of                    |                 |
|                                  | plants/fruits/seeds.                           |                 |
|                                  | Food/feed safety evaluation in animals         |                 |
| 3. Multi-location trials         | Agronomic advantage                            | RCGM/GEAC       |
|                                  |                                                |                 |
| 4. Large-scale field             | Agronomic advantage                            | GEAC            |
| trials                           |                                                |                 |
| 5. Environmental, food           |                                                | GEAC            |
| & agronomic approval             |                                                |                 |
| 6. Variety                       | Agronomic advantage                            | ICAR, National  |
| registration*                    |                                                | and State Seed  |
|                                  |                                                | Quality control |
|                                  |                                                | agencies        |
| 7. Approval for                  |                                                | GEAC            |
| commercial                       |                                                |                 |
| production                       |                                                |                 |
| production                       |                                                |                 |

Source: Department of Biotechnology, unpublished paper, 2003

Table 2: Time Line of Approvals of MMB Hybrids

# **Bollgard Development Process in India**

Mahyco Institutional Biosafety Committee established in 1995

Review Committee on Genetic Manipulation

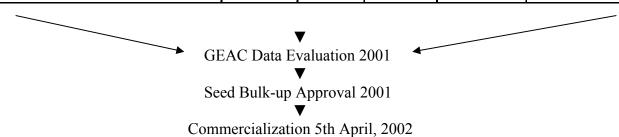
Import of Seeds 1996

Backcrossing

Studies conducted

 $\blacksquare$ 

| <b>Environmental Safety</b> | Environmental Safety |         | cy &<br>nic benefit | Biosafety studies              |      |
|-----------------------------|----------------------|---------|---------------------|--------------------------------|------|
| Pollen Flow                 | 1997                 |         |                     | Allergenicity<br>Study         | 1998 |
| Aggressiveness Studies      | 1997-98              | Year    | No. of trials       | Goat Study                     | 1998 |
| Pollen flow                 | 2001                 | 1998-99 | 40                  | Cow Study                      | 2001 |
| Soil Studies                | 2001-02              | 1999-02 | 19                  | Buffalo<br>Study               | 2001 |
| Gene stability              | 2001                 | 2000-01 | 25                  | Chicken<br>Study               | 2001 |
|                             |                      | 2001-02 | 376                 | Fish Study                     | 2001 |
|                             |                      |         |                     | Protein<br>detection in<br>oil | 2001 |



Source: Sharma (2005)

#### **Table 3: Commercialization Decisions of GEAC**

#### North India (Punjab, Haryana, Rajasthan):

**Approvals:** Ankur 651 Bt, Ankur 2534Bt of Ankur Seeds for 2 years on March 4th 2005; MRC 6301 Bt, MRC 6304 Bt of MMB for 2 years on March 4th 2004; RCH 134 Bt and RCH 317 Bt of Raasi Seeds for 2 years on March 4th 2005.

#### Central India (Madhya Pradesh, Gujarat, Maharashtra, Chattisgarh)

**Approvals:** MECH 12, MECH 162 & MECH 184 of MMB are approved for all regions for 3 years in April 2002;

RCH 2 of Raasi Seeds approved for Madhya Pradesh and Chattisgarh for 3 years in April 2004;

RCH 138 Bt of Raasi Seeds approved on April 13th 2005 for 2 years;

MECH-12, MECH-162 &MECH-184 of MMB are renewed permission on 3rd May 2005 for 2 years;

RCH-144 Bt, RCH-118 Bt of Rasi Seed, approved for 2 years on 3rd May 2005;

MRC-6301 Bt of MMB, approved for 2 years on 3rd May 2005;

Ankur-681 and Ankur-09 of Ankur Seeds approved for 2 years on 3rd May 2005.

# South India (Karnataka, Andhra Pradesh, Tamil Nadu)

Andhra Pradesh:

**Approvals:** MECH-12, MECH-162 & MECH-184 approved for 3 years in 2002

**Rejections:** MECH-12, MECH-162 &MECH-184 are not renewed permission on 3rd May 2005.

**Approvals:** MRC-6322 Bt and MRC-6918 Bt of MMB approved for 2 years on 3<sup>rd</sup> May, 2005.

RCH-20 Bt and RCH-368 Bt of Raasi Seeds approved for 2 years on 3rd May 2005.

#### Karnataka and Tamil Nadu:

**Approvals:** MECH-12, MECH-162 & MECH-184 approved for 3 years in 2002

**Rejections:** Mech-12 is not renewed permission on 3rd May 2005.

**Approvals:** MRC-6322 Bt and MRC-6918 Bt of MMB approved for 2 years on 3<sup>rd</sup> May, 2005; RCH-20 Bt and RCH-368 Bt of Raasi Seeds approved for 2 years on 3rd May 2005.

