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The cost of biosafety regulations: the Indian experience

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Abstract

This paper presents the costs incurred and estimated by firms and government research institutes in India to obtain regulatory approval of genetically modified (GM) crops, specifically Bt cotton. The direct costs include the costs of research and laboratory trials needed to fulfill information requests by the regulators and also the government's costs of the bureaucracy for implementing the regulatory rules. The indirect costs or opportunity costs are farmers' foregone incomes and the biotech industry's foregone profits if regulation prevented the sale of safe and profitable technology. After describing the Indian regulatory system, we describe its impact on firms' cost of compliance. We then describe the spread of Bt cotton and its impact on the seed industry and farmers. The Bt cotton experience is used to analyze the impact of regulation on biotech research done by private firms, the structure of the seed industry, and farmers' welfare. We develop alternative policy scenarios that show that the indirect costs of regulation can be large. Regulatory costs must therefore be taken into account in designing regulation.

Keywords: transgenic crops, regulatory policies, costs of regulation, seed industry, farmers' welfare
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1. Introduction

The establishment of a transparent and credible biosafety regulatory framework is essential for the commercialization of biotechnology products. This is a task that confronts many developing countries. It involves the establishment of appropriate institutions, risk protocols, and legal structures. Regulation is not costless. The direct costs include the costs of research and laboratory trials needed to fulfill information requests by the regulators and also the cost of the administrative structure to

implement the regulation. The indirect costs or opportunity costs are benefits to farmers and consumers and profits to seed companies that are foregone if regulation prevents or delays them from getting access to safe and profitable technology. Indirect costs could also arise when regulation alters market structure because of entry barriers.

Specific apprehensions that are commonly voiced usually have to do with the indirect costs of regulation. A primary concern is that biotech regulations could make it very expensive and time consuming for companies and research institutes to commercialize genetically modified (GM) products, reducing their incentives to do further research and transfer technology. This could be a serious issue because few of the GM crops that have been commercialized for the developed countries are directly suited to developing countries. Yet another possible concern with regulation is that it could serve as a barrier to the adoption of GM crop varieties by small farms that are unable to afford the increased prices of the varieties due to the costs of regulatory compliance and the non-competitive market structures that result from it. As a result, farmers could fail to appropriate as much gains from biotech applications as they could have from more competitive market structures.

In this paper, we focus on these costs of regulation as exemplified by the Indian experience. Within India, there has been a vigorous debate on the design and implementation of biosafety regulations. However, this discussion has been conducted without an analysis of regulatory costs. It is important for farmers, consumers, government policy makers, and regulators to have some idea of the costs and impacts of these regulations. This will help them to make better decisions about how the current system could be made more efficient, which new regulations should be implemented, and how much to invest in enforcement of regulations. We also expect that, as studies of this nature are carried out for different countries, it would be possible through comparison to benchmark efficient regulatory systems.

2. Biosafety regulation in India

The biosafety regulatory system in India has evolved in response to breakthroughs in biological science and the concerns of Indian citizens, scientists, and government agencies about the biotechnology products that were being produced through the new biology. The goal of the Indian regulatory system is to ensure that GM crops pose no major risk to food safety, environmental safety, and agricultural production, and that there are no adverse economic impacts on farmers. This last goal is one that many developed countries do not include in their regulatory systems.

Indian regulatory institutions have three layers. At the bottom, the institutional biosafety committees (IBSCs) must be established in any institute using recombinant DNA in their research. They contain scientists from the institute and also a member from the Department of Biotechnology (DBT), which is part of the federal Ministry of Science. There are 230 plus IBSCs 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 large-scale field trials. It requests food safety, environmental impact, 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. The committee members are primarily bureaucrats representing different ministries and they draw on the scientific expertise of each ministry.

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) are shown in column 1 of table 1. Columns 2 and 3 show 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 the 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.[1]

Table 1. Regulation of research and commercialization of GM plants

Steps in GM plant commercialization process	**Data generated at this step** (more can be requested if needed)	**Who approves**
1. Lab & greenhouse experiments	• Rationale for development of GM plant • Cloning strategy • Characteristics of expression vectors, inserted genes, promoters • 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	IBSC risk category I & II RCGM risk category III
2. Contained open field trials & generation of biosafety data	• Germination rates & phenotypic characteristics • Studies of gene flow, invasiveness, weed formation • Implications of outcrossing • Susceptibility to diseases & pests, • Toxicity & allergenicity of plants/fruits/seeds • Food/feed safety evaluation in animals	IBSC/RCGM
3. Multi-location trials	• Agronomic advantage	RCGM/GEAC
4. Large-scale field trials	• Agronomic advantage	GEAC
5. Environmental, food & agronomic approval		GEAC
6. Variety registration*	• Agronomic advantage	ICAR, National and State Seed Quality control agencies
7. Approval for commercial production		GEAC

Source: Department of Biotechnology, unpublished material (2003)

[1] 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 Mahyco-Monsanto, took 2 years. The non-Bt counterpart RCH2 is a notified hybrid and had already gone through varietal testing. Mr. M. G. Ramaswami, the Managing Director of Rasi believes that the approval process for non-notified hybrids could take 3 years (RAO, 2005).

3. Financial costs of compliance with regulations

So far only two events – the Bt gene Cry1Ac in cotton and the genes for hybrid mustard – have reached the final regulatory layer of the GEAC. In addition, Bt eggplant and high protein potato have been tested extensively. Our cost estimates are based on these crops. In addition, some private companies gave us their best estimates of what they think it will cost to bring new products to market in the near future.

The first event to be approved (in 2002) was a Bt gene from Monsanto that was inserted in three cotton hybrid cultivars belonging to the Indian seed company Mahyco. This event was commercialized by a joint venture called Mahyco-Monsanto-Biotech (MMB), which is equally owned by the two partners. Table 2 is based on a series of interviews with Monsanto in India in late 2002 and 2003. MMB's permission for commercializing Bt cotton is for only three years at which time it has to be reviewed again, and also there are refuge requirements (20 percent of fields are supposed to be non-Bt varieties) that have to be met. Thus, there are post-approval regulatory costs as well as pre-approval costs.

The total pre-approval cost is between US $1.6 million and $1.8 million (depending on whether the 400 field trials in 2001/2 were really necessary or not), which is a substantial sum. Subsequent industrial crops could be less expensive because some of the tests that Monsanto did in the US can now be done in India such as the brown Norway rat allergenicity test ($35,000 in India instead of $150,000 according to J. Carpenter, personal communication, 2003). However, more data will be required for food crops, and new requirements are being added that increase the time and cost of meeting the regulatory requirements. All crops will have to go through 2 years of multi-location field trials in the all-India coordinated trials of the Indian Council of Agricultural Research (ICAR) at $1,000/site. These trials were not required originally, and ICAR did not charge Mahyco-Monsanto when they were required for the first Bt cotton event (thus, they are not included in table 2). Monsanto expects that in the future, GM events such as Bt maize (primarily an animal feed in India) would cost about $500,000 in regulatory costs, excluding salaries, to bring to market. For comparison, the Monsanto India government affairs officer said in December 2003 that only about $200,000 was required to meet the regulatory costs of bringing a new pesticide to market in India.

The cost figures 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 today, they belong to Bayer

CropScience. 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.

Table 2. Mahyco/Monsanto costs in India for Bt cotton (US$)

Study	Number	Cost/study	Total	In house?
Pre-approval				
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	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	?
IPM package	2	10,000	20,000	No
Salaries & office expense			125,000	
Total post approval			195,000	

Source: Monsanto India (personal communication, 2003)

The genes that were used to produce hybrid mustard have been used in canola to produce hybrid canola cultivars in Canada and the US. They have cleared the biosafety regulations in those countries. However, the use of these genes in mustard has not been

approved for commercialization 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 (TIMES OF INDIA, 2002). In addition to this amount, that was spent primarily on food safety, environmental, and agronomic research in India, between US $3 million and $4 million was spent in the US and Europe to ensure that it met international food safety and environmental requirements. These costs are shown in the top section of table 3. After spending between $4 million and $5 million on meeting regulatory requirements in India and elsewhere, GEAC required additional studies, which are listed with their estimated costs in the bottom section of table 3. Because of the continued costs, the uncertainty about whether this product would ever be approved, and the potentially small 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.

Table 3. Regulatory cost of developing a novel gene in India (hybrid mustard)

	Studies	**Costs (US$ thousands)**
Product characterization [a]	Unique identifier, reference material, validations, etc.	1,500
Environmental safety studies [b]	Gene flow, impact on key species of insects, etc.	500 -1,000
Food safety studies [a]	Allergenicity, toxicology	1,500
Nutritional assessment [b]		500
Total		4,000-5,000
Requested studies in India		**Estimated costs (US$ thousands)**
Environmental safety	Pollen flow (8 locations)	9
Food safety	Feed safety (goat)	22
	Feed safety (cow)	22
Food safety	Immunological studies in BNR	33
Agronomic evaluation	Agronomic evaluation ICAR	17
Total cost of requested studies		103

[a] Primarily conducted in US or Europe.
[b] Primarily conducted in India

Source: Bayer CropScience (personal communication, 2003)

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 commer-

cialization efforts. They felt that the years lost in the regulatory process were 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 in 1996, and developed a Bt eggplant using the Cry1Ab gene that controls 70 percent of the fruit borer attack. IARI 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 environmental and field trials so far has been about $10,000 (see table 4). If they are required to do two more years of field trials in 10 locations, this would add another $11,000. IARC had also asked for estimates of the cost of meeting the food safety requirements in 2003. They received 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 million to 1.5 million ($22,000 to 33,000) for everything needed (A. Kumar, personal communication, 2003). Thus, with this food safety data and two more years of field trials the total cost would come to around $53,500. This is a large sum for the Indian research system, but IARI has grant money to cover it.

Table 4. Incurred and estimated cost for Bt eggplant

Component	US$
Estimated cost for food safety tests (allergenicity/toxicity)	33,000
Agronomic trials completed	
Contained trial 1998/9	2,222
Contained 1999/2000	2,222
Contained 2000/1	2,222
Multi-location (5) in 2003	2,778
Agronomic trials needed	
Multi-location (10) in 2004	5,556
Multi-location (10) in 2005	5,556
Total	53,556

Source: A. Kumar (personal communication, 2003)

IARI's problem is delays in obtaining regulatory approval and the time that it takes scientists to shepherd their applications through the regulatory process. For example, they had Bt eggplant ready for multi-location testing in 10 places in 2001/02 but were not granted permission. The earliest they could hope to get permission was for the 2004/05 crop year – three years later. The testing of new Bt rice varieties from IARI

had already been delayed by two years in December 2003 due to slow responses from the regulatory committees at the central government and state levels (S. Raina, personal communication, 2003).

When a project has the full support of the DBT 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 DBT as an example of the consumer benefits from GM technology. The lead scientists on this project, N. Chakraborty (personal communication, 2004), reported that their costs of meeting regulatory requirements have been negligible – some costs of the allergenicity/toxicity tests 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 have 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 has already been approved by regulators in India, whether it has been approved elsewhere (e.g., in the US or Europe), and whether the tests could all be completed in India or not. In addition, there may be differences because some companies may wish to do more research than is required by Indian regulators; 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 5. 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 is 15 in the first season and 40 in the next two seasons, and each ICAR trial costs about $1,000, the total 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 and Pineland variety that has been in commercial use in the US. Much basic information and the results of many field trials and toxicity/allergenicity tests are available from the US and elsewhere. US and European companies now spend from $5 million 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 additional tests are required. These new tests at least take into account differences in the way the crop is consumed, 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 "Terminator" genes which are prohibited in India).

Table 5. Estimates of full cost of meeting regulations in future

Type of crop (example)	Event approved in US, Europe, Canada, Australia, or Japan	Event approved in India	Estimated costs of meeting regulations
Food or non-food crop (MMB cotton)	Yes	Yes	$100,000
Non-food crop (cotton)	Yes	No	$500,000-1,000,000
Food crop (maize)	Yes	No	$500,000-1,500,000
Non-food crop (jute)	No	No	$1,000,000-1,500,000
Food crop (rice)	No	No	$1,500,000-2,000,000
Food crop – possible exports (vegetable)	No & have to seek approval in export markets	No	$4,000,000

Source: survey of private firms by authors

No GM 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 US, Argentina, and South Africa. These costs were estimated in the $500,000 to $1 million 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 cannot 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 100,000 or more 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 US 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 exports. There is also the risk that seeds will be transported to neighboring countries for growing. To

avoid blame for not anticipating on that impact, Bayer 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 US or Europe are the reason for the $4,000,000 estimate in the case of GM vegetables.

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 programs are managed in the public sector. Public sector research programs 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 those reported by public sector scientists, as a substantial part of their costs is not borne by their research program. In the future we would expect the gap between private and public sector compliance costs to narrow. As public sector organizations move 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 the 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 MMB'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).

4. The spread of Bt cotton

As noted earlier, the GEAC approved commercialization of the Monsanto Bt gene in three Mahyco cotton hybrids in 2002. Mahyco sold enough seed to cover 80,000 to 100,000 acres in the 2002/03 season (see table 6). In 2003/04, Monsanto India estimated the level of adoption of Mahyco hybrids at 213,000 acres. In 2004, the GEAC also permitted the commercialization of Monsanto´s Cry1Ac Bt gene in a cotton cultivar belonging to Rasi Seeds. The combined sales of Mahyco and Rasi Bt cotton seeds were estimated by Monsanto India to be sufficient to cover more than one million acres in 2004/05.

Table 6. Area planted with Bt cotton India (acres)

	2000/01	2001/02	2002/03	2003/04	2004/05
Mahyco			100,000	200,000	800,000
Rasi					200,000
NB-151 F1 and F2	200	6,000	100,000	600,000	2,000,000
Total Bt cotton			200,000	800,000	3,000,000
Total cotton Area	21,242,000	21,489,000	18,772,000	19,760,000	20,995,000

Source: seed industry estimates; SINGH (2004) for total cotton area

Although until 2004, the Mahyco hybrids were the only officially approved Bt cotton cultivars, farmers in the western Indian state of Gujarat and increasingly elsewhere have also had the choice of planting NB-151 introduced by NavBharat company. NB-151 was developed by NavBharat using a US variety, which contained Monsanto's Cry1Ac Bt gene, as the male parent and the female line of the popular Gujarat hybrid H-8 as the female parent. It was approved by the Gujarat government's variety testing system as a bollworm-resistant cotton hybrid and first sold to farmers in 2000. However, it was not submitted to the biosafety regulatory authorities in New Delhi for approval. The violation was discovered in 2001 on a complaint from Mahyco. The GEAC ordered the Gujarat government to destroy all of the NB-151 cotton that was being grown and launched a criminal case against NavBharat for violating the Environmental Protection Act of 1986. For a number of reasons – primarily opposition by farmer groups – the Gujarat government did not destroy the crop. However, they did force NavBharat to stop selling NB-151.

NB-151 was grown on between 6,000 and 12,000 acres when the biosafety violation was discovered in 2001. NavBharat had to stop selling it after 2001, but smaller seed companies, former contract seed producers for NavBharat, and large farmers had the inbred lines needed to produce this seed, and so they kept producing the hybrid. In addition many farmers saved their NB-151 seeds and planted the second generation of the hybrid (the F2 generation). Most experts expect that the decline in yield due to planting the F2 hybrids would only be about 5 to 10 percent. Officials of the Seed Association of India estimated in December 2003 that about 400,000 acres of F2s were planted and the total Bt cotton acreage was between 700,000 to one million acres in 2003/04. Of this, 80 to 90 percent was covered with NB-151 F1 or F2, and 10 to 20 percent with Mahyco hybrids. Recently, industry officials estimated that in 2004/05 about 2 million acres of NB-151 and its relatives were planted. The Gujarat Seed Producers Association estimated that in 2003/04 there were about 600,000 acres of Bt cotton in Gujarat alone. Gujarat Agriculture Department officials said that there were 42,000 acres of Mahyco hybrids, 200,000 of NB-151 F1, and 175,000 to 200,000 acres

of NB-151 F2 seeds (GUJARAT SAMACHAR, 2003), which is close to the industry estimates.

5. Impact of Bt cotton on the seed industry

The spread of Bt cotton (of both the approved and unapproved hybrids) has had a major impact on the seed industry in India. In Gujarat, where Bt cotton is most popular, it has nearly put the former market leader – Vikram Seeds – out of business. It was the market leader with 80 percent of cotton hybrid market in 1998. After 2000, its market share fell dramatically, largely due to the introduction of Bt cotton from NavBharat. In 1998, Vikram Seeds sold 350,000 packets of hybrid cotton seed. In 2003, this was down to 25,000 packets (G.I. Patel, personal communication, 2004). Cotton seed used to be a major line of business for the Gujarat State Seed Corporation (GSSC), but their sales and profitability has been gravely affected by Bt cotton (R.C. Chowdhury, personal communication, 2004).

NavBharat started to profit from NB-151 in 2001. Then it was forced to stop selling the seed when the government found out that it was genetically modified. NavBharat's contract seed growers, who continued to produce and sell the seed, have been the main seed companies that benefited of this combination of new technology and regulations. The Gujarat government has not tried very hard to close down these operations. One of the few seed companies that was being prosecuted reported that the prosecution had improved their sales because it assured farmers that they were selling the genuine NB-151. As NB-151 diffuses to other states, its success threaten the market share not just Mahyco-Monsanto's legal Bt cotton but of all cotton hybrid producers. 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.

6. Impact of Bt cotton and regulations on farmers' income

Based on field trials of Mahyco Bt hybrids in 2001/02, QAIM and ZILBERMAN (2003) found large gains in yield of fiber and reductions in pesticide use. It has been argued that their findings should not be taken as representative of gains from Bt cotton, because they are based on data from only one season (SAHAI, 2003). However, similar findings were reported for the 2002/03 season (when pest pressure was reportedly lower) by BAMBAWALE et al. (2004), who analyzed farmers' field trials in the state of Maharashtra depending on the check variety and pest management practices. BAMBAWALE et al. (2004) reported yield increases from Bt cotton ranging from 29 to

75 percent, and profit increases from 30 to 54 percent. BENNETT et al. (2004), who used farm data from Maharashtra, found that Bt cotton reduced pesticide use, but the cost savings from reducing pesticide use was offset by increases in seed costs. The main economic benefit has been to increase output per unit of land between 45 to 63 percent, which has led to a large increase in net income. A large study of more than 3,000 farmers in six states (including Gujarat) for the crop year 2002/03 found that MMB's Bt cotton increased yields by 29 percent, reduced pesticide use by 60 percent, and increased farmers' net profits by 78 percent. The study, financed by MMB, also reported that Bt cotton had received an 8 percent price premium over conventional hybrids (MMB, 2004).

Some unpublished reports from the state of Andhra Pradesh found that the MMB hybrids did not yield as much as non-Bt hybrids (KRISHNAKUMAR, 2003). SAHAI and REHMAN (2004) report a similar result from a survey of farmers in four districts of Andhra Pradesh in 2002/03 and 2003/04. According to their findings, in spite of pesticide savings, non-Bt cotton outperformed Bt cotton decisively in 2002/03 and marginally in 2003/04. They attribute the better performance of Bt varieties in 2003/04 due to the diffusion of NB-151 and its variants. The rapid adoption of Bt cotton, however, suggests that the findings of its poor performance are not representative.

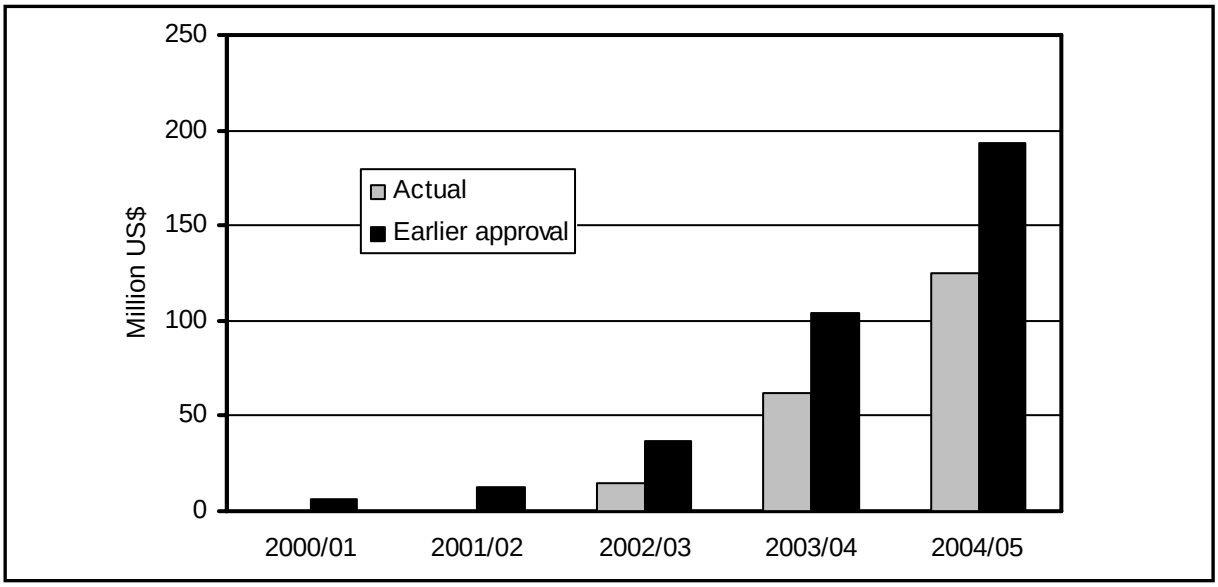
Newspaper reports (JAIN, 2001; JAYARAMAN, 2001), which seem to originate with the seed industry, claim that farmers growing NB-151 earned more money because of higher yields, reductions in pesticide use, and their ability to grow an extra crop after cotton, because the duration of the Bt varieties is much less than older hybrids. To get these benefits farmers pay as much as Rs. 1,000 per ha more for NB-151 F1 seeds, or much less if they use F2 seeds with a likely quality decline.

The social benefits are difficult to measure accurately at this early stage in the adoption process. To calculate a rough measure of the benefits, we have multiplied the area under MMB Bt cotton times the net income of farmers as estimated by QAIM and ZILBERMAN (2003) and QAIM (2003). For the area under NB-151 we assumed the same yield and cost improvements that were measured by QAIM (2003), but adjusted the price of seed from the Rs. 1,600 per packet charged by Mahyco down to the levels reportedly being charged for NB-151, which was Rs. 900 per packet. Figure 1 shows the dramatic benefits from Bt. Already in 2003/04 farmers increased their net income by about $50 million, and by approximately $120 million in 2004/05.

Figure 1 also shows what the farmers' benefits might have looked like if the MMB hybrids had been approved two years earlier. This calculation is based on projections of adoption of Bt cotton from the Seed Association of India. The difference between

the two bars is the indirect cost of regulations in terms of income that farmers did not earn. That amount grew from $6 million in 2000/01 to almost $70 million in 2004/05.

Figure 1. Benefits to farmers using approved and unapproved Bt cotton



Note: 'Actual' refers to estimated farmer benefits from Bt cotton. 'Earlier approval' refers to what estimated farmer benefits would have been if the regulators had approved the release of Bt cotton in 2000 instead of 2002.

Source: authors' calculations

7. Impact of regulations on private research

Regulations can provide both incentives and disincentives to do research. The incentive effect of the cost of regulation in the Indian institutional context is that it essentially provides intellectual property rights (IPRs) on specific transgenic events for those companies or research institutes that can obtain approval. The disincentive effect is that regulations increase the cost of bringing a new product to market. If firms have to pay $1 million to get something through the regulatory process, they will only transfer technology or invest in research on a technology that is going to have substantial payoffs. In addition, this $1 million is not available for research. Since only the largest Indian seed and biotech firms have research budgets over a million dollars, and the largest seed firms in India only have annual sales of about $30 million to $40 million, $1 million is a lot to pay for approval of one gene.

Based on interviews with a large number of seed/biotech firms in 2003 and 2004, the regulatory climate has clearly induced private firms to shift research and technology transfer priorities away from rice and mustard toward cotton. Table 5 indicates that firms expect that the costs of obtaining regulatory approval of GM rice or any food

crop are going to be higher than the costs of getting approval for new GM cotton hybrids. As transgenic rice has not been approved for commercial cultivation elsewhere in the world, regulatory costs will be higher here. India is a center of bio-diversity for rice. So, there are special ecological concerns. These issues are not major concerns for cotton. These reasons add up to private firms estimating that it will cost perhaps a $1 million more to obtain regulatory approval for GM rice than for GM cotton (see table 5). In addition, rice is the most important food grain in India, and so regulators are going to be particularly careful about the food safety risks concerning GM rice. There is considerable uncertainty about if and when GM rice will ever receive approval.

As a result of these factors and similar factors in other countries in Asia, rice biotech research is declining in India. Private rice biotech programs in India reached a peak about 5 years ago and have been declining since then, largely due to decisions by the head offices of multinational corporations. In the late 1990s, Monsanto, Proagro (then owned by Aventis, now owned by Bayer), Syngenta, and Mahyco were all working on insect-resistant rice. Now, only Mahyco and two biotech start up companies – Meta-Helix and Avesthagen – are conducting research on GM rice. Monsanto stopped working on GM rice several years ago, when they decided to focus their worldwide research on maize, soybean, cotton, and wheat. Monsanto's biotech laboratory in Bangalore stopped its Bt rice work. 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. Bayer CropScience recently decided to stop working on GM rice worldwide and has stopped Proagro's GM rice program in India. Bayer continues to work on conventional hybrid rice.

The trend in rice biotech research by local companies is less clear. Mahyco continues to have a substantial biotech program on rice. Meta-Helix has the one rice research program that has grown in recent years. It was started in 2001 by scientists who were leading scientists in Monsanto's rice biotech programs in India and the US. It 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 and possibly transgenic rice. 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.

MMB and now Rasi are the only organizations that are legally allowed to sell the Bt gene for cotton in India. This gives it a monopoly until other insect-resistant genes are approved by GEAC. Mahyco is charging Rs. 1,600 for a 450 gram packet of Bt hybrid cotton seed, which is far higher than the price of conventional hybrid seeds which is

about Rs. 300-500 per packet. MMB has reportedly licensed the technology to at least 10 firms in India and is charging a one time fee of $100,000 to $200,000 plus a 70 percent royalty on sales (SHAH, 2003). Thus, despite high costs of regulation and the fact that most of the market is captured by unauthorized hybrids from NavBharat, by 2004 MMB could be making as much as $13 million in net income from seed sales and from the one time fees.

The current Bt technology is so clearly superior to the combination of local hybrids and pesticides, and the profits are high enough that every seed company that produces American type cotton seeds will have to have some type of Bt to stay competitive. As mentioned above, in Gujarat the cotton seed sales of Vikram Seed Co., that did have the largest market share, plunged to almost zero in three years due to the popularity of NB-151. In order to regain its market share, Vikram is licensing the Bt gene from Monsanto.

As a result private sector research on transgenic cotton is clearly 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, and Vikkis' Agrotech – have recently formed a consortium called Swarna Bharat Biotechnics Private Limited (SBBPL). This consortium 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.

8. Impact of policy alternatives on companies and farmers

To see how alternative policies would impact a private biotech firm's incentive to do research, we calculated financial internal rates of return (IRRs) to a private biotech firm assuming the profit formula that members of the Gujarat seed industry ascribed to MMB (SHAH, 2003) ($75,000 down payment and royalties amounting to 70 percent of sales) and the spread of Bt cotton and MMB's hybrids based on table 6. We assumed that benefits end in 2006, which minimizes the amount of extrapolation into the future

that we have to do, but also reduces the rates of return. We assumed that the costs of compliance were the main costs of bringing the product to market in India. It does not include costs of other research, which MMB had to do after transforming Mahyco's three hybrids. These costs were probably rather small and Monsanto and Mahyco could not provide the costs of that research. With these assumptions we find the biotech firm's internal rate of return to its investments in regulatory costs to be about 45 percent.

In addition to the above baseline estimate, we consider five hypothetical scenarios and the rate of return that would have been obtained in each of them. These are the following:

1. Suppose biosafety rules were rigorously enforced and there were less plantings of illegal Bt cotton; MMB would capture the NB-151 F1 market (about 50 percent of total NB-151 area).

2. This is the reverse of scenario 1. Suppose the government's enforcement policy continues to be lax and the illegal Bt seeds capture half of MMB's market.

3. Suppose the regulators had been speedy, and MMB had received the approvals for commercialization in 2000 instead of 2002.

4. Related to scenario 3, we ask here what if the costs of regulation and research would have been only $500,000 rather than the $2 million paid?

5. The last simulation looks at the combination of earlier adoption (i.e., commercialization in 2000) and stronger enforcement (i.e., MMB captures 50 percent of the market for illegal cotton seeds).

Table 7 shows the results of each of these scenarios. If the government more effectively enforced the ban on NB-151 and the biotech firm was able to capture the market for NB-151 F1 seeds, it would raise the biotech firm's rate of return from 45 to 56 percent (scenario 1). On the other hand, if we assume that there was less enforcement (scenario 2), and NavBharat captures half of MMB's markets, then the biotech firm's return to investments in technology transfer and research would be reduced to 41 percent. If MMB received approvals in 2000 rather than 2002, it would increase the rate of return to the firm's investment in regulation to 61 percent. Similarly, the rate of return is greater than 60 percent if the costs of regulation and research were only $500,000 rather than the $2 million. Finally, the combination of earlier adoption and stronger enforcement would substantially hike the rate of return to 74 percent.

So far we have only talked about the costs to seed and biotech companies. To assess the costs of regulations to farmers and consumers one would have to have data on: (i) how much more research private firms would do if regulatory costs were lower, (ii) how the increased research would affect society, (iii) what changes in government expenditures would be associated with the policies, and (iv) the impact of these changes on the social welfare of farmers and consumers through their impact on seed prices and the time of adoption. We do not have information on the first three issues, but we can make a rough estimate of the impact of changing seed prices and delaying adoption of Bt technology on farmer welfare. As mentioned above, several studies (QAIM, 2003; BAMBAWALE et al., 2004; and BENNETT et al., 2004) appear to agree that there was an increase of net income of about $60 per acre for farmers that adopted Bt cotton. So we can do a rough calculation of benefits by multiplying $60 per acre times the area of Bt cotton. In the last column of table 7 we indicate the change in benefits to farmers that would have taken place if policies had been changed. It summarizes the changes in benefits to farmers by simply adding up the undiscounted changes in benefits to farmers during the years 2000 through 2004.

Table 7. Returns to private research under different policy scenarios

Scenario	First year of approval	Research/ regulatory costs	Enforcement of biosafety regulation (i.e., enforcing ban on illegal Bt cotton)	Private biotech firm's IRR (percent)	Short run impact of policy change on farmers [a]
Baseline	2002	$2 million	Current level	45	
Scenario 1	2002	$2 million	MMB captures half of NB-151 market	56	-$17 million
Scenario 2	2002	$2 million	NB-151 captures half of MMB market	41	$8 million
Scenario 3	2000	$2 million	Current level	61	$360 million
Scenario 4	2002	$500,000	Current level	62	0
Scenario 5	2000	$2 million	MMB captures half of NB-151 market	74	$342 million

[a] This impact is calculated as the sum of the benefit changes for 2000-2004 over the baseline scenario.

Note: The calculations assume that costs are spread evenly across the years 1996 until approval; the biotech firm captures the down payments from licensees plus 70 percent of the sales price of seeds to farmers.

Source: authors' calculations

The changes in enforcement of the biosafety regulations have dramatically different impacts on farmers. In policy scenario 1, if the Ministry of Environment working with the States were able to reduce the use of NB-151 effectively and MMB hybrids capture part of that market, farmers' benefits would decline. Instead of paying Rs. 900 ($20)

per packet of NB-151 seed as they do now, they would have to pay Rs. 1,600 ($36) per packet. This puts a substantial dent in their profits from Bt cotton. If MMB's hybrids are not as productive as NB-151, enforcement would reduce the benefits even further. If the governments decided not to bother with enforcement and allowed NavBharat back into the cotton seed business, they might be able to capture part of MMB's market (policy scenario 2). If they captured half of it, MMB's profits suffer, but farmers' incomes improve because they are getting a similar product at a lower price. If the government can speed up the regulatory approval process by just two years, and keep the current enforcement system (policy scenario 3) farmers would capture major benefits from the change – over $300 million up to 2004. Policy scenario 4, which improves the efficiency of the regulatory system by reducing the cost of regulation, increases the rate of return to research, but does not affect the short term benefits to farmers. Finally in scenario 5 the government speeds up the approval process by 2 years and improves enforcement. This leads to the highest increase in MMB's rate of return, but, because it forces some farmers to switch from less expensive NavBharat hybrids to MMB hybrids, farmers get lower returns than in scenario 3.

The highest rates of returns to MMB and thus presumably the most incentive for future research or technology transfer of GM crops is the combination of more efficient regulations and more enforcement of the regulations. However, there is a price to pay for the stricter enforcement – farmers earn less than they would have. Three other scenarios provide MMB with rates of return over 50 percent – scenarios 1, 3, and 4. However, they have very different impacts on the short run benefits for farmers. Scenario 3 is clearly superior for the farmers and increases incentives for research by MMB, which indicates the importance of a faster regulatory system for both farmers and companies.

9. Conclusions

The biosafety regulatory system in India is one of the oldest in developing countries, but it is still evolving. It has approved the commercial production of several Bt cotton hybrids and is considering the applications for trials of a wide variety of GM crops. We were able to obtain estimates of the direct costs incurred by firms and government research institutes to obtain regulatory approval of GM crops. The two firms that first applied for commercialization of a GM crop were willing to provide us with data on their costs. The one firm that has obtained permission to sell GM seed reports to have spent almost $2 million, while the other firm reports about $4 million. In contrast, no government agencies have yet commercialized a GM crop, but some are in multi-location testing. The government scientists do not expect that the financial cost of meeting regulatory requirements will be more than about $50,000 to $60,000 per event, but the years of delays are probably a larger concern than cost. The low cost is

because government research programs do not separately budget for salaries (as they are already paid for) and much of the biosafety testing is done at other public sector institutes at nominal cost.

Our review of the spread of GM crops in India and the impact of the spread of technology shows that illegal GM Bt cotton varieties are spreading more rapidly than the MMB hybrids. In total about 800,000 acres of Bt cotton were planted in 2003/04 and that figure at least tripled in 2004/05. Because of the rapid adoption of Bt cotton, illegal and legal GM varieties have increased farmers' welfare substantially. The earlier approval of this product would have improved farmer income even more.

Given the regulatory costs, the private sector will only look at developing GM traits for hybrids that have large markets. Cotton is a crop that meets this requirement, and the impact of Bt cotton has already changed the structure of the cotton seed industry of the country – greatly increasing the possibilities for profits and throwing the whole industry into turmoil. As we saw, the first entrant has reaped impressive returns that would have been even more but for the mushrooming of illegal Bt. Each of the larger private firms is now pursuing a "Bt strategy". The smaller firms have to ally with a larger partner for technical collaboration and passage through the regulatory system. While cotton biotech research is on the rise, biotech research by the private sector on other crops like rice and mustard seems to be declining. This appears to be the result of high returns to the pioneers in Bt cotton in contrast to the lack of opportunities to make money on GM food crops.

The review of the direct and indirect costs of the biosafety regulatory system shows that these costs are substantial. Reducing the years required for approval, and the costs of related research, would have a large positive income impact on seed companies, while improving the speed of approval would increase seed company's income and dramatically increase farmers' incomes in the case of products that win wide acceptance from them.

The major implication for the government is that investing more resources in the regulatory system so that it could process these requests more rapidly would have major payoffs for farmers and research companies. In addition, it suggests that regulators must weigh the benefits of regulatory requirements against the direct and indirect costs. Other policy alternatives such as strengthening the enforcement of regulations, which in effect strengthens IPRs on innovations, has the problem that – while it does increase the benefits to the firms and their incentive to do research – it could reduce farmers' income, at least in the short run. In contrast, weaker enforcement of regulations such as legalizing NB-151, which weakens IPRs, would

help farmers and small companies such as NavBharat but would reduce incentives for biotech research.

One sensible policy reform would be to eliminate the requirement of two or three seasons of biosafety field trials for new GM varieties made from transgenic events that have already been approved. Eliminating the biosafety field trials on already approved transgenic events could reduce seed companies' costs by $50,000 to $100,000 per variety. Seed companies would be able to start selling the new varieties a year or two earlier and thus would gain some profits from sales. Farmers would gain producer surplus from earlier adoption of cost-reducing technology. What would be lost by this policy change? It is supposed to protect farmers from GM varieties that have no agronomic or economic benefits. However, the new seed law already requires evidence from several years of trials that all new varieties prove better than current ones. It is not clear how much more trials would protect farmers. Furthermore, if it is a poor variety, farmers will not adopt it. Unless he or she has a lot of resources, farmers typically try new varieties on only a part of their fields. If it has agronomic problems, they are not likely to plant it again the next year. Thus any losses that occur would be by more wealthy farmers who adopt first and can afford to adopt on more of their land.

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