The Role of Knowledge Flows in Bridging North-South Technological Divides

A case analysis of biotechnology in Indian agriculture

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Abstract

This study analyzes global- and national-level vehicles and regulatory frameworks that influence the generation and uptake of biotechnological knowledge in the Indian agricultural sector. The aim is to examine whether and how a transition to global sustainability is hampered by knowledge or technology divides between North and South. The study examines evolving domestic intellectual property rights and biosafety policies and their influence on the generation and uptake of biotechnological innovations in Indian agriculture. It also examines how these policies are influenced by a larger macro-economic and trade policy context.

The study finds that biotechnology uptake in Indian agriculture has to date been shaped as much by domestic economic and social concerns and priorities in the area of agricultural research, trade, biosafety and intellectual property protection, as by inadequate access to knowledge or a knowledge divide. The priorities that appear to have most influenced the pace of biotechnology uptake in Indian agriculture include the desire to retain a strong role for the public sector in agricultural research, and avoid foreign or excessive private sector control over food production, particularly of basic commodity crops.

The implication of this is not that knowledge divides do not exist and may not be pernicious to a more globally equitable sustainable development. Rather, the analysis suggests that any intervention to bridge technological divides to contribute to global sustainability must begin from an identification of the societal priorities that might cause persisting knowledge divides. The study also shows that, in the absence of fora and institutional mechanisms through which to debate the socioeconomic, ethical, and political concerns relating to biotechnology use, the *domestic biosafety regime in India has become a key arbitrator of conflicts* relating to transgenic crops, including those conflicts which transcend technical safety concerns. This is problematic and points again to the need for institutional fora where the implications of technological innovations for the public good can be debated.

1. Introduction: Knowledge Flows and Global Inclusion

In the knowledge-intensive 21st century, is a transition to global sustainability hampered by "knowledge divides" between North and South? A number of alleged divides, such as a 'digital divide' or a 'genetic divide' are increasingly posited. To date, scholarly and policy attention has focused on ensuring greater access to knowledge and new technologies as a way to bridge potential divides. However, a transition to sustainability, in both North and South, requires more than access to knowledge alone. Most urgently, it requires governance structures to ensure that knowledge and innovations are used to fulfill desired societal goals.

This case study explores hurdles to access and appropriate use of transformative new technologies in developing countries. It does so through focusing on one technology in one key sector of a developing country: biotechnology uptake in the agricultural sector of India. Biotechnology is selected as the focus because it is one of the cutting-edge technologies of the new millenium, with potential to transform patterns and processes of future food production. Further, uptake of modern biotechnology in agriculture is uneven across developed and developing countries,[1] even as it is portrayed by proponents as critical for the latter, given the pressing need to ensure food security in such contexts.

In selecting to focus on India, this analysis chooses a developing country context where there is substantial scientific and technical infrastructure already in place, as well as an indigenous effort to develop and adapt biotechnological innovations in agriculture. Selecting a country with the capacity and political commitment to develop and adapt biotechnological innovations is important, in order to avoid contexts where a potential knowledge divide is the straightforward result of either (a) total lack of capacity and hence no immediate potential to adopt biotechnology in agriculture; or (b) existence of capacity but little current political interest or commitment to use of biotechnological innovations in the food sector.

Given, furthermore, that agriculture employs a significant component of the population in India, it provides an important developing country context within which to assess constraints and opportunities for appropriate use of biotechnological knowledge in future food production. It is also important to focus on hurdles to biotechnology uptake in a tropical agricultural context, as compared to temperate zone developed countries, because of the greater socioeconomic and ecological challenges of ensuring the safe use of biotechnology in such a context. As Eric van Dusen (2000) points out, the greater crop genetic diversity in tropical agriculture results in wild relatives and landraces being intermingled, making hybridization and gene flow harder to ascertain and manage. Furthermore, biotic and abiotic stresses and heterogeneous growing conditions make new crop adaptation more difficult. Equally, socioeconomic conditions such as complex land tenure and technology interactions, small land-holdings, and farmer saving and mixing of modern and traditional seed, make governing use of transgenic crops complicated.

In assessing implications of a potential genetic divide between North and South, this case study thus analyses potential vehicles of biotechnology knowledge generation and use in India and the regulatory environment within which they function. Section 2 examines the nature of transgenic research currently underway, within the broader context of public and private sector Indian agricultural research. Section 3 analyzes the impact of regulatory policies for intellectual property rights (IPRs) and safe use of biotechnology (biosafety) on the generation and diffusion of biotechnology knowledge in India. Section 4 concludes by assessing potential causes for a genetic divide and the means to encourage appropriate (i.e. in keeping with developing country priorities) biotechnology knowledge generation and use.

2. Use of Biotechnology In Indian Agriculture

Little systematic research has been undertaken to date about public perceptions of biotechnology use in India. However, media reports and a spate of recent controversies sur-

rounding use of transgenic technology reveal that the issues that generate the most impassioned debate have less to do with ecological or food safety, and more to do with socioeconomic concerns relating to increased dependence on novel technologies that may be controlled by external actors. The socioeconomic concern voiced most often is that reliance on transgenic seeds might exacerbate small farmer (and national) dependence upon multinational companies, especially for vitally important commodity crops. Vocal critics of transgenic technology, such as the environmental activist Vandana Shiva, often cast their arguments in overtly nationalist idioms, with slogans such as "Monsanto Quit India" and "bija satyagrah" (seed-related civil disobedience) evoking images of the anti-colonialist freedom struggle of the early 1900s (RFSTE 1998).

Socioeconomic concern over increased foreign dependence, especially in the agricultural sector, is linked to the always complex issue of food security in countries such as India, where close to 70% of the population relies on agriculture for its livelihood and a majority live below the poverty line (Mruthyunjaya and Ranjitha 1998, Mubashir 1999). Food security in developing countries is evoked by supporters of biotechnology as a central reason to embrace transgenic crops, given the need to increase agricultural productivity in the face of a declining resource base. This claim is dismissed as disingenuous by opponents, who point out that hunger is not necessarily related to insufficient food production. Notwithstanding persistent rhetorical references to food security in the debate on transgenic crops, a concern with it is nonetheless salient for a developing country such as India. The critical question turns on whether adoption of transgenic technology will help to ameliorate or will further exacerbate the multi-dimensional challenge of ensuring food security for all.

While the empirical jury is still out on this question, there is high-level political support within segments of the Indian bureaucracy, and among politicians and prominent members of the elite scientific establishment to explore the potential of transgenic technology to meet food security needs (Sharma 1999, 2000, Rai and Prasanna. 2000, Raina 2000). Research and use of biotechnology has received formal attention and governmental support in India since at least the mid-1980s, when a Department of Biotechnology (DBT) was formally established under the Ministry of Science and Technology. In the first decade of its operations (from 1989 to 1997), DBT support for transgenic research was Rs. 270 million (about $6 million) or 4% of its total budget, much of it provided to the public sector agricultural research establishment under the auspices of the Indian Council of Agricultural Research (DBT undated).

The Council is an apex national body funded by the central government and by taxes levied on export commodities (Mruthyunjaya and Ranjitha 1998). It oversees numerous national institutes and research centers, as well as over 25 State Agricultural Universities. In addition, a number of All India Coordinated Research Projects/Networks link the Indian Council of Agricultural Research to the state agricultural universities. By the late 1990s, 60% of funding for agricultural research came from the central government, 20% from state governments, and 12% from the private sector, with foreign donors making up the rest (Mruthyunjaya and Ranjitha 1998).

Through providing support to this vast public agricultural research system, the Department of Biotechnology seeks to accomplish the goals laid out in its "Biotechnology – A Vision (Ten Year Perspective)". This states the Department's objectives as:

> Attaining new heights in biotechnology research, shaping biotechnology into a premier precision tool of the future for creation of wealth and ensuring social justice – especially for the welfare of the poor. (DBT Undated, 1)

Attaining "new heights" in biotechnology research is thus explicitly seen as a means to the longer-term end of wealth creation and social justice, with special focus on the poor. Yet, what kind of transgenic research currently underway might be a means to such an end?

Table I provides an illustration of the transgenic research underway in India, within both the public and private sectors. As can be seen from the Table, both the domestic public

sector and private sector companies (most in collaboration with a foreign partner) are developing and field-testing a number of transgenic crops in India. These include staples such as rice, oilseeds like mustard, and vegetable and commercial crops such as cotton, tobacco, potato, tomato, brinjal, cauliflower, cabbage, chili and bellpepper. Of the genetic modifications, the majority to date have focused on pest resistance. This is seen as a priority in the Indian context, given the greater biotic stresses of tropical agriculture (Rai and Prasanna 2000, 25). Another focus of genetic transformations has been production of higher-value hybrids, in crops such as mustard. According to their mainly private sector developers, such transgenic crops respond to a market opportunity and meet a priority need, given that India imports large quantities of oilseeds (Mubashir 1999, 281).

Table 1: Developments in transgenic research in India

Institute	Transgenic crop	Transgene inserted	Aim of project and progress made
Central Tobacco Research Institute	Tobacco	Bt toxin gene	To confer plant resistance to pests. One round of contained field trials completed
Bose Institute, Calcutta	Rice	Bt toxin gene	To confer plant resistance to lepidopteran pests. Ready for greenhouse testing
Tamil Nadu Agricultural University, Coimbatore	Rice	Reporter gene	To study extent of transformation frequency.
University of Delhi, South Campus, Delhi	Mustard	Bar, Barnase, Barstar	To develop better hybrid cultivars suitable for local conditions. Ready for greenhouse trials
-same-	Rice	Selectable marker genes	To undertake gene regulation studies. Transformations completed
National Botanical Research Institute, Lucknow	Cotton	Bt toxin gene	To confer plant resistance to lepidopteran pests. Transformation in progress
Indian Agricultural Research Institute, Shillong substation	Rice	Bt toxin gene	To confer plant resistance to lepidopteran pests. Transformation in progress.
Central Potato Research Institute, Simla	Potato	Bt toxin gene	To confer plant resistance to lepidopteran pests. Ready for greenhouse trials
ProAgro-PGS India Ltd. New Delhi	Brassica (mustard), cauliflower	Bar, Barnase, Barstar	To develop better hybrid cultivars suitable for local conditions. Glasshouse experiments underway for cauliflower. Contained field trials in over 15 locations completed for mustard. Further contained open-field research trials in progress at many locations
-same-	Tomato, Brinjal, Cauliflower, Cabbage	Bt toxin gene	To confer plant resistance to lepidopteran pests. Glasshouse experiments in progress. One season contained field trials completed for tomato.
Mayhco, Mumbai	Cotton	Bt toxin gene	To confer plant resistance to lepidopteran pests. Multicentric field trials in over 40 locations completed and further contained field trials in progress
Rallis India Ltd. Bangalore	Chili, Bell pepper, Tomato	Snowdrop Lectin gene	To confer plant resistance to pests. Transformation experiments in progress.
Jawaharlal Nehru University, New Delhi	Potato	Gene expressing for protein with lysine	To increase nutrient value. Transformation complete, under evaluation.
Indian Agricultural Research Institute, New Delhi	Brinjal, Tomato, Cauliflower, Mustard	Bt toxin gene	To confer plant resistance to lepidopteran pests. Transformation and greenhouse trials completed. One season field trial completed for brinjal and potato

Source: Compiled by author from Ghosh, P.K., "Biosafety Guidelines: International Comparisons" in *Genetically Modified Plants: Benefits and Risks* (Proceedings of a Workshop held on 24 June 1999, Tata Energy Research Institute, New Delhi), Table I, pp. 59-60; and from Ramanaiah (1999: pp. 30).

As Table 1 also reveals, the private sector in India has focused largely on developing hybrid crops, or back-crossing genetic modifications already developed for other markets into traditional Indian varieties. As discussed in the next section as well, such choices are influenced by the extent of intellectual property protections available for new varieties of transgenic crops. In contrast, research in the public sector has also sought to tackle open-pollinated crops, as well as more complex modifications, such as nutritionally altered or stress tolerance (including drought, salinity or cold tolerance). Examples include enhancing protein content in potatoes, isolating salt and cold resistance genes, or promoting delayed ripening for commodities requiring long shelf life (Rai and Prasanna 2000, DBT 2000a,b).

Despite the "public good" motivation of much of the DBT-supported public sector transgenic research, the public sector lags behind the private sector in field testing and commercializing the products of its basic research. One important reason for this is that stress tolerance and nutrient enhancing are more complex traits to genetically engineer. Another important reason is that a very small percentage of public funds get allocated for product development and safety testing, as compared to basic research.[2] Resources and infrastructure needed to undertake the requisite biosafety assessments, for example, are currently lacking or uncoordinated across public sector institutes. If so, public sector transgenic research in India runs the risk of moving from one basic research project to another, with little longer-term planning on how the research relates to desired societal goals.

Given the funding and infrastructural constraints facing the public sector's research efforts, and the growing interest of the private sector in transgenic crop development, there is an opportunity now to develop public-private partnerships, which mobilize the strengths of the two sectors, and hence develop both economically viable and socially relevant transgenic crops. The potential for synergies between the public and private sectors is dependent, however, not only on agricultural policy in India, but also on evolving biosafety, trade and intellectual property rights policies. These policies are likely to influence the potential for collaboration, as well as the extent to which biotechnology knowledge generation produces desired societal outcomes. The next section analyzes these regulatory policies and their inter-play with trade, market access and national competitiveness concerns.

3. Regulatory Regimes Impacting Biotechnology Uptake

Domestic regulatory frameworks dealing with biosafety and intellectual property protection are critical to biotechnology knowledge generation and diffusion in India, and remain the subject of much controversy and public scrutiny. While the impact of intellectual property regimes on hindering or facilitating equitable access to new technologies is at the center of worldwide debate,[3] how biosafety regulations impact biotechnology uptake and adaptation has received relatively less attention. Section 3.1 discusses intellectual property policy in India and its implications for use of transgenic technology. Section 3.2 analyses the emerging biosafety framework and its relevance for biotechnological research and diffusion.

3.1. Policies for Intellectual Property Protection

The debate on intellectual property rights for transgenic crops is part of a larger and more long-standing debate about plant variety protection and plant breeders' rights in India (Paarlberg 2001). This section examines the development of Indian IPR legislation and the influence of global regimes on domestic laws. It then discusses how the intellectual property environment has affected the process of transgenic technology uptake in Indian agriculture.

3.1.1. Indian plant variety protection legislation

Until recently, there was no legislation allowing for intellectual property protections

over plants and live organisms and no explicit acknowledgement of plant breeders' rights to new crop varieties in India. The 1970 Indian Patent Act explicitly excluded living materials. After extensive debate, however, the Indian Parliament passed a new legislation, the Indian Protection of Plant Varieties and Farmers' Rights Bill (henceforth PPVFR), in late 2001 (Seshia 2002). Unlike Indian biosafety regulations, which were first adopted in the 1980s, and which have been amended *post facto* as a result of public concerns and recent controversies, domestic IPR legislation is the outcome of a decade-long nation-wide debate (Seshia 2002).

Global regimes, in particular, the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), have provided further impetus to the development of the plant variety protection law in India. The TRIPs Agreement requires, in its much-debated Article 27.3(b), the adoption of *sui generis* plant variety protection systems in developing countries by the end of the 1990s (TRIPs 1994), an obligation that most developing countries have not yet managed to fulfill.

In India, debate over plant variety protection predates TRIPs, and relates not only to concern over patenting and the growing privatization of knowledge, but also to ensuring adequate protection and compensation for indigenous and traditional knowledge. India has long been a leader, for example, in urging global fora such as the United Nations Convention on Biological Diversity or the United Nations Educational, Scientific and Cultural Organization (UNESCO) to set up mechanisms to "recognize and conserve knowledge systems that predate the scientific revolution" (Jayaraman and Masood 1999).

There has, in particular, been vocal opposition to patenting of seed, which is tied to socioeconomic concerns over increased foreign and private sector dependence in this critical area. As stated by a prominent critic of seed patenting in India, Dr. Suman Sahai of the Gene Campaign:

> The issue of gene and seed patents has exploded on the scene…the battle for political and economic control over the genetic resources of the world has begun. This battle cannot be fought in laboratories, between scientists… The Campaign's sustained position continues to be against patents and privatization in this field…Instead of a few large seed companies pushing their successful varieties, a de-centralized seed industry should be established in rural areas…to ensure the country's food security and livelihood of farmers (Sahai, undated, pp. 4, 7, 16).

Shaped by these debates, the first draft of the Indian plant variety protection legislation was introduced as early as 1993, with subsequent iterations in 1997, 1999 and 2000, which sought to both adhere to newly acquired TRIPs obligations, but also accommodate the concerns and priorities of a developing country such as India (Seshia 2002). The new legislation provides, first and foremost, for Plant Breeders' Rights for plant varieties that fulfill the criteria of distinctiveness, uniformity and stability (the so-called DUS criteria). In this, the Indian legislation is similar to the 1978 version of the reigning international framework for plant variety protection, the International Convention for the Protection of New Varieties of Plants (UPOV).

Yet, it also differs from it in significant ways, with potentially important implications for biological knowledge flows to and from India. First, the legislation calls for mandatory licensing of protected plant varieties after three years. This reflects the importance attached to ensuring that plant varieties protected under the Act become available for public sector research and use in a timely manner. Second, and in another striking feature, the Indian PPVFR allows for protection of "extant varieties" of modified plants, defined as "varieties that are notified under Section 5 of the Seeds Act, 1966" (Draft PPFVA 1999, quoted by Seshia 2002).

As Seshia points out in one of the first analyses of this very recently concluded legislation, inclusion of protection for extant varieties in the PPVFR reveals the influence of the public sector agricultural research establishment in its formulation, since the provision benefits primarily the Indian public sector, given that only public sector extant varieties are registered

under the 1966 Seed Act. Third, and perhaps the most far-reaching acknowledgement of developing country agricultural practices and priorities, is the provision to allow farmers to save and exchange seed. This was a long battle, and one that is still on-going, as the intellectual property environment evolves both domestically and internationally.

Fourth, the PPVFR is also innovative in its enshrining of the concept of Farmers' Rights in the bill. Farmers' Rights has its genesis in discussions at the global level within the Food and Agricultural Organization (FAO) in the context of negotiating the International Undertaking on Plant Genetic Resources. As articulated within India by the M.S. Swaminathan Institute:

> Farmers Rights' stem from the contribution of farm women and men and rural and tribal families to the creation, conservation, exchange and knowledge of genetic and species diversity of value in plant breeding (Swaminathan 1994: 20, quoted in Seshia 2002].

Through enshrining farmers' rights, the PPVFR is thus one of the first domestic plant variety protection legislations to acknowledge that farmers are also plant breeders and innovators and hence merit recognition as such. However, the Act does not interpret farmers rights to mean awarding farmers' exclusive rights to plant varieties whose evolution they have contributed to, as is the case for plant breeders. Instead, according to the Act, farmers' contributions to varieties that subsequently receive protection under the PPFVR should be acknowledged, through financial compensation from a national-level Gene Fund.

Although the PPFVA debates have so far been more broadly about the merits of allowing and encouraging greater private sector involvement in the agricultural and seed sector, developments in the broad arena of plant variety protection have important implications for transgenic plants and seed as well, which are explored further below.

3.1.2. Implications of domestic IPR legislation for transgenic crops

To date, as seen earlier, the private sector has responded to the lack of formal intellectual property protections within India by choosing to develop hybrid rather than open-pollinated crops, since intellectual property concerns are less salient for hybrids. Since such a strategy has been feasible so far, and with the lowering of barriers to private sector entry into the seed market over the last decade, the lack of intellectual property protection has not been the key hurdle to private sector activity in the Indian agricultural sector (Paarlberg 2001).

This has also been the case for transgenic crops, especially those crops which use genetic modifications and techniques that have first been developed for use in developed country markets. In the case of transgenic technology, the dominant mode of private sector involvement has been through collaborations between foreign multinationals and domestic seed companies. One of the most prominent and visible of these collaborations is between the Monsanto Company and the well-reputed Indian seed company Mahyco or the Maharashtra Hybrid Seed Company. The aim of this collaboration has been to develop transgenic pest resistant cotton suited to Indian ecological and socio-economic conditions.

The collaboration dates back to 1995, when Mahyco first acquired a Bt toxin gene[4] from Monsanto and backcrossed it into Indian cotton crop varieties. Mahyco then requested approval to field test the resultant transgenic cottonseed. During this same period, Monsanto acquired a 26% stake in Mahyco. Permission to conduct 40 field tests in 9 states was granted to Mahyco by the Department of Biotechnology in 1998[5]. In March 2002, the Mahyco-Monsanto transgenic Bt cotton became the first crop to receive approval for commercialization in India (Jayaraman 2002). Given that this was a hybrid crop, and given that the relevant Bt technology was shared by Monsanto with an Indian private sector company in which Monsanto has a stake, intellectual property protection or lack thereof in India was not a key hurdle. If anything, the domestic biosafety regime, discussed later, proved to be the main obstacle to the private sector's desire to develop and commercialize Bt cotton in India.

It is unclear, however, whether and how implementation of the recently concluded PPFVA, and its subsequent evolution, will change the incentive structure for private sector transgenic crop development and for collaborative public-private partnerships in this area. This is critically important for the future, however, as all important components and production processes in a transgenic crop (whether hybrids or open-pollinated varieties) are increasingly patented or considered "confidential business information". As illustrated by the general manager of ProAgro PGS (a private sector joint venture company at the forefront of developing transgenic crops in India), multiple intellectual property protections cover almost all key components of a transgenic crop, where permitted. For example, the protections cover the plant variety germplasm, the selectable marker gene, the novel gene's trait, the promoter and coding sequence, the transformation technology, and the gene expression technology (Kapur 1999: 90, figure 6).

The Department of Biotechnology and public sector research institutes have responded to such challenges and the changing environment for intellectual property protection in India in a number of ways. One of the most immediate has been to try to raise awareness amongst researchers about rapidly evolving policy developments in the field of intellectual property rights and the implications for public sector research. Thus, the Department of Biotechnology has expended substantial effort on disseminating information amongst potential affected parties by organizing "roving seminars" on biotechnology patenting which are widely attended by scientists from around the country (DBT 2000a).

Another activity, with potential relevance for intellectual property rights, has been to establish or mirror databases of genomic research. Genomic databases are being established under the aegis of the National Jai Vigyan Science and Technology Mission for Genomic Research at premier Indian institutes such as the Indian Institute of Science in Bangalore and the Jawaharlal Nehru University in New Delhi. From DBT's perspective, these will:

> provide unhindered access to large amount of databanks for analysis of not only the primary information but also secondary information resources. Important research leads are expected to be generated through in-depth analysis of such data and it is hoped that these Mirror sites will act as knowledge pathways for discoveries in modern biology and biotechnology. (DBT 2000b)

This suggests that, even as the need for intellectual property protection for modified plants and seed is acknowledged at the highest political and regulatory levels in India, the importance of keeping information accessible for public sector use is seen as critical as well. The challenge is to continue to strike this balance in a manner that will facilitate socially beneficial knowledge flows relating to biotechnology in the near future.

3.2. Policies for Ensuring Safe Use of Biotechnology

In addition to intellectual property rights, regulatory policies dealing with biosafety (i.e. safe use of biotechnology) have been a key influence on the speed and process of biotechnology uptake in Indian agriculture. Evolving global- and national-level biosafety regimes have important implications for the flow of biotechnology into a country and for development of appropriate domestic innovations, even though such regimes have received relatively less attention in the technology diffusion literature than have IPR regimes.

The presence (or absence) of domestic biosafety regimes can impact knowledge flows in two ways. In the case of controversial new technologies such as genetic engineering, weak biosafety regimes may slow down the flow of biotechnological innovations into a country. Since adoption of such innovations remains controversial, and their safe use is context-dependent, there is clear need for existence of a domestic regulatory framework, with rules for safety assessments and with the capacity to undertake such assessments. The absence of such a frame-

work can then be a disincentive (also for the private sector) to operate in a country.

Equally, however, overly stringent biosafety regulations can also impede the flow and development of appropriate biotechnological innovations, if the stringency stymies research or discourages investment in long-gestation transgenic crops. Striking a balance between *adequate and onerous biosafety oversight* is thus the critical challenge facing developing countries, a challenge that is exacerbated by the fact that experience with biosafety standard-setting is also most limited in such countries. The struggle to strike this balance has been evident in India as well, with implications for adoption of transgenic technology in Indian agriculture.

3.2.1. An evolving biosafety regime: excessive or appropriate?

India's biosafety regulations date back to the late 1980s, making it one of the first developing countries to formulate such policies. Safety of genetically modified organisms is regulated in India under the Indian Environment (Protection) Act of 1986 (henceforth the EP Act)[6]. The objective of the EP Act is the protection and improvement of the environment. To meet this objective, the Act calls for regulation of "environmental pollutants" which are defined as "any solid, liquid or gaseous substance present in such concentration as may be, or tend to be, injurious to the environment" (EP Act 1986: Chap. 1, Section 2b). The Ministry of Environment and Forests used this broad definition of "environmental pollutant" in 1989 to issue a set of legally binding rules to govern use of genetically engineered organisms under the EP Act[7].

The 1989 "Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells" (henceforth 1989 Rules) constitute the legally binding regulatory framework for safe use of genetically modified organisms in India (Rules 1989, Ghosh and Ramanaiah 2000). As required by the 1989 Rules, biosafety guidelines were first issued by the Department of Biotechnology under the Ministry of Science and Technology in 1990. These guidelines were revised and expanded in 1994 and 1998 (DBT 1994, 1998).

The Indian biosafety regulatory framework thus comprises of the 1989 Rules and the 1990, 1994 and 1998 DBT Guidelines. These cover the entire spectrum of activities relating to genetically modified organisms, including:

> research involving genetically modified organisms,... genetic transformations of green plants, rDNA technology in vaccine development, and large-scale production and deliberate/accidental release into the environment of organisms, plants, animals and products derived from rDNA technology (DBT 1990, 1).

Production facilities such as distilleries and tanneries that use genetically modified organisms are also covered (Rules 1989, Article 1). The 1990 "Recombinant DNA Safety Guidelines" and 1994 "Revised Guidelines for Safety in Biotechnology" provide guidance on containment and safe laboratory practices for GMOs in the agricultural and pharmaceutical sectors (DBT 1990, 1994). They also, however, contain an important change from the 1989 Rules in their treatment of deliberate release of GMOs. While the 1989 Rules effectively banned such releases (permitting them only under special circumstances)[8], the 1990 Guidelines permit them, with a shift to assessing and managing ecological and health risks that might result. In doing so, the Department of Biotechnology is following a similar path taken by developed country leaders in transgenic research such as the United States in the 1970s, where self-regulation by scientists initially prohibited deliberate release of GMOs. However, this was revoked in short period of time, in a move that was contested within the scientific community (Wright 1994).

The 1998 "Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts" add to the regulatory architecture by calling for toxicity and allergenicity data for ruminants, such as

goats and cows, from consumption of transgenic plants (DBT 1998). Biosafety regulators claim that Indian risk assessment is "even stricter than the best models elsewhere"[9] in pointing to such requirements, which are portrayed as very relevant to the Indian context. The question of whether such stringency is also appropriate, or is counterproductive, remains very much a matter for continuing dispute, as discussed further below.

3.2.2. Safety concerns or socio-economics?

The push to extend and clarify biosafety oversight in India can be partly traced back to sustained controversy around transgenic crops in late 1998 and 1999, which centered on alleged testing of "terminator technology". Called "genetic use restriction technologies" (GURTs) by developers, such technologies can be used to produce sterile seed. The objective is to prevent farmers from saving transgenic seed. This is defended by proponents of the technology as a necessary biological method of intellectual property protection and is attacked by opponents as depriving farmers of an age-old right to save, share and exchange seed (Science for People 1999; Hindustan Times 1998a; Indian Express 1999; Hindu 1999b).

Disputes over terminator technology thus reveal the inter-linkages between socioeconomic concerns and biosafety considerations in regulating use of transgenic crops. The origin of the allegation that terminator technology was being tested in India is unclear, yet the (false) rumor became tied to the biosafety field-testing of Mahyco's transgenic cotton underway at the time[10]. As a result, farmers uprooted transgenic cotton from field trials in the southern Indian states of Andhra Pradesh and Karnataka (Hindustan Times 1998c). A period of media debate and questions in Parliament culminated in an announcement by the Minister of State for Agriculture, Som Pal, that terminator technology was not being tested and that products with terminator genes would not be imported (Hindustan Times 1998b).

This controversy had the concrete impact, however, of mandating one entry point into the country for all imports of transgenic material, whether for research, field-testing or commercial use. This entry point is now the National Bureau of Plant Genetic Resources (NBPGR) under the Indian Council for Agricultural Research, which has traditionally been responsible for quarantine procedures for imported live organisms. Following the terminator debate, the NBPGR has also been mandated by the Government of India to develop probes to detect presence of terminator genes in imported material, notwithstanding promises by Monsanto that it will not bring this technology into India (Hindu 1998, Monsanto 1998).

This commitment of scarce public resources to monitor and prevent entry of as yet uncommercialized technology highlights the importance of socioeconomic and dependency concerns as well as the force of public opinion in shaping biosafety rules in India. In general, it highlights that concerns over transgenic crops in India go beyond technically assessable ecological and health harm, and hence cannot be mediated within a biosafety regime alone.

This primacy of the socioeconomic is also evident in Indian policy toward imports of transgenic commodities (i.e. transgenic seed varieties that are intended for processing rather than for planting). Following a 1998 outbreak of illness in New Delhi from contaminated mustard oil, the Ministry of Agriculture authorized imports of soybean seed from the United States for processing into edible oil. A few watchdog groups alerted the media to the fact that genetically modified soybean had been imported into the country, without the authorization of the GEAC under the Ministry of Environment and Forests, which must approve all imports of genetically modified material for commercial use.

In responding to questions in Parliament, the official stance of biosafety regulators was that no genetically modified material had been imported, a stance made possible by the fact that the soybean imports from the United States are not currently labeled "transgenic" nor are they segregated from non-transgenic soybean[11]. Following this incident, the Ministry of Agriculture and Ministry of Commerce are now jointly responsible to ensure that no transgenic commodi-

ties are currently being imported into India. Although no formal amendments to the biosafety regulations have been made to this effect, implementation of this new decision as of late 2000 required that exporters provide a written guarantee on a case-by-case basis that commodity imports did not contain transgenic varieties[12].

Again, this decision has to be seen not just from a safety but from a socioeconomic perspective. In India, the seed sector remains heavily regulated, in keeping with a long history of opposition to food imports, dating back to fears of food dependence in the early 1960s prior to launch of the Green Revolution (Paarlberg 2001, Seshia 2002). While restrictions on imports of vegetable seeds are now being lifted through amendments to existing seed legislation, both imports and exports of seed for major crops such as wheat and rice remain strictly limited (Seshia 2002). As of late 2000, oilseeds, such as groundnut, cotton, sunflower, canola and soybean could be imported, but only through agencies specified by the central government (Kapur, undated, 16-17).

In this context of an extremely restricted commodity trade, it is reasonable from the Indian biosafety regulator's perspective to prevent entry of transgenic commodities into the country, as long as there is public concern about such imports, and as long as there is no perceived urgent socioeconomic need for them. Such primacy of the socioeconomic is equally evident, paradoxically, in emergencies such as the Orissa famine of 2000, when food aid containing transgenic commodities was distributed, notwithstanding NGO claims about risks posed by such imports and violations of Indian biosafety regulations (RFSTE 2000).

Another key trade consideration is maintaining export markets for primary agricultural products. Given growing domestic opposition to transgenic crops within agricultural trading partners such as the European Union, countries like India may face an economic imperative to maintain their "GM-free" status in agricultural commodities aimed primarily at such markets (Paarlberg 2000, 2001). While restrictions on commodity imports into India are driven by a geo-political desire for food self-sufficiency (even if such self-sufficiency is cost-ineffective), a clear economic imperative, that of maintaining primary commodity export markets, may drive hesitation to develop and export transgenic crops. In light of this, a biotechnological divide in the agricultural sector, i.e. a slower development of some transgenic crops, may be a strategic domestic decision driven by export and market imperatives, rather than lack of access to relevant knowledge or inadequate research capacity.

Such socioeconomic imperatives are also reflected in a key addition in the 1998 Revised Biosafety Guidelines – the requirement to generate data on comparative economic benefits of a modified plant (DBT 1998, Ghosh and Ramanaiah 2000). The 1998 Biosafety Guidelines call for a demonstration that a transgenic crop is both "environmentally safe and economically viable" (DBT 1998, 6). In addition to safety testing, an agronomic evaluation to determine economic advantage to farmers from a transgenic crop is seen as a necessary component of the crop approval in a developing country context.

Thus, when the government granted permission for large-scale field-testing of transgenic cotton in India in July 2000 (the first crop to receive such approval), the mandatory data to be generated by its private sector developers included "cost of transgenic seed, projected demand, and the area to be covered under transgenic cotton cultivation" (Government of India 2000)[13]. This highlights again the socioeconomic dimension to transgenic crop approval in India, even if executed under the auspices of a biosafety regime.

3.2.3. Determining stringency of regulations: who has the authority?

In disputes over stringency of biosafety regulations, a critical issue has also been where the authority to regulate and approve transgenic crops lies. This is currently divided in India between the Department of Biotechnology of the Ministry of Science and Technology, and the Ministry of Environment and Forests. All transgenic experimental research in the country is to

be overseen by the Review Committee on Genetic Manipulation (RCGM) under the Department of Biotechnology. Deliberate release and commercialization of GMOs is to be overseen by the Genetic Engineering Approval Committee (GEAC) under the Ministry of Environment and Forests (Rules 1989, Ghosh and Ramanaiah 2000).

In addition to these national-level committees, every institution engaged in genetic engineering research is required to establish an Institutional Biosafety Committee. Furthermore, State Biotechnology Coordination Committees and District-Level Committees are to be set up to facilitate information exchange between the center and the states. The most recent addition to this institutional framework is a Monitoring and Evaluation Committee to oversee the agronomic evaluation of the transgenic crop during field tests and to monitor biosafety data generation. Finally, a Recombinant DNA Advisory Committee is to meet occasionally to review national and international developments in biotechnology and recommend appropriate biosafety regulations for India (Rules 1989, DBT 1990, 1998). The composition and functions of these committees are summarized in Table 2.

Table 2: Biosafety decision-making structure in India (as of 2000)

Competent Authority	Composition	Functions
Recombinant DNA Advisory Committee (RDAC)	As determined by the Department of Biotechnology—to consist of experts in their individual capacity	To review biotechnology developments at national and international levels; to recommend suitable biosafety regulations for India.
Review Committee on Genetic Manipulation (RCGM)	Member Secretary, Department of Biotechnology; Indian Council of Medical Research; Indian Council of Agricultural Research; Council of Scientific and Industrial Research; other experts in their individual capacity	To issue guidelines for GMO research; to authorize rDNA projects in high risk category III; to authorize controlled field experiments; to permit imports of GMOs for research
Institutional Biosafety Committees (IBSC)	Head of the Organization; scientists engaged in rDNA work; Biosafety or Medical Officer; Nominee, Department of Biotechnology	To oversee rDNA research activities; to seek RCGM approval for category III risk; to ensure adherence with biosafety guidelines; to prepare an emergency plan; to inform DLC, SBCC & GEAC about relevant experiments.
Genetic Engineering Approval Committee (GEAC)	Chair, Additional Secretary, Ministry of Environment and Forests; Co-Chair: Dept. of Biotechnology representative; Representatives from Ministry of Industrial Development, Departments of Biotechnology and Atomic Energy; Indian Council of Agricultural Research; Indian Council of Medical Research; Council of Scientific and Industrial Research; Directorate of Plant Protection; Central Pollution Control Board; others in individual capacity.	To authorize commercial use (including import) of GMOs or their products; to authorize large scale production and release of GMOs and their products into the environment; to mandate restrictions or prohibitions on production, sale, import or use of GMOs, if necessary.
State Biotechnology Coordination Committee (SBCC)	Chief Secretary, State Government; Secretaries, Department of Environment, Health, Agriculture, Commerce, Forests, Public Works, Public Health; Chairman, State Pollution Control Board; State microbiologists and pathologists; Other experts in individual capacity	To periodically review safety and control measures in institutions handling GMOs; to inspect and take punitive action in case of violations through the State Pollution Control Board or the Directorate of Health; to act as nodal agency at the state level to assess damage, if any, from release of GMOs, and to take on site control measures.
District-Level Committee (DLC)	District Collector; Factory Inspector; Pollution Control Board Representative; Chief Medical Officer; District Agricultural Officer; Public Health Department Representative; District microbiologists/pathologists; Municipal Corporation Commissioner; Other experts in individual capacity	To monitor safety regulations in installations; to investigate compliance with rDNA guidelines and report violations to SBCC or GEAC; to act as nodal agency as district level to assess damage, if any, from release of GMOs and to take on site control measures
Monitoring and Evaluation Committee (MEC)	Chairman, jointly elected by Secretary, Department of Biotechnology and Secretary, Department of Agricultural Research and Education. To include Plant Biotechnologists, Plant Ecologists, Seed Technologists, and Plant Breeders (nominated by RCGM or ICAR), an NBPGR nominee, an MOEF nominee, and the Member-Secretary of the RCGM.	To undertake field visits at experimental sites; to suggest remedial measures to adjust original trial design; to assist RCGM in collecting and analyzing field data; to collect or cause to collect information on comparative agronomic advantages of transgenic plants

Source: Compiled by author from Rules (1989), DBT (1998), Ghosh and Ramanaiah (2000).

While this is an elaborate decision-making structure on paper, its functioning remains far from smooth. As can be seen from the table, the two national regulatory committees, the RCGM and the GEAC, consist mainly of scientists from public sector institutions as well as government bureaucrats. Scientific disciplines represented include genetics, molecular biology and the agricultural sciences, yet there are almost no social scientists and no members of the public involved. Representatives from industry and non-governmental organizations can be invited to participate in their individual capacities as experts, but there is no formal requirement to involve them (Rules 1989, DBT 1990, 1994, 1998).

Furthermore, although the division of responsibility for biosafety appears clearly delineated between the Ministry of Environment and Forests and the Department of Biotechnology, it has been a source of much controversy (RFSTE 1999, DBT 1999b). As seen earlier, according to the 1989 Rules, experimental research with transgenic crops is under the jurisdiction of the Department of Biotechnology, while deliberate releases are to be regulated by the Ministry of Environment and Forests. One key dispute is whether field trials constitute experimental research or a deliberate release (and hence whether the Department of Biotechnology's biosafety committee, the RCGM, or the Ministry of Environment and Forests' committee, the GEAC, should oversee such trials).

This question received sustained scrutiny in a public interest litigation filed in the Indian Supreme Court in 1999 by Vandana Shiva's Research Foundation for Science, Technology and Ecology (RFSTE), a vocal critic of biotechnology use in agriculture. The case, filed against the Department of Biotechnology, the Ministry of Environment and Forests, the Ministry of Agriculture, the Maharashtra Hybrid Seeds Company or Mahyco (an Indian private sector seed company), and Mahyco-Monsanto Biotech India Ltd (a joint venture established between Monsanto and Mahyco) alleged that improper authorization was given to field-test the transgenic cotton in India and, moreover, that the Indian biosafety framework fails to protect against ecological and health harms (RFSTE 1999a, 1999b).

More particularly, the RFSTE alleged that the field-testing of transgenic crops constituted a deliberate release into the environment, and hence approval for such testing should have come from the GEAC under the Ministry of Environment and Forests, rather than from the RCGM under the Department of Biotechnology (RFSTE 1999a). In response, government biosafety regulators argued that the field tests constituted small-scale "experimental research" rather than deliberate release (DBT 1999b).

The 1989 Rules clearly state, however, that release of GMOs into the environment is to be overseen by the Ministry of Environment's biosafety committee. Partly as a result of this controversy, a late addendum to the 1998 Biosafety Guidelines (issued in September 1999) now states that the RCGM under the Department of Biotechnology has the authority to approve "small experimental field trials for research" limited to a total area of 20 acres in multi-locations in one crop season, with any one location not exceeding one acre.

Field trials exceeding these limits are to be considered large-scale releases and will require approval from the GEAC under the Ministry of Environment and Forests (DBT 1999a). It is striking, however, that no ecological or biosafety rationales are offered for the "one-acre plots in 20 locations" distinction between experimental research and release[14]. Rather, the main purpose in defining field trials as "research" rather than "deliberate release" seems to be to ensure that the Department of Biotechnology (which can only regulate experimental research) retains authority over initial field-testing of transgenic crops.

The role of other relevant ministries in biosafety governance, such as the Ministries of Agriculture and Health, is still uncertain and evolving. Issues that remain to be determined include whether transgenic seed is to be governed under biosafety regulations alone or whether and how the 1966 Indian Seed Act also applies. The Ministry of Agriculture is considering amendments to Indian seed legislation to cover transgenic seed. A particular concern is ensuring seed purity, i.e. ensuring that use of transgenic seed does not contaminate regular seed lines

(Singhal 2000, Katiyar 2000, Kapur undated, Dhillon and Randhawa 2000). Related to this is the question of whether deregulated transgenic seed is to be treated as regular seed or whether it will require distinct seed varietal registration procedures. If so, a critical challenge facing developing countries such as India is ensuring that transgenic seed can be segregated from non-transgenic seed, to both make sure that preconditions attached to transgenic seed are being met (a biosafety concern) and that farmers have a choice regarding whether or not to use transgenic seed (an agronomic and socio-economic concern) (Katiyar 2000, Singhal 2000).

The Ministry of Agriculture sees this issue as within its regulatory domain and outside the competency of either the Department of Biotechnology or the Ministry of Environment and Forests. Current varietal registration rules in India offer two routes for placing new seed on the market: testing of seed and certification of efficacy through "all-India coordinated trials" administered by the public sector agricultural research system (a process which can take many years) or the alternative option of "truthful" labeling of new seed to be placed on the market. The debate turns on whether the "truthful labeling" option, historically preferred by the private sector for speedy entry into the market, should be permitted for transgenic seeds or whether the all-India coordinated trials should be made mandatory (for a detailed analysis, see Dhillon and Randhawa 2000). Given the lack of long-term empirical experience, not just with safety, but also with efficacy and performance of transgenic crops, mandatory all-India coordinated trials may well be the legitimately precautionary way forward. With recent approval to commercialize the first transgenic crop, the pressure to clarify processes for transgenic seed certification and segregation is greater[15].

Furthermore, currently a transgenic crop approved for commercialization is only "conditionally" deregulated[16]. Thus, some form of continued monitoring is also mandatory during commercial growing of a transgenic crop. Two concerns arise, however. First, who is responsible for ensuring that the conditions are being met? Second, are certain conditions, such as mandatory isolation distances or refugia, even feasible on a large scale in the Indian context? These questions have long been posed, since the first testing of transgenic crops in India. As a leading agricultural scientist and a supporter of transgenic crop use in India points out with regard to resistance management for Bt crops:

> ...it is recommended that as much as 20% of the cropped area should be maintained as a refuge. However, under Indian farming conditions, a 20% crop area as a refuge for susceptible insects is unthinkable. Most of our farmers have small land holdings of about one hectare. ...Alternate strategies of resistance management need to be developed that are especially suitable to the agricultural systems of developing countries. (Raina 2000, 11-12)

The recent approvals for commercial planting of transgenic varieties of cotton bring this issue to the forefront. Furthermore, whether meeting such conditions is feasible or not, the responsibility for monitoring whether the conditions are being met is placed on the individual states where the transgenic crop is to be grown (TI 2002). Yet, as controversies over the earlier and more spatially limited transgenic crop field-tests revealed, the infrastructure at the state-level for monitoring is underdeveloped at best.

During field-testing of Mahyco's transgenic cotton across India, for example, a State Biotechnology Coordination Committee had not yet been set up in most of the states where the crop was being field tested, and state and district-level authorities were unaware that transgenic cotton was being tested in their territories. It was only in response to the terminator gene controversy that the Karnataka government, for example, established a State Biotechnology Coordination Committee in 1998. The government portrayed this as a major step forward in enhancing vigilance over transgenic crops even though such a Committee was required by the 1989 Rules (Rules 1989, Hindu 1998). The lack of state-level monitoring capacity was also vividly illustrated by a scandal in the Indian state of Gujarat last year, where unapproved Bt

cotton seed was found growing on large tracts of land.

Of course, oversight of safe use of biotechnology will continue to evolve in response to these challenges and many good faith efforts are underway to address the most egregious gaps in the regulatory framework and the most vocal public concerns. For example, there are efforts underway to clarify who has jurisdictional authority for human health and food safety concerns raised by GMO use in agriculture. The 1954 [Indian] Prevention of Food Adulteration Act does not specifically cover transgenic entities. However, this is dependent upon how broadly food adulteration is understood and whether transgenic food additives can be considered adulteration, an issue which goes to the heart of whether transgenic modification *per se* is potentially hazardous[17].

As with the Ministry of Agriculture, the Ministry of Health is thus also engaged in a process of internal consultation to determine its role in regulating transgenic foods, once available. The Ministry of Health is the lead ministry responsible for negotiating labeling requirements for genetically modified foods within the Codex Alimentarius Commission (a United Nations standard setting body jointly established by the Food and Agricultural Organization and the World Health organization). With approval of the first transgenic crop (even though Bt cotton is not a traditional food crop), there is renewed impetus to clarify its domestic jurisdictional authority for both labeling and safety of transgenic foods.

In responding to criticisms of the biosafety regime, government regulators have thus both attempted to clarify regulations (as seen in the examples above) and make them more stringent. Yet, in doing so, a key risk is that broad and myriad concerns voiced by different groups about use of biotechnology in agriculture are sought to be translated into assessments of technical risk. Furthermore, as more safety information is required of private sector producers, ensuring its credibility becomes a key challenge. These issues are examined next.

3.2.4. The credibility challenge: whose biosafety tests are sound and which biosafety tests are necessary?

A critical challenge facing the nascent biosafety regime in India, with implications for development of transgenic crops, is ensuring the credibility of biosafety data being generated by producers of such crops (to date mainly the private sector). The Monitoring and Evaluation Committee, established by the Department of Biotechnology in 1998, was an explicit response to a need to enhance credibility of biosafety data being produced by the private sector and hence facilitate the approval process. However, this government appointed committee only visits a transgenic crop field site a couple of times a year for a few hours, in visits that are preplanned and organized by the private sector producers (although on paper the committee can visit at any time). According to a member of the Committee, such a mode of functioning is patently inadequate and serves a mere “policing” rather than a monitoring and evaluation function, with the main accomplishment being only “to establish that the field sites actually exist”[18].

In contrast, adequate monitoring would require, at minimum, more frequent and longer site visits during different stages of growth of a transgenic crop. It would require taking samples away for independent testing, rather than merely reviewing data provided to the Committee by producers of transgenic crops. It would require modifications in the composition of the Committee (currently consisting of high-level scientists with multiple managerial responsibilities) to also include junior scientists with both the time and on-the-ground training to monitor diverse biosafety aspects of the field tests.

In response to the perceived inadequacy of current monitoring regimes, recent actions by regulators to enhance the credibility of private sector biosafety data include mandatory involvement of state-level agricultural university scientists, not only to monitor safety tests, but also to participate in generation of biosafety data. Biosafety regulators have also mandated that

public sector laboratories generate the required toxicity and allergenicity data for transgenic crops produced by private entities (Government of India 2000).

The challenge of ensuring appropriateness and credibility of biosafety testing has also been highlighted, for example, in the debate over generation of toxicity and allergenicity data for ruminants, as called for by the 1998 Biosafety Guidelines, and mandated by the government during biosafety evaluation of Mahyco's transgenic cotton (DBT 1998, Government of India 2000). Although the requirement to generate such data is defended as scientifically valid by Indian biosafety regulators, it is characterized as unscientific by some producers of transgenic crops asked to generate such data. Private sector transgenic crop producers perceive such requirements as reflecting regulators' need for the appearance of stringency rather than a scientifically sound judgement that such data are necessary[19]. Furthermore, as these producers point out, such tests can be expensive, especially if public laboratories have to be contracted and if the animals tested are to be subsequently destroyed.

In this context, an issue that has acquired importance is how to mandate only "necessary" biosafety tests and how to distinguish necessary from unnecessary testing. This is particularly important in contexts, such as India, where there is little prior experience with biosafety standard-setting, and where such standard-setting is occurring in an environment of controversy over transgenics crops.

Whether or not the particular example of ruminant testing for toxicity and allergenicity is "scientifically sound" and appropriate within an Indian context or not, an important consideration the example highlights is that mandating more and more safety tests, if this becomes a *de facto* effort to "buy time" in response to myriad public concerns, may have the unintended and harmful effect of discriminating against small producers of transgenics or the public sector, with only the largest private sector producers of transgenic products able to undertake the costly testing required to meet biosafety requirements.

Since development of transgenic crops, especially by the private sector, is guided by market imperatives rather than desired societal outcomes, it certainly falls to a public biosafety regulatory regime to define "safe use" in a manner that is rigorous and consistent with the context, needs and concerns of a developing country such as India. At the same time, however, the risk that broad concerns surrounding use of transgenics in agriculture become voiced in the language of safety or technically assessable harm has to be avoided.

The onus to govern appropriate flows and use of biotechnology in agriculture cannot lie with a biosafety regime alone, as it largely has in India to date. Instead, biosafety should be but one component of a larger debate over appropriate technology use. There is a clear need for institutional mechanisms and fora through which broader (non-safety) concerns over transgenic technology in agriculture can receive a hearing and can influence the process of technology diffusion and uptake, and thus enhance socially appropriate knowledge flows.

4. Enhancing Socially Appropriate Knowledge Flows

As seen above, emerging policies in the area of biosafety, trade and intellectual property rights all affect the process of biotechnology knowledge generation, dissemination and use in India to varying degrees. While this is not surprising, the important question is whether such policies are conducive to appropriate uptake of biotechnology or whether they hinder appropriate biotechnology knowledge generation and use. In addressing this, it is important to first ascertain the priorities that underlie the policy choices in each of these areas.

4.1. Priorities underlying existing national policies

Priorities driving domestic trade policy in India appear to be to maintain or enhance export markets for important traditional commodity crops, especially given limited capacity to

segregate transgenic from non-transgenic varieties of these crops in the immediate future. An equally important concern is to ensure continuing public sector control (albeit to a more limited extent than in the past) over production of critical staple foods, to ensure food self-sufficiency, partly through ensuring the competitiveness of public sector agriculture.

In the area of biosafety, the priorities appear to be to address context-specific safety concerns, such as toxicity or allergenicity testing for ruminants, even if these are seen as "non-scientific" by overseas or domestic producers of the technology. Debates over biosafety in India do point, however, to the need to ensure sufficient testing without translating non-safety concerns into costly safety testing requirements, thereby potentially discriminating against the public sector and small producers of transgenic crops.

In the area of IPR, the priorities appear to be to enshrine the innovative concept of farmers' rights in the new domestic legislation, as well as institute mandatory licensing where plant breeders rights are awarded. In support for public sector agricultural research, the clearly stated priorities are to foster public sector innovativeness while seeking beneficial partnerships with the private sector. This is fueled by wide-spread belief (which still requires empirical verification) that such partnerships will help overcome hurdles to knowledge generation posed by privatization of knowledge, and will facilitate the conversion of basic public sector research into products with socially beneficial impacts. However, successful and replicable models for such mutually beneficial partnerships are yet to clearly emerge.

These Indian trade, biosafety, and intellectual property rights policies can and have been characterized as obstructionist and overly precautionary by proponents of rapid technology dissemination and use, given that they may impede quick adoption of transgenic crops[20]. However, the analysis here suggests that, instead of focusing on whether existing policies slow adoption of transgenic crops in agriculture, a prior concern should rather be whether the priorities underlying current policies are the appropriate ones for a developing country such as India. In considering how to bridge potential knowledge divides to facilitate sustainable development, there remains a strong need to analyze the social acceptability and appropriateness of the priorities driving current policy choices.

Such an analytical process can better illuminate whether a biotechnological divide exists because of overly stringent biosafety testing, lack of adequate intellectual property protection, or lack of capacity and structural inadequacies of the public sector research system (the most-oft cited reasons), or whether it also exists because it reflects certain legitimate agricultural priorities for a developing country such as India, especially given an uncertain global context within which national technology uptake decisions have to be made.

4.2. Global regimes impacting biotechnology knowledge flows

This global context is important because international institutional arrangements also facilitate or impede knowledge flows to developing countries, as well as influence the shape of national regulations. As already discussed in Section 3.1, the intellectual property rights debate in India is clearly influenced by requirements of global regimes, particularly the World Trade Organization's recently concluded TRIPS Agreement, as well UPOV, which establishes global principles and standards for plant breeders' rights.

In addition to global regimes for IPR, biosafety regimes are the second important pillar of a global governance architecture influencing knowledge and technology flows to developing countries. Global regimes with relevance for biosafety include the newly concluded Cartagena Protocol on Biosafety, the only legal regime seeking to ensure safe trade in genetically modified organisms and the World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement). The main objective of the SPS Agreement is to facilitate trade, through encouraging national-level human, plant and animal health and safety standards to be harmonized on the basis of scientific evidence of harm (to prevent them from

becoming non-tariff barriers to trade).

Although both these global regimes regulate biosafety and/or trade in potentially risky technologies, they vary in their mandates, norms, regulatory instruments and technology transfer vehicles. While the SPS Agreement dates back to 1994, the Cartagena Protocol on Biosafety has been recently concluded in 2000 and is only now coming into force and being implemented in national contexts. Thus, whether and how these two global regimes negate or bolster each other in governing access to and appropriate use of biotechnology in developing country agricultural sectors requires urgent research and policy attention (for analyses now emerging, see Bail, Falkner and Marquard 2002, Gupta 2001a. see also Runge and Lee 2000 on the trade regime).

One initial analysis suggests that, although its relationship with the SPS Agreement was a key bone of contention during negotiation of the Cartagena Protocol on Biosafety, both regimes now appear to privilege science-based national decision-making about imports of transgenic products (Gupta 2001a). The SPS Agreement mandates that all national plant, animal and human health and safety standards have a scientific justification to prevent them from becoming unjustified barriers to trade. It allows for only provisional restrictions on imports of potentially risky products, and only in the face of scientific uncertainty about harm posed by such products. Finally, it largely excludes socioeconomic factors from being considered in national decisions about imports of risky products (SPS Agreement 1994).

The Cartagena Protocol on Biosafety, in contrast, does mandate that imports of certain genetically modified products should require the advance informed consent of an importing country. Yet, as in the SPS Agreement, the grounds for such consent are largely restricted to a scientifically sound risk assessment, with precautionary restrictions on imports allowed in the face of insufficient scientific evidence of harm, although the scope of such restrictions remains open to interpretation[21]. Importantly, socioeconomic considerations are allowed only to the extent that they are compatible with a country's "other international obligations" - a reference to the trade regime's SPS Agreement requirements (CP 2000).

Such a privileging of science-based decisions about imports of contested new technologies can be characterized as a problematic "technicalization" of what are fundamentally normative conflicts in the area of technological change. A potentially far-reaching implication of this privileging of science-based decisions by global governance regimes is that broader concerns about the nature and consequences of technology transfer and adaptation will increasingly need to be articulated in the language of technical risk. Although normative concepts such as equity, fairness or choice are key drivers in North-South conflicts over global technological governance, they may increasingly get recast in the language of technical harm, with detrimental consequence for appropriate technology use.

This is amply illustrated by the contrast in rationales relied upon by India, in domestic versus global fora, in order to restrict imports of transgenic agricultural commodities. In the global forum of the Cartagena Protocol negotiations, developing countries, including India, justified the need for national choice in restricting trade in transgenic products by invoking potential risks to biodiversity or human heath from such trade. However, as seen earlier, the primary concern in India over imports of transgenic commodities are socioeconomic, rather than relating merely to ecological or human health harm. Yet, such broader national-level concerns over technological change become couched in the global arena in terms of risk, in order to receive a hearing within global governance fora that privilege the language of technically assessable harm (Gupta 2001a).

The analysis in Section 3.2. shows also that such a privileging of technical risk assessment as a basis for national decisions about technology uptake is increasingly evident in domestic biosafety regulations in India as well. This study argues, however, that in anticipatory areas of technological change, where concerns about adoption and safe use of technologies transcend scientifically measurable harm, it is important to go beyond science-based mediation of norma-

tive conflicts. Some form of social impact assessment should also be a critical component of determining appropriate use of new technologies (WWF 1998, Gaskell et al. 2000). While calls to assess the social impact of technological change go against the grain of the fundamental premises of an increasingly globalized market system, its perils and its promise for the infrastructure of governance need to be explored.

Even as it privileges science-based decisions about imports, the Cartagena Protocol on Biosafety does seek also to strengthen scientific capacity for national-level biosafety assessments, as well as increase the transparency and availability of risk and safety information about transgenic products entering international trade. The latter tasks are to be undertaken through an information sharing clearing house and capacity building initiatives, both key vehicles of biotechnology knowledge generation and flows encouraged by this global regime. For example, a pilot phase of the Cartagena Protocol's Biosafety Clearing-House is currently being established at the international level, to share risk assessments and other biosafety regulatory information between exporters and importers of transgenic crops.

Yet, disputes over the establishment of the pilot phase for the Biosafety Clearing House continue to highlight diverse views about the breadth and kind of information required to facilitate "informed agreement" about transgenic crops by developing countries, as well as potential tradeoffs between disclosure of safety information versus protection of confidential business information (Africa Group 2000, Canada 2000, EU 2000).

In balancing this latter conflict, the Cartagena Protocol states, for example, that "a general description of a …[genetically] modified organism" and "a summary of the risk assessment" shall not be considered confidential information (CP 2000, Art. 21). Yet the conflict between protecting confidential information and ensuring public access to information persists. As an article about the potential risks posed by genetically modified trees states:

> …it is impossible to say exactly what scientists are putting into trees. Although the [United States] Animal and Plant Health Services web site summarizes every application for field tests, many say 'CBI' for 'confidential business information' in the column that is supposed to describe the gene being studied and the organism that it came from. (IHT 2000, 5)

Clearly, access to "confidential" information such as the inserted gene and the host organism is critical to informed decision-making about safe use of genetically modified products. Even if such information is made available to biosafety regulators, however, concerns over confidentiality can affect what is available to a broader public. Under such circumstances, the onus is even more strongly upon national regulators to ensure an accountable decision-making process.

Another challenge facing the Cartagena Protocol's Biosafety Clearing House is its reliance on internet-based information dissemination, which exacerbates concerns of some countries about lack of domestic capacity to effectively use information provided. A position paper distributed by the Africa Group (an alliance of African countries formed during deliberations of the Cartagena Protocol) states, under the revealing heading of "equity and access", that:

> The BCH [Biosafety Clearing House] should not be the mechanism that further divides the technology 'have-nots' from the technology 'haves'… the Africa Group wishes to emphasize the need for capacity building, especially the enhancement of technological capabilities of countries…the BCH is a cornerstone for the implementation of the Protocol and hence a very important area for capacity building. (Africa Group 2000, para 1,9)

As reflected here, exercising national choice regarding trade in transgenic products depends critically upon whether countries have the institutional wherewithal to utilize infor-

mation provided to a Biosafety Clearing House.

This also provides an impetus to capacity building initiatives currently being launched under the aegis of the Cartagena Protocol on Biosafety. Such initiatives are being led by the private sector, in collaboration with international organizations such as the United Nations Food and Agricultural Organization (FAO), the United Nations Development Programme (UNDP) and the World Bank, to discern the information needs of developing countries and build capacity for transfer and safe uptake of products of genetic engineering (UNEP and GEF 2000a, 2000b).

Again, these newly launched capacity-building initiatives deserve research and policy attention to assess the potential of capacity building as a powerful vehicle for the dissemination not only of technologies but also of diverse (and often contested) approaches to technology use. These include risk assessment models as well as scope of information about risks versus benefits of contested new technologies (Lin 2000 and GIC 2000).

Particularly in the case of knowledge divides in contested yet "infrastructural" technologies such as biotechnology, the process of capacity building requires acknowledgement that perceptions of "sound" risk assessment, biosafety and the scope of necessary information about risks and benefits is distinct and inextricably linked to particular contexts (Gupta 2000). As evident from the example of ruminant toxicity and allergenicity testing requirements in India, what is viewed as legitimate safety information varies from country to country. Thus, capacity building cannot be a unidirectional learning relationship. Instead, there is a need to balance the priorities of capacity providers and capacity recipients.

An example of a capacity building programme for biotechnology use in India, the *Andhra Pradesh and Netherlands Biotechnology Program* (the APNL), is also instructive here. The programme, begun in 1996, seeks to develop biotechnological innovations suited to the needs of subsistence and small-scale farmers, in keeping with developing country needs. The capacity building focus of this programme, therefore, has been on developing the abilities of scientists and farmers to interact with one another. Its functioning for the last 5 years has highlighted key challenges in implementing such an objective, including the effective use of participatory methods to solicit farmer input, as well as overcoming reluctance of scientists to engage with farmers, given a belief that "decent science has to take place exclusively in a laboratory" (Siva Prasad and Reddy 1999, 5).

Most striking, however, is an underlying premise of the programme that national-level agencies "are developing appropriate systems... for biosafety and risk assessment, IPR and patenting procedures" and hence that such issues will not impede development of appropriate biotechnology products for small farmers (Siva Prasad and Reddy 1999, 6). Yet, as the analysis in this study suggests, the development of "appropriate" regulatory structures requires some minimum social consensus about the need for and direction of biotechnology use in the country's agricultural sector. Such a consensus is a logical pre-requisite, not only for mutually beneficial capacity building programmes and public-private partnerships, but also for development of adequate regulatory frameworks. Prior and clear identification of social priorities, and supportive governance structures to promote them, will then allow tools such as capacity building and public-private partnerships to not just enhance knowledge flows but to enhance socially appropriate knowledge flows relating to biotechnology use.

4.3. Enhancing socially appropriate knowledge flows

Yet the question that remains, of course, is: how might a social consensus on appropriate use of particular technologies be generated? Even if unlikely to be attained, the process of ensuring appropriate uptake and use of biotechnology in India requires, at the very least, existence of institutional fora where fundamental value conflicts can be mediated. There have been some efforts by intermediary institutions to bring diverse perspectives on use of biotechnology in agriculture together. Notable among these are the M.S. Swaminathan Research Institute in

Chennai and the Tata Energy Research Institute (TERI) in New Delhi (TERI 1999, 2000, MSSRI 1999). A key recommendation of a National Consultation on GMOs organized by the MS Swaminathan Institute was to establish an autonomous body, a National Commission on Genetic Modification of Crop Plants and Farm Animals, to regulate use of transgenic technology in agriculture. It suggested that such a body could be headed by an independent chairperson and consist of government representatives scientists, academics, local groups and the media (Hindu 1999).

TERI has also organized a series of workshops to bring together diverse perspectives on transgenic use in Indian agriculture (TERI 1999, 2000). The TERI workshop proceedings constitute one of the few sources of information about a broad spectrum of views on transgenic research in India and thus fulfill a valuable function. However, to date, they have largely seemed to preach to the already converted, given participation mostly from prominent agricultural scientists, government regulators and the private sector who are also most supportive of expanding transgenic agricultural research in India. Opposing viewpoints are few and until recently (despite the term "stakeholder dialogues") there was little representation from farmers, a critical constituency.

In a government initiative responding to the perceived hurdles to appropriate public sector transgenic research, the National Bureau of Plant Genetic Resources (NBPGR) organized a first-of-its-kind biosafety training seminar in July 2000, to bring together public sector and university scientists engaged in transgenic research. The aim was to debate the relevance of biotechnology for public sector agricultural research, as well as to discuss how to approach the biosafety and IPR challenges facing such research (NBPGR 2000). For many participating scientists, it was the first airing of the myriad challenges surrounding appropriate development and use of biotechnology in the Indian context, and the first opportunity to share common concerns with colleagues engaged in research from different parts of the country. More such domestically initiated programmes that explicitly target public sector research are essential if appropriate innovations are to be developed.

In addition to fora for debate and participatory decision-making, there is also need, however, for concrete mechanisms with which to assess the relevance of on-going and future transgenic research in meeting desired societal goals. As Gaskell et al emphasize in the case of European biotechnology regulation:

> debate and decision-making must go beyond evidence based solely on scientific risks. The moral and ethical dimensions of biotechnology that underlie public concerns need to be understood and taken into account. (Gaskell et al. 2000, pp. 938)

For developing countries, consideration of socioeconomic impacts, in addition to the moral and ethical dimension, is equally critical. A variety of tools, including social impact assessments and participatory technology assessments, have long been advocated in different contexts for assessing the utility and impact of technological innovation (van den Daele, Puhler and Sukopp 1997, WWF 1998, Brush 2001). Yet, developing countries such as India have yet to experiment seriously with such tools in assessing impacts of public sector research and technological development in meeting desired social goals.

In addition to social impact assessment, there are other new and innovative mechanisms currently being developed, such as "real-time technology assessment" and "public value mapping" of publicly funded research, with which to analyze whether current directions in research and technological innovations will further desired societal goals. Real-time technology assessment is a process by which to observe and influence how particular social values become embedded in technological innovations at the outset (Guston and Sarewitz 2001). Public value mapping seeks to go beyond assessing the economic or scientific impact of public-sector research to also include its social and distributive impacts (Bozeman 2001, 2002). Such tools are of key relevance for developing countries, where scientific R&D is still largely in the

domain of the public sector, and where social and distributional impacts of technological innovations are critical to poverty alleviation.

Increasingly, scholars of science and technology policy in India are pointing to the need for broader assessments of the societal impacts of technological developments. As V.V. Krishna, for example, points out, given the increasing rhetoric surrounding the knowledge society, it is yet more urgent, in a country with 50% of the population illiterate, to ensure that "human and social development indicators acquire a central policy concern in any discourse on creating a knowledge society" (Krishna 2001: 193). As he further suggests, developing countries are now caught in a "double-bind" situation, whereby they must adjust to an increasingly globalized market, even as they seek to ensure that scientific research and technological developments remain oriented to the "public good" (Krishna 2001,193). The central challenge that remains, of course, is determining what the public good is and how it is to be attained. This emphasizes anew the need for assessment and decision-making tools that go beyond mere scientific or economic impact assessments[22].

At the very least, however, a focus on the public good allows for a re-articulation of the implications of knowledge divides for sustainable development and global inclusion. In considering a "successfully bridged" technological divide, a public good focus goes beyond criteria such as rapid development and bringing to market of transgenic crops, fostering technical capacity and know-how, ameliorating resource and capacity constraints, and increasing access to information, all of which have traditionally been the subject of policy intervention. While all such criteria or foci of action can certainly contribute to bridging knowledge divides, the central question of whether a bridged divide will further the public good remains, suggesting that such policy interventions should be seen as the means to the larger end of accomplishing desired societal goals, not the end in themselves. In moving closer to a social consensus around technology uptake and use, newer variations on decision-making tools and technology impact assessments, as noted above, offer promising avenues.

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[1] It is also uneven across developed countries. Adoption of transgenic crops in agriculture is minimal in Europe, even as it has expanded the last decade in the United States and Canada (James 2000). As discussed

later, this has implications for global flows of knowledge relating to transgenic crop technologies.

2 Interviews with public sector agricultural scientists in New Delhi, January 2000 and August 2000.

3This an enormous and growing literature. For a general overview, see Lesser 1997. For IPR regimes and biotechnology in India, see Sahai 1999, Chaturvedi 2002, see also Mashelkar 1999.

4 Bt stands for *Bacillus thuringiensis*, a naturally occurring soil bacterium that contains a protein that is toxic to Lepidopteran pests (or "bollworm" pests that attack the cotton plant). Spraying the Bt bacterium over crops has long been a pest-control strategy employed by organic farmers. Transgenic Bt cotton is cotton which has been genetically engineered to contain the Bt toxin, thus making the plant pest-resistant (Choudhary 2001).

5 It is striking how consistently media reports have referred to "Monsanto's Bt cotton" rather than focusing on Mahyco's involvement, in reporting on the field trials. This highlights again the concern with foreign dependency rather than with safety issues alone (see, for example, Hindu 1999c,d,e).

6 The discussion in this section draws on Gupta 2002.

7Given persisting conflicts over whether GMOs should be equated with potentially hazardous substances, it is noteworthy that they are regulated under the EP Act in the category of potential environmental pollutants. For analysis of disputes over whether or not GMOs are seen as intrinsically hazardous in the global Cartagena Protocol on Biosafety, see Gupta 1999 and 2000.

8 Thus, Paragraph 9(1) of the 1989 Rules states that "Deliberate or unintentional release of genetically modified organisms/hazardous microorganisms or cells, including deliberate release for the purpose of experiment, shall not be allowed". Paragraph 9 (2) states, however, that "the Genetic Engineering Approval Committee may in special cases give approval for deliberate release" (Rules, 1989: para 9.1 and 9.2).

9 Interview with Dr. Manju Sharma, Secretary, Department of Biotechnology, Ministry of Science and Techology, January 2000. Expressing a similar sentiment, Dr. Sharma states elsewhere that Indian biosafety rules "are acknowledged as the best available even by the United States Department of Agriculture" (Sharma 1999: 15).

10 See Monsanto (1998) for a "Statement issued in the Public Interest" explaining the difference between terminator technology and Bollgard (Bt) cotton, and promising to "only bring to India technologies that are thoroughly tested and approved by the Indian government".

11 For an analysis of global rules for segregation of transgenic commodities, see Gupta 2000a, b.

12 There appears to be little written documentation of this incident. The account here is based on interviews with individuals from the Ministry of Agriculture and the Department of Biotechnology, Ministry of Science and Technology in January 2000 and August 2000.

13 However, undertaking a comparative agronomic evaluation remains fraught with multiple challenges. For a clear exposition of these challenges, see Dhillon and Randhawa 2000, pp. 5-10.

14 For contentious global-level disputes over whether field trials constitute a "contained use" or a "deliberate release" of genetically modified organisms, see Gupta 1999, 2002.

15 See Singhal 2000 for a perspective from the Ministry of Agriculture's Seed Science and Technology Division on the relevance of seed quality laws for transgenics.

16 Thus, for example, in the case of the recently approved transgenic Bt cotton varieties, the conditions include planting 20% of every field with non-Bt varieties and/or five rows of non-Bt varieties along the periphery of a field, as well as monitoring for development of pest resistance to the Bt toxin (Ramachandran 2002).

17 In regulating safety of transgenic foods, a key principle relied upon in many OECD countries, particularly the United States, is that of "substantial equivalence". For a perspective from Monsanto on substantial equivalence, see Nair 2000. For analysis of diverse views on whether it provides a "scientifically sound" basis for GMO regulation, see Gupta 2001: 272-274.

[18] Confidential interview with a member of the Monitoring and Evalution Committee, January 2000.

[19] Confidential interview with private sector transgenic crop developer in India, January 2000.

[20] For a perspective on Indian biosafety, IPR and other policies as largely precautionary, in that they have prevented or slowed down rapid adoption of transgenic technology in agriculture, see Paarlberg 2001.

[21] For a detailed analysis of the bases for informed consent in the Cartagena Protocol on Biosafety, see Gupta 2001a. For a detailed analysis of the history and diverse interpretations of the precautionary principle and the implications for regulating genetically modified organisms, see also Applegate 2001.

[22] For a more detailed justification of the need for and components of a public value mapping analysis focusing on agricultural biotechnology in developing countries, see Gupta 2000b.