Table 4. Monsanto/MAHYCO's Costs in India for Bt cotton (US\$s)

| Study                                   | Number     | Cost/study   | Total     | In house? |
|-----------------------------------------|------------|--------------|-----------|-----------|
| Preapproval                             |            |              |           |           |
| Goat Feeding study – 90 day             | 1          | 55,000       | 55,000    | No        |
| Cow feeding study                       | 1          | 10,000       | 10,000    | No        |
| Water buffalo feeding study             | 1          | 10,000       | 10,000    | No        |
| Pollen flow                             | 1          | 40,000       | 40,000    | yes       |
| Soil microflora                         | 1          | Small        |           | yes       |
| Absence of terminator                   | 1          | Small        |           | No        |
| Poultry feeding studies                 | 1          | 5,000        | 5,000     | No        |
| Fish feeding studies                    | 1          | 5,000        | 5,000     | No        |
| Brown Norway rat allergenicity          | <i>/</i> 1 | 150,000      | 150,000   | No        |
| Gene stability                          | 1          | Small        |           |           |
| Expression in oil and lint              | 1          | Small        |           |           |
| Socio-economic study                    | 1          | 15,000       | 15,000    | No        |
| Baseline resistance study               | 1          | 20,000       | 20,000    | NA        |
| Greenhouse trials 1996                  |            | Small        |           |           |
| Limited field trials 96, 97-98          | 6          | 5,000        | 30,000    | yes       |
| Multi location field trials 98/99       | 41         | 5,000        | 205,000   | yes       |
| Multi location field trials 99/00       | 10         | 5,000        | 50,000    | yes       |
| Large scale trials 2000/1               | 40         | 2,500        | 100,000   |           |
| Large scale farm trials 2001/2          | 400        | 500          | 200,000   | yes       |
| Salaries & office expenses              |            |              |           |           |
| Years 1996 – 2001                       | 6 years    | 150,000/year | 900,000   |           |
| Total Pre Approval                      |            |              | 1,795,000 |           |
| Post approval                           |            |              |           |           |
| Socio economic study                    | 2          | 15,000       | 30,000    | No        |
| Resistance study                        | 1          | 20,000       | 20,000    | ?         |
| •                                       | 2          | 10,000       | 20,000    | ?<br>No   |
| IPM package 2 Salaries & office expense |            | 10,000       | 125,000   | INU       |
| Monitoring costs???                     |            |              | 125,000   |           |
| •                                       |            |              | 195,000   |           |
| Total Post Approval                     | , T        | 1: 1 2004    | 190,000   |           |

Source: Interviews with Monsanto India, July 2004.

Table 5. Regulatory Cost of Developing Novel Gene for India e.g. Hybrid Mustard

| Table 5. Regulatory Cost of Developing Novel Gene for India e.g. Hybrid Mustard |                              |                        |  |  |  |
|---------------------------------------------------------------------------------|------------------------------|------------------------|--|--|--|
| Studies                                                                         |                              | Costs                  |  |  |  |
|                                                                                 |                              | (US \$ thousands)      |  |  |  |
| Product characterization*                                                       | Unique identifier, reference | 1,500                  |  |  |  |
|                                                                                 | material, validations, etc.  |                        |  |  |  |
|                                                                                 |                              |                        |  |  |  |
| Environmental safety                                                            | Gene flow, impact on key     | 500 -1,000             |  |  |  |
| studies**                                                                       | species of insects, etc.     |                        |  |  |  |
| F - 1 f 1: *                                                                    | A 11 : :                     | 1.500                  |  |  |  |
| Food safety studies*                                                            | Allergenicity, toxicology    | 1,500                  |  |  |  |
| Nutritional assessment**                                                        |                              | 500                    |  |  |  |
| Traditional assessment                                                          |                              | 300                    |  |  |  |
| Total                                                                           |                              | 4,000 - 5,000          |  |  |  |
|                                                                                 |                              |                        |  |  |  |
| <b>Requested Studies in</b>                                                     |                              | <b>Estimated costs</b> |  |  |  |
| India (December 2003)                                                           |                              |                        |  |  |  |
| Environmental esfets                                                            | Dellar flav. O lacations     | 0                      |  |  |  |
| Environmental safety                                                            | Pollen flow - 8 locations    | 9                      |  |  |  |
| Food Safety                                                                     | Feed safety (goat)           | 22                     |  |  |  |
|                                                                                 |                              | 22                     |  |  |  |
|                                                                                 | Feed safety (cow)            | 22                     |  |  |  |
| Food safety                                                                     | Immunological studies in BNR | 33                     |  |  |  |
| A susua susia a sustinutia u                                                    | Agronomic evaluation ICAR    | 4.7                    |  |  |  |
| Agronomic evaluation                                                            |                              | 17                     |  |  |  |
| Total cost of requested studies                                                 |                              | 103                    |  |  |  |

<sup>\*</sup>Primarily conducted in U.S. or Europe.

\*\* Primarily conducted in India

\*\*\* Source: Bayer

Table 6 : Incurred and Estimated Cost for Bt Eggplant

| Allergenicity/toxicity     | U.S.\$s |  |  |
|----------------------------|---------|--|--|
| Estimated                  | 33,333  |  |  |
| Agronomic trials completed |         |  |  |
| Contained trial 1998/9     | 2,222   |  |  |
| Contained 1999/2000        | 2,222   |  |  |
| Contained 2000/1           | 2,222   |  |  |
| Multilocation (5) in 2003  | 2,778   |  |  |
| Agronomic trials needed    |         |  |  |
| Multilocation (10) in 2004 | 5,556   |  |  |
| Multilocation (10) in 2005 | 5,556   |  |  |
|                            |         |  |  |
|                            | 53,889  |  |  |

Source: IARI Scientists December 2003.

 Table 7: Estimates of Full Cost of Meeting Regulations in Future

| Type of Crop                             | Event approved in                            | Event approved | Estimated Costs of         |
|------------------------------------------|----------------------------------------------|----------------|----------------------------|
| (example)                                | U.S., Europe, Canada,                        | in India       | Meeting Regulations        |
|                                          | Australia, or Japan                          |                |                            |
| Food or non-food crop (MMB cotton)       | Yes                                          | Yes            | \$100,000                  |
| Non-Food Crop<br>(cotton)                | Yes                                          | No             | \$500,000 - 1,000,000      |
| Food Crop (maize)                        | Yes                                          | No             | \$500,000 - 1,500,000      |
| Non-Food Crop (jute )                    | No                                           | No             | \$1,000,000 -<br>1,500,000 |
| Food Crop (rice)                         | No                                           | No             | \$1,500,000-<br>2,000,000  |
| Food crop – possible exports (vegetable) | No & have to seek approval in export markets | No             | \$4,000,000                |

Source: Survey of private firms by authors.

**Table 8: Area Planted with Bt Cotton India (acres)** 

|                                          | 2000/2001 | 2001/2002 | 2002/2003 | 2003/2004 | 2004/2005 |
|------------------------------------------|-----------|-----------|-----------|-----------|-----------|
| NB 151 F <sub>1</sub> and F <sub>2</sub> | 200       | 6,000     | 100,000   | 600,000   | 2,000,000 |
| MMB                                      |           |           | 100,000   | 200,000   | 800,000   |
| Rasi                                     |           |           |           |           | 200,000   |
| Total Bt Cotton                          |           |           | 200,000   | 800,000   | 3,000,000 |

Table 9: Differences between Bt and non Bt variety: All in Rs/acre (except yield which is kgs/acre)

|                                     | Qaim (2003)                                      | Bambawale et.al (2004) | Bennett et. al (2004) | Naik et. al (2005)                                             | Sahai &<br>Rehman<br>(2004) | Bennett et. al (2004) | Sahai &<br>Rehman<br>(2004) |
|-------------------------------------|--------------------------------------------------|------------------------|-----------------------|----------------------------------------------------------------|-----------------------------|-----------------------|-----------------------------|
| Year                                | 2001                                             | 2002                   | 2002                  | 2002                                                           | 2002                        | 2003                  | 2003                        |
| Sample<br>Size (#<br>of<br>Growers) | 157                                              | N. A.                  | 2709                  | 341                                                            | 136                         | 787                   | 136                         |
| States                              | Maharashtra,<br>Madhya<br>Pradesh,<br>Tamil Nadu | Maharashtra            |                       | Maharashtra,<br>Karnataka,<br>Andhra<br>Pradesh,<br>Tamil Nadu | Andhra<br>Pradesh           | Maharashtra           | Andhra<br>Pradesh           |
| Controls                            | Yes                                              | Yes                    | Yes                   | No                                                             | No                          | Yes                   | No                          |
| Seed +<br>Pesticide<br>Cost         | 651.00                                           | 839.68                 | 301.21                | 213                                                            |                             | 46.15                 |                             |
| Total<br>Cost                       | 1159.00                                          | 940.89                 | -                     | 1217                                                           | 983.00                      | -                     | 950.00                      |
| Yield (kgs)                         | 283.00                                           | 214.98                 | 275.30                | 168                                                            | -70.00                      | 352.23                | 0.00                        |
| Revenue                             | 5573.00                                          | 4948.99                | 5474.49               | 3378                                                           | -2425.00                    | 8809.72               | 0.00                        |
| Returns                             | 4414.00                                          | 4010.53                | 5178.54               | 2161                                                           | -3408.00                    | 8755.06               | -950.00                     |

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