

# REGULATING GMOs IN INDIA: PRAGMATISM, POLITICS, REPRESENTATION, AND RISK

DPHIL RESEARCH OUTLINE

RANA GHOSE

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## 1. WHY REGULATION?

The market introduction of genetically modified (GM) crops presents a series of concerns to all societies globally, but are of particular relevance to those developing economies that are creating domestic legislation addressing the management of these resources. In economies that are primarily agrarian, GM crop technologies may improve yields in the face of biotic and abiotic stressors, provide opportunities to grow new crops that command higher returns, address concerns relating to population growth and limited resources, and provide a more stable nutritional source to combat the adverse economic development that malnutrition presents.

However, these new technologies often cost more, the long-term environmental, health, and socio-economic impacts are mired in uncertainty, the rise of substitute suppliers taking advantage of these technologies may adversely effect developing economies that historically supply these markets, and the market forces behind commercial research do not necessarily take nutrition, and correspondingly, poverty reduction, as their primary incentive. As a corollary to this broad swathe of potential effects, the implication of the regulation of these technologies are equally as broad, incorporating intellectual property rights (IPR), incentives to trade, the conduct of research and direct investment, and the development of participatory public processes directed toward the creation of this regulation.

The formulation of regulation in current practice is rooted in a post second world war context where neo liberal treatises on trade have become the lingua franca among most policy makers. The notion of multilateralism, most acutely represented by the prescriptive measures mandated via the over sixty agreements within the World Trade Organization (WTO), has epitomized the primary catalyst for domestic regulatory reform. From a regulatory perspective, these agreements present an attempt at regulatory harmonization among member states to a nearly homogenous set of principles, with an implicit minimization of the role of national governments towards these ends. This has two main implications on the role of domestic governance in creating regulation within what still remain sovereign nations.

First, the deliberative process by which, historically, sovereign states have created regulation, has moved into a realm where it requires compliance to an externally prescribed set of minimum criteria, is determined complaint by parties that reside outside the legal jurisdiction of sovereign member states, is based on a series of terms and concepts that are often transposed from one geographic and cultural context to another<sup>1</sup>, and is enforced by a body that does not impose legally punitive measures under a domestically enforced legal construct, but rather a system of often opaque dispute settlement.

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<sup>1</sup> In nations where the technical capacity to develop regulatory regimes is lacking, or where deadlines imposed by multilateral bodies to establish regulation present a sense of urgency, the exercise of creating regulation often refers to existing frameworks as a reference, and on occasion are used verbatim. Such an approach, while pragmatic in the face of the limitations stated here, assumes that these terms (i.e. "risk", "uncertainty", "participation", "scientific principles") can be successfully transposed easily from one geographic and cultural context to another in order to frame debates and proceed with the exercise of creating regulation. This is regardless of the fact that these terms may be defined differently among different cultures, classes, and livelihoods.

Second, participatory processes where the perspectives and inputs of citizens are utilized in formulating regulation (i.e. referenda and public discussions) are left to individual member states and agents to facilitate. These processes are often compromised by bilateral negotiations occurring outside of a multilateral context, or the requirement of domestic regulation to be created along a predetermined schedule, rendering what historically may have taken generations to develop into a process that necessitates results in a matter of years.

These challenges are particularly relevant to developing economies, where prior regulation may not have existed, where the human capital required to effectively develop effective regulatory frameworks may be low, and where local systems of governance, market epistemologies<sup>2</sup>, and political and legal representation may be either diverse or non-existent. Moreover, technological innovation has introduced goods that, when compared to their historical analogs, present a higher level of risk due to their novel applications of recent advances in scientific research and development. In the context of the regulation of GM crop technologies, uncertainty is conventionally characterized by a quantified measure of risk, as determined by a process of scientific inquiry in a closed system, namely the laboratory and controlled field trials, often initiated by private sector agents. These procedures can only characterize what scientists “know”, and thus any metric of risk with regards to GM is reflective of an embedded, if not explicit, level of ignorance regarding the full consequences of market introduction.

Regulation in the developing country context presents two sets of challenges; one that applies to all parties developing policy, namely the capacity to create effective policy under time, capital, and knowledge constraints, and one that is more unique, namely the navigation of distinct market realities, the diversity of market epistemologies, and dissimilar concepts of citizenship. The result of these divergences can be characterized as the challenge of developing and implementing regulation that is effective, tenable, and compliant in the global area within the context of goods and services that are available with an often inaccurate (or at least incomplete) characterization of risk.

In such a milieu the process of creating regulation is thus a complex and highly involved undertaking, one that encompasses and challenges notions of legal representation and culpability, the role and efficacy of science and citizens in rendering uncertainty legible, and the power dynamics and real politik implicit in multilateral trade negotiations. Yet regardless of these contexts and challenges, regulatory frameworks must be developed, due both to the commitments of multilateral membership and the market incentives that surround the development and availability of these “risky” goods and services.

This study will address how domestic biosafety regulation, as a consequence of both supranational obligations and national interest, is navigated, established, and referred to in practice. Specifically, this work will concentrate on which actors and processes, both formal and informal, are truly effective in affecting policy aimed towards the regulation of a technology bound with uncertainty. The area of interest will be the Vidarbha region in the state of Maharashtra in India, and the

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<sup>2</sup> Market epistemologies are those overarching theories of knowledge that dictate how agents rationalize the incentives they are faced with in deciding how to act within a market, as dictated by the normative frameworks - as determined by cultural factors - that these agents operate in. This diversity is a product of the variety of cultures that economic agents work within, and the variety of perspectives that color and imbue how these agents make decisions; for instance, the accumulation of debt among families due to the cost of paying for the marriage of daughters and/or dowries. In practice, this can be applied to farmers in India who appear willing to accept significant amounts of debt secured from private money lenders in order to afford a new technology such as Bt Cotton, regardless of the uncertain performance of the technology. Such behaviour counters the “risk averse” and “informed” agent of neoclassical economics, perhaps due to a distinct definition of risk due to a distinct market epistemology.

technology in consideration is Bt Cotton, a GM variety engineered to be resistant to a common biotic stress, the bollworm<sup>3</sup>.

## 2. THE EMERGENCE OF BIOSAFETY REGULATION IN INDIA

The past fifteen years has seen an ongoing debate regarding the alleged success, failure, and safety of genetically modified organisms (GMOs) in agriculture. In India, this debate has focused primarily around Bt Cotton, and the sowing of this crop in the context of various stresses and controversies since its formal commercial release in 2002. This debate has taken place both within formal institutions (i.e. the state, academia/scientific “experts”, practitioners) as well as informal (i.e. civil society, popular media, internet discussion groups). It has touched on issues such as state sovereignty in the context of corporate influence and incentives, legal culpability and agency in context of unauthorized commercially released technologies, how the public perceives and negotiates the introduction of new technologies and which parties (i.e. the public, civil society, the state, and both transnational and domestic private sector agents) are included within the deliberation and creation of regulation, and how these new technologies may affect the future of those who derive their livelihood from agriculture. The experience of regulating GMOs in India presents a classic study on how one nation grapples with the exercise of creating regulation in the context of a technology burdened with uncertainty due to scientifically incalculable risk, and how formal and informal processes interact and influence such a regulatory regime<sup>4</sup>.

While some elements of India’s regulatory regime predate independence, much of the regulatory framework was first established in the mid to late 1980s. This period in India’s history corresponds with the Rajiv Gandhi administration, characterized by some observers as distinct from previous administrations due to the support lent to the liberalization of the Indian economy (Rodrik and Subramanian 2004). In particular, his administration increased government support for science and technology and associated industries, and reduced import quotas, taxes, and tariffs on technology-based industries.

From a regulatory perspective, two events during his tenure characterize the first efforts taken by India in managing the emerging biotech industry. First, in 1986, the Ministry of Science and Technology (MST) established the Department of Biotechnology (DBT). The aims and objectives of the DBT as stated by the MST are to facilitate a “deep” involvement of the scientific community via consultations, but also to foster the growth of the India’s capacity for R&D (MoEF 2006a). This reflects two objectives: to ensure scientific validation via procedural rigour and review, and to ensure and promote the overall development of India. During the same year, the Environmental Protection Act (EPA) under the Ministry of Environments and Forests (MoEF) was established. The management of GMOs in the EPA is mandated in the context of environmental pollution; the EPA

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<sup>3</sup> Briefly, *Bacillus thuringiensis*, or Bt, is a soil-dwelling bacterium. The bacteria forms protein toxins from Cry1ac genes. When Bt is genetically incorporated into crop species, these toxins have lethal effects on species of caterpillars and beetles, and more specifically, the bollworm. As a result, the application of pesticides used to combat these pests is allegedly not required, as the pesticide is incorporated into the plant itself.

<sup>4</sup> The general notion of informal vs. formal in the social sciences poses an institutional framework against something outside, or the *other*, often characterized as non-governmental. The primary point of departure for this delineation is well defined in economics, namely the notion of the informal economy. More recently, and outside of economics, Peters (2005) discusses informal governance; namely, governing through mechanisms that depend to some extent upon the cooperation with non-state (non-governmental, private sector) actors. The economic literature characterizes the informal sphere as where certain types of income and the means of their generation are *unregulated* by the institutions of society (i.e. government) in a legal and social environment in which similar activities are regulated (Portes et. al 1989, de Soto 1989). While the classical notion of formal regulation is based on processes that are standards-based, government driven, and contingent on legal recourse in cases of non-compliance (*command and control*), informal regulation (Pargal and Wheeler 1997, Kathuria 2003, Peters 2005) exists as a response to absent or ineffective formal regulatory mechanisms, created by communities using tools outside the realm of legal instruments, and compliant to shared community determined standards of acceptable performance.

establishes the role of the government to “make rules” relating to “the procedures and safeguards for the handling of hazardous substances” (MoEF 1986). In 1989 the MoEF established the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms and