Costs and enforcement of biosafety regulations in India and China

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Abstract: This paper examines the cost of compliance and the enforcement of biosafety regulations in China. Costs were higher in India, and enforcement of regulations was more effective in China. Lower costs in China may be because national companies, government research institutes and foreign firms were all pressing for less costly regulation, while in India there was less pressure by these groups to reduce regulatory costs. Enforcement of regulations was less effective in India because farmers and small seed firms have more influence on policy makers and local agricultural departments are supposed to be enforcing decision from the environmental ministry.

Keywords: biosafety regulation; biotechnology; enforcement; compliance costs; India; China.

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1 Introduction

Most proponents and opponents of transgenic crops (also known as genetically modified or GM) agree on the need for biosafety regulations to minimise the risk of food safety problems, environmental damage, and agricultural problems. Many scholars, however, argue that the biosafety regulatory systems have become an important constraint to the spread of safe transgenic crops that could increase agricultural productivity and improve the environment in developing countries (Cohen and Paarlberg, 2004; Kent, 2004). In addition to criticism from scholars, current biosafety regulations on transgenic crops in developing countries are under attack from many interest groups. Private biotech companies think the regulations are too expensive, too time consuming, too arbitrary, not science based, and poorly enforced. Non Government Organisations (NGOs) who are sceptical about biotechnology argue that current regulations on transgenic crops are inadequate because they do not require enough research on risks, the regulators are too easily influenced by the biotech companies, and the regulators have little capacity to enforce their regulations.

The first objective of this paper is to examine the evidence regarding two components of this controversy about biosafety regulations: first, the cost of complying with biosafety regulations and second, the enforcement of biosafety regulations. India and China have two of the most well developed regulatory systems in developing countries, but as we shall see, the costs of complying with biosafety regulations are much higher for private firms in India than in China, and China has had more success in regulating the spread of unapproved genes and transgenic varieties than India. The second objective of this paper is to explain why costs and enforcement are so different in these countries.

The paper is organised as follows. Section 2 provides an overview of the activities of the regulatory systems and the spread of transgenic crops. Section 3 describes a simple political economy model of induced institutional reform which can help explain who pays the costs and what rules are enforced. Section 4 describes the structures of the biosafety regulatory systems of the two countries. Section 5 looks at the costs of compliance in both countries and discusses some of the reasons for these differences. Section 6 discusses the problems of enforcing regulations and the ways in which the governments are attempting to deal with these problems. The concluding section summarises the results and draws some lessons from the experience of these countries.

2 Activities of the regulatory system and spread of regulated transgenic crops

2.1 India

In India, the biosafety regulatory system has tested GM cotton, rice, mustard, maize, potatoes, eggplant, tomatoes, pigeon pea and cabbage, but the government has not revealed the precise numbers of field trials. By mid 2003, at least 34 events (genes introduced into a specific background variety of plants) from the private sector were being tested in the nine crops just listed (Sharma et al., 2003). Most of the genes were *Bacillus thuringiensis* (Bt) genes for pesticide resistance, followed by some genes for herbicide tolerance; one set of genes for improving yield through better hybrids and finally, some genes for disease resistance. GM rice varieties for improved nutrition had not started trials in 2003 but are now at the early stages of field trials. So far the only two crops which have been put forward for commercialisation are Bt cotton and hybrid mustard.

The transgenic hybrid mustard programme 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 2001, Bayer, the German chemical company, purchased Aventis. The genes that were used to produce hybrid mustard have been used in canola to produce hybrid canola cultivars in Canada and the USA. They started working towards biosafety approval in the mid 1990s. Government regulators asked for another set of trials in 2003, but Bayer officials in India decided that they would not continue trying to commercialise hybrid mustard in India.

Monsanto's Bt gene in cotton is the only one that has been approved for cultivation. Monsanto formed a joint venture with Maharashtra Hybrids Company (MAHYCO) called Monsanto MAHYCO Biotechnology (MMB) to commercialise transgenic cotton. Three varieties of Bt cotton from MAHYCO were approved for cultivation in 2002 in central and southern India, and one Bt cotton variety from Rasi Seed Company was approved in 2004, also for south India. In 2005, ten more Bt cotton varieties of several different companies were approved. The approved GM cotton has spread quite rapidly in India – in 2004 it was planted on about 400,000 ha (Monsanto, 2004). The Bt cotton in India has reduced pesticide use, but the cost savings from reducing pesticide use have been offset by increases in seed costs. The main economic benefit has been to increase output per unit of land of between 45–63%, which has led to a large increase in net income (Bennett et al., 2004). Industry sources report that 800,000 ha of illegal Bt cotton was grown in 2004.

2.2 China

More money has been invested in biotechnology research and technology transfer in China than in India (Huang et al., 2002), which accounts, in part, for the fact that there have been many more field trials of transgenic crops in China. In China, from 1997 to July 2003, the government received 1044 applications for field trials, environmental release, pre-production, or commercialisation. Seven hundred and seventy seven of the applications were approved, covering more than 60 crops and several animals, as well as numerous microorganisms. The GM crops that have been approved for commercial cultivation are cotton, tomatoes, sweet and chili peppers, and petunias. A total of 30 transgenic cotton varieties by 2003, and more than 140 transgenic cotton varieties by 2004 that use Chinese Academy of Agricultural Sciences' (CAAS) Bt or the stacked Bt and Cowpea Trypsin Inhibitor (CpTi) or Monsanto's Bt have been approved for 14 Provinces. Most of these varieties use the CAAS gene. Only six transgenic cotton varieties in nine provinces using Monsanto's Bt had regulatory approval for commercial production in 2003. In five provinces, varieties with Monsanto Bt were approved in 2004. No new crops have been approved since 1999.

In addition to cotton, the crop which has attracted the most interest among scientists and regulators is rice, which is China's major food crop. Many types of transgenic rice varieties and hybrids have reached and passed field trial and environmental trial phases since the late 1990s. Transgenic Bt rice varieties and hybrids that are resistant to rice stemborer and leaf roller were approved for environmental trials in 1997 and 1998 (Zhang et al., 1999). Other scientists introduced the CpTi gene into rice creating rice varieties with another type of resistance to stemborers. This product was approved for environmental trials in 1999 (Chen, 2000). Transgenic rice with Xa21 and Xa7 genes for resistance to bacterial blight were approved for environmental trials since 1997 (Chen, 2000). In interviews with scientists we also found field trials have been underway since 1998 for transgenic rice with herbicide tolerance (using the Bar gene) as well as varieties expressing drought and salinity tolerance.

Four transgenic rice hybrids have advanced to the pre-production trials stage – the earliest pre-production trials started in 2001. Two insect resistance hybrids – GM Xianyou 63 and Kemingdao – contain stemborer-resistant Bt genes. The hybrid GM II Youming 86 contains the CpTi gene which provides resistance to stem borers also. A fourth hybrid contains the Xa 21 genes, which provides resistance to bacterial blight, one of the most prevalent diseases in rice production areas in central China (Huang et al., 2005).

The transgenic cotton varieties spread rapidly since 1997. By 2004 they covered almost 3.7 million ha or about 65% of the cotton area of China. A survey by the Center for Chinese Agricultural Policy (CCAP) of Chinese Academy of Science found that about 60% of the Bt area contained the CAAS insect resistant genes, while the rest contained the Monsanto Bt gene. Most of the area is covered by approved varieties, but a portion of the area – at most about 20% – may be varieties containing unapproved seed. Their adoption has reduced pesticide use to control bollworm and increased cotton yields (Pray et al., 2002). It has also pushed cotton prices down, but the net result is higher net income for farmers who adopt Bt cotton (Pray et al., 2002).

3 Political economy of regulation

Hayami and Ruttan (1985) developed a model of induced institutional innovation in which changes in government institutions – whether the institutions are policies, regulations, or the enforcement of regulations – are a function of demand for change on the part of various interest groups outside the government and the payoffs to suppliers of institutional change who are politicians and government bureaucrats. The strength of the demand for change will be depend on the size of the rents, or producer and consumer surplus, that interested groups can capture if the institution is changed. As an example of the demand for institutional change they discuss farmers who lobby for government agricultural research which will produce technology which will increase farmers' profits. Another example is agricultural input firms that lobby for intellectual property rights so that they can capture more of the benefits from the new technology that they develop. The suppliers of these changes – public agricultural research investments and intellectual property rights laws in the USA and Japan – were the politicians who passed these laws in order to get re-elected.

In the case of biosafety regulations both the regulations and their enforcement are the result of a process in which the imposition of regulations creates costs and benefits to different interest groups which then leads them to push for or against institutional changes that will reduce their costs or increase their benefits in the future. The size of the expected gains and losses will influence how much time, money, and effort they will use to influence the political process to change the regulations or the way the regulations are enforced. They can lobby for change by allying themselves with other groups with similar interests. For example, the companies who feel that they are losing potential profits because biosafety regulations take so long come together in business organizations to lobby for speedier, more efficient regulatory decisions.

The costs of changing rules and regulations are likely to be different for different actors depending on a country's ideology, values and the payoffs to the regulators and politicians who control the regulations. For example, both India and China have strong nationalist sentiments and anti-multinational values, which makes it relatively difficult and costly for a company like Monsanto to influence policy. In contrast, the demands for policy change and enforcement by local research institutes and seed companies are much more likely to be supported by policy makers and bureaucrats.

In the next sections we present the overall structure of the biosafety regulatory system as given, and the current pattern of use of transgenic crops as evidence of the size of the potential payoffs from regulations and their enforcement. Then we describe the pattern of costs and the enforcement of regulations and analyse these patterns using this political economy framework.

4 Biosafety regulations in India and China

4.1 Indian biosafety regulations

The goal of the Indian regulatory system is to ensure that their GM crops pose no major risk to food safety, environmental safety or 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 biosafety regulatory systems, but one which most developing countries have included in their systems. The biosafety regulatory system was established in its current form in 1990 by guidelines issued through the Ministry of Science's Department of Biotechnology (DBT) ('Recombinant DNA Guidelines'), with some modifications, in August 1998 ("Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity, Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts").

The Indian biotechnology regulatory system has three layers. At the bottom, institutional biosafety committees (IBCs) must be established in any public or private institute using rDNA in their research. The IBCs contain scientists from their respective institutes and a member from the DBT. 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 DBT and regulates agricultural biotechnology research up to large-scale field trials. It requests food biosafety, 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. The RCGM is primarily made up of scientists (including agricultural scientists) and can request people with specialised knowledge to review cases. It has a Monitoring-cum-Evaluation Committee (MEC) that monitors limited and large-scale field trials of GM crops and is primarily made up of agricultural scientists.

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 is shown in column 1 of Table 1. Columns 2 and 3 have the data generated for regulators and for the committees that 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, an IBC could not approve a 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 food, the environment, and agriculture, and will be economically beneficial for farmers, the GEAC approves it for commercial use. It will also have to go through several years of testing by the state and national variety trials to prove its agronomic superiority over the current varieties.

Table 1 Comparison of Indian and Chinese biosafety laws, institutions and impacts

	India	*China*
Policy objectives	Ensure GM crops pose no major risks to food safety, environmental safety, agricultural production, and no adverse economic impacts on farmers	Promote biotechnology R&D Tighten safety control of genetic engineering work Guarantee public health Prevent environmental pollution Maintain ecological balance
Legislative history	1986 Environmental Protection Law	1993: 'Safety Administration Regulation on Genetic Engineering' (MOST)
	1990: Recombinant DNA Guidelines (Ministry of Science, Dept. of Biotechnology)	1996: 'Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering' (MOA)
	1998: Revised Guidelines for Research in Transgenic Plants; Guidelines for Toxicity, Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts (Ministry of Science, Dept. of Biotechnology)	2001: 'Regulation on the Safety Administration of Agricultural GMOs' (State Council)
	–	2002: Implementing regulations: Safety Evaluation Administration of Agricultural GMOs; Safety Administration of Ag GMO Imports; Ag GMO Labelling Administration (MOA)
Institutional structure	Ministry of Environment and Forests' multi-ministry GEAC (for commercial production; large field trials; GM product imports)	Allied Ministerial Meeting (MOA, MOST, State Development and Planning Commission, MPH, Ministry of Foreign Economy and Trade; SEPA)
	Ministry of Science's Dept. of Biotechnology's Review Committee on Genetic Manipulation (RCGM)(for contained research on hazardous gene or technique, and all research up to large scale field trials)	Office of Agricultural Genetic Engineering Biosafety Administration (OGEBA), within MOA
	State biosafety committees	National Agricultural GMO Biosafety Committee
	Institutional Biosafety Committees (IBSC) at each research institute	Provincial Biosafety Management Offices
	–	Institutional Biosafety Committees

Table 1 Comparison of Indian and Chinese biosafety laws, institutions and impacts (continued)

	India	*China*
Submissions and approvals		
Cases considered	Unknown	1044 applications
Approved – field testing	Nine crops	60 crops
Approved – commercialisation	One crop (cotton) 4 varieties in 2004	Four crops (cotton, tomatoes, peppers, petunias) 181 varieties in 2004
Diffusion – commercial production	Cotton: 1.2 million ha 2004	Cotton – 3.7 million ha (60% CAAS; 40% Monsanto) 2004 small areas of tomatoes and peppers.
Enforcement – institutions that are active	Environmental ministry GEAC	Ministry of Agriculture – National Agricultural GMO Biosafety Committee OGEB
	State Departments of agriculture	Provincial and local agricultural bureaus
	Courts	–
	Local NGOs and international NGOs such as Greenpeace	No local NGOs only Greenpeace allowed
Enforcement – percentage of area that is illegal	66% illegal Bt cotton 2004	20% was illegal in 2000. Now less?

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 and then it has to go through several more years of the variety trials.

4.2 China's biosafety regulations

In response to the emerging progress in China's agricultural biotechnology, the first biosafety regulation, 'Safety Administration Regulation on Genetic Engineering', was issued by the Ministry of Science and Technology (MOST) in 1993. The last column in Table 1 summarises the Chinese regulations. This regulation consisted of general principles, safety categories, risk evaluation, application and approval, safety control measures, and legal responsibilities. After this Regulation was decreed, MOST required relevant ministries to draft and issue corresponding biosafety regulations on biological engineering (i.e., the Ministry of Agriculture (MOA) for agriculture and the Ministry of Public Health for food safety). The MOA issued the 'Implementation Regulation on Agricultural Biological Genetic Engineering' in 1996. Labelling was not part of this regulation, nor was any restriction imposed on imports or exports of GM products. The regulation did control GMOs for research and commercial production. Under this regulation the National Agricultural GMO Biosafety Committee (Biosafety Committee) was established in 1997 to provide MOA with expert advice on biosafety regulations.

In May 2001 the State Council decreed a new and general rule on biosafety called the 'Regulation on the Safety Administration of Agricultural GMOs'. This new regulation replaced the 1993 regulation issued by MOST. Under the new regulation, the MOA issued three new implementing regulations on biosafety management, trade, and labelling of GM farm products. The implementing regulations were to take effect after March 20,

2002. They included several important changes to existing procedures and details of regulatory responsibilities after commercialisation. The changes included an extra preproduction trial stage prior to commercial approval, new processing regulations for GM products, labelling requirements for marketing, new export and import regulations for GMOs and GMO products, and local and provincial-level GMO monitoring guidelines. In the meantime, the Ministry of Public Health also promulgated its first regulation on GMO food safety in April 2002, to take effect after July 2002.

The MOA is the primary institution in charge of the formulation and implementation of biosafety regulations on agricultural GMOs and their commercialisation. In order to incorporate representation of stakeholders from different ministries, the State Council established an Allied Ministerial Meeting comprising leaders from the MOA, the State Development Planning Commission (SDPC), the MOST, the Ministry of Public Health, the Ministry of Foreign Economy and Trade (MOFET), the Inspection and Quarantine Agency, and the State Environmental Protection Authority (SEPA). This Allied Ministerial Meeting coordinates key issues related to biosafety of agricultural GMOs, examines and approves the applications for GMO commercialisation, determines the list of GMOs for labelling and establishes import or export policies for agricultural GMOs and their products. The routine work and daily operations are handled by the Office of Agricultural Genetic Engineering Biosafety Administration (OGEBA) under MOA.

The Biosafety Committee remains the major player in the process of biosafety management. Currently, the Biosafety Committee is composed of 56 members who are primarily agricultural scientists. The committee meets twice each year to evaluate all biosafety assessment applications related to experimental research, field trials, environmental release, pre-production trials, and commercialisation of agricultural GMOs. It makes recommendations to OGEBA based on the results of its biosafety assessments. OGEBA is responsible for the final approval of decisions.

The Ministry of Public Health (MPH) is responsible for food safety management of biotechnology products (processed products based on GMOs). The Appraisal Committee, consisting of food health, nutrition, and toxicology experts nominated by MPH, is responsible for reviewing and assessing GM foods since they have been designated a novel food. SEPA participates in GMO biosafety management through the Allied Ministerial Meeting and through its members on the Biosafety Committee. Although SEPA has taken the responsibility of international biosafety protocol, its focus on biotechnology in China is limited to biodiversity.

In 2005, all provinces (31 provinces) in China established provincial biosafety management offices under provincial agricultural bureaus. These biosafety management offices collect local statistics on and monitor the performance of research and commercialisation of agricultural biotechnology in their provinces and assess and approve (or disapprove) all applications of GM related research, field trials and commercialisation in their provinces. Only those cases that are approved by provincial biosafety management offices are submitted to the Biosafety Committee for further assessment.

4.3 Comparison of Chinese and Indian biosafety regulatory systems

Indian and Chinese regulations can be compared in Table 1. The goals, history and structure of the regulations are quite similar. The major difference in the structure of these systems is that, in China the regulatory and enforcement machinery is all under the

Ministry of Agriculture while in India regulation is implemented by the Ministry of Environment and Forestry and the Department of Biotechnology, which is part of the Ministry of Science and Technology.

5 Cost of compliance

5.1 India

As discussed above, only two genes – the Bt gene Cry1Ac in Cotton and the genes for hybrid mustard – have been proposed to the GEAC for commercial release. In addition, Bt eggplant and high protein potato have been tested fairly extensively. Our cost estimates are based on these crops. We collected the cost data through extensive interviews with the companies or research institutions in December 2003.

The first event approved (in 2002) was Monsanto's Bt gene in three cotton hybrid cultivars from MAHYCO. The government gave MMB a temporary permission for commercialising Bt cotton for three years, at which time it had to be reviewed again. Thus, there are post-approval regulatory costs as well as pre-approval costs.

The pre-approval compliance costs without salaries were about $900,000 and total pre-approval costs were perhaps $1.8 million.[1] It took six years of trials to get approval. Several of these years would have been required to produce and obtain approval for a new conventional (non-transgenic) variety anyway, but the biosafety requirements added three to four years of trials and tests to the commercialisation process. In addition, MMB estimated that it would have between $100,000 and $200,000 of further expenses in order to meet the three year renewal requirement. 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. In contrast, in December 2003 the compliance cost for a new chemical pesticide in India was about $200,000 according to Monsanto India's government affairs officer.

The genes that Bayer Agrosciences and its predecessors used to produce hybrid mustard have been used in canola (which is closely related to mustard) to produce hybrid canola cultivars in Canada and the USA. They have cleared the biosafety regulations in those countries. However, these genes have not been commercialised in mustard anywhere in the world. Therefore, Bayer and its predecessors decided that they would not commercialise transgenic mustard in India before they conducted research to show India's neighbours and trading partners that this particular genetic event was safe. They started working towards biosafety approval in the mid 1990s. Since then, between US$3 and 4 million was spent in the USA and Europe to ensure that it met the international food safety requirements. In addition, $1–1.5 million was spent in India on environmental trials and nutritional standards.

After Bayer and its predecessors spent between $4 and $5 million on meeting regulatory requirements in India and elsewhere, GEAC asked for another set of trials in 2003. 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 New Delhi informed us in December 2003 that they have decided not to continue trying to commercialise hybrid mustard in India.

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 commercialisation. If the number of biosafety trials are 15 in the first season and 40 in the next two seasons and each ICAR trial costs private companies about $1000 as they do at present, the cost of introducing a new variety would be almost $100,000 (Pray et al., 2005).

In contrast to the high costs estimated by the private sector, most public sector scientists felt that compliance costs were not a major constraint on their research or commercialisation efforts. For them, the years lost in the regulatory process is the main problem. One of the few institutes that has a long experience with the biosafety process is the National Research Centre for Biotechnology at the Indian Agricultural Research Institute (IARI). Their vegetable programme has had Bt varieties in the regulatory system for a number of years. They started Bt research eight years ago in 1996. They developed a Bt eggplant using a Cry1Ab gene that controls 70% of the fruit borer attack. They had agronomic trials in a controlled environment in 1998–1999, 1999–2000, and 2000–2001. In 2003 they were permitted to conduct field trials in five locations. The cost of controlled environment trials and field trials so far has been about $10,000. If they are required to do two more years of field trials in ten locations, this would add another $10,000. Late in 2003 they asked for and received estimates of the cost of meeting the food safety requirements. They received cost estimates from three government institutes on providing the food safety information requested by the regulators. The estimates ranged from Rs. 1–1.5 million ($22,000–33,000) for everything needed (Personal communication IARI scientists, New Delhi, December 2003). Thus with no more food safety 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.

The high protein potato research at the Centre for Plant Genomics Research in New Delhi was often used by 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 were costs of the allergenicity / toxicity and the costs of labour and fertiliser for three years of field trials. The institutes that conducted the tests absorbed all other costs. They still have 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.

5.2 China

The data on the costs of complying with biosafety regulations in China suggests a pattern somewhat different from India's system – the cost of compliance paid by the government institutes and private companies is low relative to India and the Chinese system for approving new varieties containing approved events has evolved into a fairly speedy one, at least for cotton. However, getting other food crops approved – such as maize or rice – has been a long process for both public and private institutions.

For foreign companies who are operating through joint ventures in China we have some data, but so far we do not have a complete accounting of compliance costs. We know that it took much less time and money to get approval for Bt cotton in the late 1990s in China than it did in India. The Chinese biosafety committee was still working out what data were required and assumed that since Bt cotton was approved in the USA, it presented no food safety or agronomic problems. Thus, for Bt cotton, Monsanto had to produce their international dossier which had evidence of food safety, environmental impact, and efficacy. The only trials that were required in China were two years' environmental impact trials and some mouse feeding trials to check the safety of the oil and seed cake. Similarly, when the Biotechnology Research Institute of CAAS wanted to get permission to commercialise their Bt cotton, they had to produce scientific data on the characteristics of the gene construct and had to show several years of field trial data indicating the efficacy of their technology in Chinese conditions. The Chinese government brought together a large group of scientists to several meetings in the mid 1990s and decided that given the mixed cropping system of cotton farmers in north China, which included several other hosts of the cotton bollworm, there was no need to set aside some part of the Bt cotton fields to be planted with non-Bt cotton as a refuge where susceptible bugs could continue to breed.

After the biosafety committee decided to allow commercialisation of Bt cotton in 1997, the international controversies about the safety of biotech started to cause concern for the press and the public. As a result, the government decided that they needed to know more about the possible health risks to humans of eating Bt cotton seed oil and the risks to animals from eating cotton seed cake. The Chinese government, after the release of Bt cotton, did conduct more studies in 2000. MOST provided the Ministry of Health's Nutrition and Food Safety Institute with about RMB 5 million (US$ 604,000) for food safety testing, first of cotton seed oil and cake and then of Xa 21 rice. An additional RMB 5 million was given to the Institute of Plant Protection, which is part of the Ministry of Agriculture, for research on the environmental impact of GM crops (personal communication Peng Yufa, Beijing July, 2000).

To find out how much research institutes and seed companies' costs of compliance to the regulations were in 2004, the authors interviewed a number of government research institutes and commercial seed companies that have been pushing varieties of Bt cotton through the regulatory system. Unfortunately, none of these companies had new varieties of Bt or CpTi; they were simply new varieties of cotton which used the CAAS or Monsanto Bt events as one of the parents. The results of these interviews are shown in Table 2. The total costs to research institutes of developing and bringing to market a new Bt cotton variety was about $88,000. Of that about $75,000 went for plant breeding while $13,000 for biosafety regulations.

Table 2 Costs for Chinese Bt cotton varieties of compliance with the biosafety requirements US$ (in 2000 prices)

	Jimian 38	*Zhong mian 41*	*GKz8*	*GKz23*	*Nannong 98-7*	*Average*
Breeding	110,775	58,717	52,906	104,116	46,247	74,576
Biosafety trials						
Small scale	1,816	4,237	242	3,995	2,421	2,542
Medium scale	3,632	4,964	605	4,843	3,269	3,511
Pre-production	5,448	8,232	969	8,111	5,085	5,569
Safety certificate	1,453	2,785	121	1,211	1,574	1,453
Sub-total	12,349	20,218	3,390	18,160	12,349	13,317
Total	123,123	78,935	56,295	122,276	58,596	87,893

Source: Survey of five Chinese research institutes

Private firms did not give us precise numbers on their costs of getting the first Bt cottons through the biosafety process but it clearly was small because the Chinese government did not require food safety tests be done in China and only required limited environmental testing in China. To calculate what it would cost now to comply with the biosafety requirements, we relied on the cost of tests that are mandated by the Chinese government. Table 3 shows the costs of these tests for the private firms and for government institutes. The cost per year is the cost per trial times the number of trials that are typically required for each type of test. The cost per trial for private firms is typically about three times more than the costs for government research institutes. The minimum number of years is the minimum required according to government regulations. The maximum number of years is a guess because all crops have been stuck in either environmental trials since 1999 or have been in pre-production trials. For example Bt maize has been at the environmental trials stage since 1999 and Bt rice has been in preproduction trials for at least three years.

Table 3 Cost in China for approval of a new GM field crop event: private and public sector (US$)

	Companies				*Government*		
	Years required	*Cost/year*	*Cost min years*	*Cost max years*	*Cost/year*	*Cost min years*	*Cost max years*
Environment safety	–	–	32,800	32,800	–	32,800	32,800
Food safety							
Anti-nutrients	–	–	120	120	–	120	120
90-day rat feeding	–	–	14,500	14,500	–	14,500	14,500
Pilot field trial	1–2	1,816	1,816	3,632	581	581	1,162
Environmental field trial	2–4	5,085	10,170	20,340	1,695	3,390	6,780
Preproduction field trial	1–3	6053	6,053	18,159	1,896	1,896	5,688
Total	–	–	65,459	89,551	–	53,287	61,150

Source: Years best guess from companies. Costs from Chinese Ministry of agriculture http://www.stee.agri.gov.cn/biosafety/jcjy/bz_jcjy/t20031029_131210.htm

The total cost of compliance for private firms, excluding the salaries of the company's regulatory staff in Beijing, is at least $65,000 (Table 3). Using a more realistic guess at the number of years, the total would be about $90,000. The big cost may be the salaries of the regulatory people in Beijing and elsewhere. There are several people in firms and the regulatory offices, and they have to work on these genes for 8–10 years. This mounts up. At today's salaries for highly trained professionals in Beijing, assuming that one person would take care of four new gene events over a number of years, the cost of personnel could easily add up to $100,000. Government institutes would pay less to meet biosafety regulations; somewhere between $53,000 and $61,000 without salaries.

In response to concerns of government research institutes and private companies about the slowness and costs of regulations for Bt cotton varieties, the Chinese government changed the way it conducted trials to reduce these costs. New GM varieties can now be simultaneously tested in the field trials and the variety registration trials. In addition, September 2004, MOA has implemented measures for Bt cotton that allow:

- developers of a Bt cotton variety that received a production safety certificate from one province can directly apply for the safety certificates for all of provinces within same cotton-ecological regions without going back to the National Biosafety Committee in Beijing
- developers of an approved variety can apply production safety certificate directly to another province in others cotton ecological regions
- a Bt variety that was developed from approved varieties with safety approval can also be entered directly to a provincial biosafety committee for approval.

5.3 Comparing India and China

The costs of compliance in India and China are summarised in Table 4. It suggests that the costs of compliance are higher in India than in China for private firms while for government research institutes the costs are less in both countries. The lower costs of compliance in China than in India may be due, in part, to the fact that the government absorbed much of the costs of testing the food safety of cotton seed oil and cake and transgenic rice and well as studies on the gene flow and other environmental issues of concern for transgenic rice and maize. Of course, the actual cost for GM events from the public sector in India is unknown since no GM varieties from the public sector have made their way through the regulatory system. In both systems, the real problem is not money, but the time and uncertainty of whether any major food grains will be approved for commercial production.

Table 4 Comparing biosafety compliance costs in India and China without personnel costs

	India – actual costs or industry estimates	*China – average costs of trials from our survey*
New Bt cotton gene private corporation	$900,000 actual	$89,500
New Bt cotton government research institute	Not available	$53,000–61,000
Approval of Bt in new variety	$100,000 estimated by multinational companies	$13,300 from survey of government research institutes
Bt eggplant Indian government	$53,000 estimate by research institute	Not available
Bt maize-private corporation	$500,000 estimate by multinational company	$89,500

Source: Interviews by authors

The Chinese system was much faster in approving Bt cotton and a few minor crops than the Indian system. Now, however, both systems are undecided about food crops which have had extensive testing – mustard in India and rice in China. Thus, there are major uncertainties for the developers of transgenic food crops about whether they will ever be approved. The Chinese system does appear to be faster in approving varieties of crops which already have transgenic cultivars in production. In addition, in China the biosafety regulations field trials (small trial, middle or environmental release trial, pre-production trial, and varietal agronomy trial / registration) are allowed to overlap with previous stage, so the time to go through all stages could be shortened by nearly half.

The political economy framework suggests why private firms in India pay so much more for regulation than research institutes in India or private and public institutions in China. In both countries there are strong nationalist and anti-multinational sentiments, which make it relatively difficult and costly for a company like Monsanto to push costs of biosafety regulations lower. In China, however, many key universities, government research institutes and seed companies were lobbying in the same direction as Monsanto to encourage the government to quickly approve cultivation of GM varieties and to keep the costs of meeting these requirements low. In India, the Department of Biotechnology ensures that local government research institutes did have very low costs of compliance and no local private seed companies had any transgenic varieties of Bt ready to start the regulatory process. Thus, there were no local interest groups that worked with MMB to counteract the precautionary approach that the NGOs were lobbying for. This increased the costs of compliance for private firms. In addition, the actual monetary costs of compliance were not a major expense for a large corporation but were for smaller Indian seed companies. Thus, Monsanto and MAHYCO may not have pushed very hard for lower costs because high costs act as a barrier to entry to the small firms and strengthen MMB's market power.

6 Enforcement

Biosafety regulation without enforcement or with uneven enforcement may be worse than no biosafety regulation, because if there is a major biosafety problem, the whole regulatory regime could be discredited. Even if there is not a major problem, well publicised avoidance of biosafety rules will greatly reduce the credibility of the system with consumers and will reduce the demand for transgenic products. The problem is that, in developing countries it may be very difficult to enforce regulations – particularly if those regulations potentially could reduce the income of politically important parts of the economy. China and India experienced similar difficulties in enforcing biosafety regulations on Bt cotton.

6.1 Indian enforcement

NavBharat Seed Pvt. Ltd, which has its headquarters in Ahmedabad, Gujarat, developed a hybrid Bt cotton variety, NB 151. It obtained a cotton line that contained Monsanto's Cry1Ac Bt gene. They used the female line of the popular Gujarat hybrid H-8 to cross with the Bt line. NB-151 was submitted to the Gujarat government's variety registration system as a bollworm resistant cotton hybrid. It was approved and first sold to farmers in 2000 (Dr. Desai, founder of NavBharat, personal communication Ahmedabad December 2003). It was not submitted to the biosafety regulatory authorities in New Delhi for approval. This violation of India's environmental protection legislation was discovered in 2001 after a complaint from MAHYCO. Their field staff noticed that while almost all cotton in Gujarat was seriously damaged by bollworms, NB-151 was not. The GEAC investigated MAHYCO's complaint and found that NB-151 did contain the Cry1Ac transgene. The Ministry of the Environment ordered the Gujarat government to destroy all of the NB-151 cotton that was being grown, and they 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 burn the crop. However, they did force NavBharat to stop selling NB-151. The neighbouring government of Maharashtra banned NavBharat from selling seed of any crops in their State.

NB-151 was growing on between 2,400 and 6,800 hectares when it was discovered in 2001. Although NavBharat was forced to stop selling Bt cotton after 2001, smaller seed companies, often former contract seed producers for NavBharat, had the inbred lines needed to produce this seed and so they kept producing the hybrid NB-151. In addition, some farmers saved their seeds, and planted the second generation of the hybrid that is known as the F2 generation, although this would lower their yield somewhat The seed industry officials now estimate that in the year 2004, about 1.2 million hectare of Bt cotton were planted, of which one million was under approved Bt varieties.

The GEAC has continued to press the governments of Gujarat and other states to crack down on the spread unapproved Bt varieties, but the states do not appear to have done much. There are newspaper reports that the NavBharat hybrids and their close relatives are being grown in Haryana, Punjab, Maharashtra and elsewhere which supports the seed industry estimate of 800,000 ha planted with illegal seed. The Indian Express, a prominent Indian newspaper, suggested in 2003 that the regulators were hoping that by approving more, better-adapted Bt cotton varieties, the legitimate Bt varieties will push out the illegal Bt (Jain, 2003). However, only one new Bt cotton from Rasi Seeds was approved for cultivation in 2004. A number of other varieties from Ankur Seed, Rasi Seeds, and Mahyco were given permission to start seed production in 2004–2005 which could mean that seed of these varieties would be available for the 2005–2006 season (Indian Express, 2004). However, it seems unlikely that NB-151 will be pushed out quickly.

6.2 China enforcement

In China, several research institutes did contract research to test Bt cotton varieties for Monsanto and Deltapine in mid 1990s. At the same time they tested Bt genes from other sources. One of these institutes developed Bt pureline varieties and some hybrids that were insect resistant. They entered these insect resistant varieties in the regional variety registration trials and got approval for sale in 1998. They started selling seed in the Yellow river basin and Yangtze river basin.

The Biosafety Committee found out about this and notified the institute in the late 1990s that because these varieties were transgenic, they had to have biosafety approval from the National Biosafety Committee. Scientists CAAS tested the institute's varieties against Monsanto Bt varieties and the CAAS Bt varieties. They found that the institute's varieties killed bollworms, but late in the season their effectiveness in killing bollworms declined faster than varieties containing the Monsanto or CAAS genes (Wu, 2002). The Biosafety committee was concerned that the spread of these varieties would lead to more rapid development of bollworms that were resistant to Bt cotton.

The Biosafety Committee was not able to stop sales of these varieties. Unpublished survey data collected by CCAP Center found that farmers in Henan and Shandong provinces were extensively using the unapproved Bt varieties in 2001. Recently released varieties from this institute contain the approved Bt gene from the Biotechnology Research Institute of CAAS. This seems to be at least partially due to pressure from the Biosafety Committee on the institute to use approved Bt in their new varieties. It also helps that only a limited amount of time and money is now required to get approval from the biosafety regulators for new Bt cotton varieties using approved genes. In addition, until recently, the royalties that CAAS has actually collected on their Bt genes has been very limited. Thus, it was quite inexpensive to use approved Bt technology.

Each new transgenic variety that incorporates approved transgenes was supposed to be approved by the Central Biosafety Committee and the provincial variety approval committee until the changes that took place in 2005. This was a difficult regulation to enforce. Most provincial and prefectural government cotton breeding programmes and some private programmes had backcrossed the CAAS and Monsanto Bt genes into their best local varieties. Surveys conducted by CCAP found evidence that farmers were using a number of hybrids and varieties that were either Monsanto or CAAS varieties that were renamed to hide their origin or were the result of backcrossing programmes. Visits to cotton counties in Shandong Province in 2001 allowed one of the authors, Carl Pray, to interview county research institutes and seed companies. He asked if they needed permission from the central biosafety committee to sell backcrossed Bt cotton varieties. They said that the Central Biosafety Committee really had no power in their State.

In 2001, the last year of the CCAP survey of Chinese cotton farmers in north China, approximately 20% of the Bt cotton fields were planted with the illegal Bt. In response to this problem and to the need for monitoring biosafety field trials in the provinces, MOA established provincial biosafety committees in all provinces by the beginning of 2005. In July 2004 MOA issued new policies to improve enforcement of GM varieties. These policies required that any new GM varieties should have biosafety certificates from MOA when the varieties are entered in regional variety trials. For any cotton varieties, the applicants must present a certificate from an MOA-designated testing institute/ organisation stating whether they are GM or non-GM varieties.

6.3 Comparing biosafety enforcement in India and China

China has been more effective at controlling the spread of unapproved genes than India. Instead of putting the violator of the Bt cotton regulations out of business in China, the violator, a government institute was encouraged to replace the unapproved Bt with an approved Bt developed in all of its new varieties. In addition to the new varieties from that institute, many other very cheap, alternative Bt cotton varieties with the approved Bt genes were available as substitutes of the unapproved Bt varieties. So, the illegal Bt gene, which made up, at most, 20% of the area of Bt cotton in 2001, was almost non-existent in 2005.

In India, the Bt cotton story is different. NavBharat, the company which introduced the illegal Bt cotton, was forced to stop selling Bt cotton varieties in India, but its former contract seed producers and others were not. A 2004 USDA report says: "according to trade sources, cotton area under 'illegal' Bt cotton varieties was twice that of approved Bt varieties" (Singh, 2004, p.27). Thus, at least at the moment, India has a much higher proportion of unapproved Bt cotton seed than China.

The differences in outcomes were was due, in part, to the greater availability and the low price of approved alternatives in China. By 2004 the Indian government had approved only four Bt cotton varieties which contained one approved Bt gene, compared to 170 Bt cotton varieties in China using two Bt genes and one CpTi gene. The fact that alternative insect resistant genes existed was due to greater Chinese investment in public research which developed the alternative genes. The number of varieties was a function both of the fact that breeding of Bt cotton has been going on much longer in China than in India and the speed and low cost with which Chinese biosafety regulators now approve new cotton varieties. The Bt cotton varieties were approved in China in 1997 and in India in 2002. All government institutes and companies in China had access to lines containing Bt which could be used to develop new varieties and most of these institutes did develop new varieties.

Enforcement depends on policy makers at local levels of government. They have personnel at the local level who can actually enforce the regulations on seed companies and farmers. There may be less transaction costs of enforcement if regulation and enforcement are in the same type of Ministry and departments. In China, the Ministry of Agriculture in Beijing is in charge of biosafety regulation. It has worked closely with the provincial agricultural departments and county agricultural bureaus for years to enforce a variety of agricultural regulations. In India, the Ministry of Environment and Forestry controls biosafety regulations and enforcement, but it needs the state agriculture departments that have seed regulators on the ground in each state to enforce their regulations. The lack of long term relationships and the different constituencies that the Ministry of the Environment and the state Departments of Agriculture serve in India could be another reason for less compliance in India.

The political economy framework also helps to explain why enforcement was more effective in China. In India when the Indian Ministry of the Environment asked the government of Gujarat to destroy the Bt cotton crop in 2001 and prohibit its use in the following years, both the farmers, who had increased their income by growing the Bt cotton and the small seed companies that were making profits by selling illegal Bt cotton seed put pressure on the provincial governments to not enforce biosafety regulations. Monsanto and its partner MAHYCO were lobbying both the Central government and the Gujarat government to enforce the regulations.

Farmers and small seed companies in Gujarat and elsewhere in India lobbied their provincial governments not to enforce the ban on the NavBharat hybrids. The farmers who grew the NavBharat hybrids had a lot to lose if they were forced to switch to MMB's Bt varieties. MMB was charging nearly four times as much for seed that was no more effective at controlling bollworms than the NavBharat varieties (Pray et al., 2005). Local seed companies also had a lot to lose if the ban on NavBharat was enforced. They would be put out of the Bt cotton seed business by the legal Bt cotton. Monsanto has not been willing to license its Bt gene to NavBharat and the other companies that Monsanto sees as potentially very unreliable partners. It was only willing to license Bt to major large seed companies at a high royalty rate with an upfront payment.

In contrast, in China, farmers and small seed firms did not resist enforcement of the prohibition against the unapproved gene because they had much less to lose by its removal. Farmers would not have to pay four times higher prices than they were paying for the unapproved varieties, because they did not have to buy from Monsanto and its local partners. There were a large number of different Chinese companies that were selling seeds with the approved gene at half or a quarter of the price of the approved Bt. In addition, the approved seeds actually were more effective against bollworms and were higher yielding than the unapproved varieties (Hu et al., 2005). Thus, unlike the Indian farmers, Chinese farmers might actually be better off using the approved Bt gene.

Similarly, small seed firms wishing to sell the approved Bt gene would not have to pay large royalties to Monsanto. Instead they could get Bt genes from the Biotechnology Research Institute in Beijing and have to pay only very limited amounts as royalties, unlike their Indian counterparts.

In addition to differing amounts of resistance by farmers, there were also differences in the ability of those who sell the legal Bt's to influence policy. In India, the main beneficiary of greater enforcement was portrayed as the foreign multinational. Local seed companies who are selling illegal Bt seed tried to gain the sympathy of politicians and the public by making the argument that the foreign multinational company was attempting to act as a monopolist and exploit Indian farmers through high seed prices (Shah, 2003). In China, the owner of two important approved insect resistance genes was an agency of the Chinese government itself – the Biotech Research Institute of the CAAS. Monsanto and its partners also had a Bt gene and would profit, but not so greatly, because the government research institute that had been using the unapproved Bt would replace it with the approved government-owned Bt. Thus, it was not surprising that governments of provinces in India were much less sympathetic to enforcement than the government of China and its provinces.

7 Lessons and policy options

The first objective of this paper was to assess the cost of complying with biosafety regulations and the evidence on the enforcement of regulations in India and China. In India, the cost for private companies of complying with regulations was high relative to the costs of government research institutes in India or Chinese companies and institutes. The costs of compliance for the first Bt cotton event were at least one million US dollars, which is more than the annual research budget of many small to medium Indian seed companies. In addition the costs and the continuing uncertainty led one company to abandon its attempts to commercialise transgenic hybrid mustard. Information from the public sector in India and from public and private sectors in China shows that the cost of compliance can be much less than it was for the first few transgenic varieties. Both countries are making efforts to reduce the cost and the inefficiencies in their systems.

The experience of India and China also makes it clear that it can be difficult to enforce regulations with small farmers. In China, however, the government has been able to push out an unapproved Bt gene. When regulators found out about the unapproved Bt gene, they were successful in replacing the illegal Bt gene in cotton with an approved Bt gene in new varieties in a few years. Indian regulators have not yet been able to do the same – two thirds of the Bt cotton in India is planted with unapproved varieties of Bt. They are using much the same strategy as the Chinese – approving new varieties and hoping that they will replace the illegal ones. As yet this strategy has not worked very well, although it may work when more Bt genes become available.

The second objective of this paper was to understand the reasons for the differences in costs and enforcement. The differences in costs and performance of these regulatory systems are partially due to the basic structure of the systems – in China, the regulatory system is largely controlled by the Ministry of Agriculture and the Ministry of Science and Technology while in India it is under the Ministry of Environment and Forestry and the Ministry of Science. The greater influence of the Ministry of Agriculture in China and the fact that agencies under this Ministry earn profits from the Bt cotton seed industry is probably part of the reason why compliance costs less in China and why enforcement works better there.

In addition to the differences due to the structural differences in the regulatory system, the political economy framework also helps explain the differences in costs and enforcement. In China it was not just a few multinationals that were pushing for speedy, low-cost regulations. There was also a powerful lobby of government scientists and local seed companies who wanted to make money from biotechnology but could not do so unless they complied with regulations which were inexpensive and rapid. In India, local researchers and seed companies were not ready with important new genes to compete with Monsanto, and so they did not lobby as vigorously for quick, low-cost regulation. Furthermore, once MMB had the first Bt gene approved they did not have a lot of incentive to reduce the costs for other companies because the high costs which kept some competitors out of the market.

The pattern of enforcement also has both structural and political economy explanations. A structural advantage of enforcement in China was that the policy making, regulatory decisions, and enforcement are all within the Ministry of Agriculture and provincial and local agricultural bureaus. In India, the decisions are made in the Ministry of Environment and Forestry in Delhi, but the provincial Departments of Agriculture are supposed to enforce the regulations at the ground level, which means that transaction costs were probably higher in India.

The political economy reasons for more enforcement in China are that farmers and small seed companies had much more to lose from enforcement in India than they did in China. Indian farmers who were growing unapproved varieties would have had to pay seed prices that were three or four times higher for varieties that performed about the same in the field. Chinese farmers ended up with little change in prices and better performance when they shifted from unapproved to approved varieties.

Chinese seed companies also had less incentive to resist enforcement. Only a limited number of Indian seed companies could get access to the approved gene in India, and those that did had to come up with a substantial down payment and then pay a large share of the seed price back to MMB as royalties. In contrast, Chinese companies had two sources of approved Bt genes including CAAS in Beijing which collected very limited royalties. Finally, the clear beneficiary of enforcement in India would be a foreign firm; while in China ,most of the benefits from enforcement would go to local government research institutions and seed companies. These different pressures went together to produce less enforcement in India than China.

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References

Bennett, R.M., Ismael, Y., Kambhampati, U. and Morse, S. (2004) 'Economic impact of genetically modified cotton in India', *AgBioForum*, Vol. 7, No. 3, pp.96–100, Available on the World Wide Web: http://www.agbioforum.org.

Chen, J. (2000) 'Transgenic plant program', *Biotechnology Engineering Progress*, No. 20, Special Issue, pp.14–16.

Cohen, J.I. and Paarlberg, R. (2004) 'Unlocking crop biotechnology in developing countries – a report from the field', *World Development*, Vol. 32, No. 9, pp.1563–1577.

Hayami, Y. and Ruttan, V. (1985) *Agricultural Development: An International Perspective*, Johns Hopkins University Press, Baltimore.

Hu, R., Pray, C.E., Huang, J., Rozelle, S., Fan, C. and Zhang, C. (2005) *Intellectual Property, Seed and Bio-safety in China: Who Benefits from Policy Reform?*, CCAP Discussion Paper, Beijing, pp.1–45.

Huang, J., Hu, R., Rozelle, S. and Pray, C (2005) 'Insect-resistant GM rice in farmers' fields: assessing productivity and health effects in China', *Science*, Vol. 308, pp.688–690.

Huang, J., Roselle, S., Pray, C.E. and Wang, Q. (2002) 'Plant biotechnology in China', *Science*, Vol. 295, pp.674–677.

Indian Express (2004) 'GEAC approves 12 more Bt cotton varieties', *Indian Express, newspaper*, April 16, http://www.financialexpress.com/fe_full_story.php?content_id=91664, retrieved January 4, 2006.

Jain, S. (2003) 'Catch cotton pirates, GEAC tells Gujarat', *Indian Express, newspaper*, June 12.

Kent, L. (2004) 'What's the holdup? addressing constraints to the use of plant biotechnology in developing countries', *AgBioForum*, Vol. 7, Nos. 1–2, pp.63–69.

Monsanto (2004) India executive in New Delhi in an email on 26th June, 2004.

Pray, C.E., Bengali, P. and Ramaswami, B. (2005) 'Costs and benefits of biosafety regulation in India: a preliminary assessment', *Quarterly Journal of International Agriculture*, Vol. 44, No. 3, pp.267–289.

Pray, C.E., Huang, J., Hu, R. and Rozelle, S. (2002) 'Five years of Bt cotton in China – the benefits continue', *The Plant Journal*, Vol. 31, No. 4, pp.423–430.

Shah, J.V. (2003) *Moving Towards Monopolistic Approach in Seed Industry*, Unpublished paper presented at the Special Meeting of the Gujarat State Seeds Producers Association, November 25, Ahmedabad, India.

Sharma, M., Charak, K.S. and Ramanaiah, T.V. (2003) 'Agricultural biotechnology research in India: Status and policies', *Current Science*, Vol. 84, No. 3, pp.297–302.

Singh, S.K. (2004) *India Cotton and Products Annual* 2004, GAIN Report Number: IN4047 5/14/2004 US Embassy, New Delhi, India.

Wu, K.M. (2002) 'Impacts of Bt cotton on status of insect pests and resistance risk of cotton bollworm in China', Presentation at *A conference on Resistance Management for Bt-Crops in China: Economic and Biological Considerations*, North Carolina State University, Raleigh, NC, April 28.

Zhang, X., Liu, J. and Zhao, Q. (1999) 'Transfer of high lysine-rich gene into maize by microprojectile bombardment and detection of transgenic plants', *Journal of Agricultural Biotechnology*, Vol. 7, No. 4, pp.363–367.

Note

[1]A detailed breakdown of this cost is available in Pray *et al.* (2005).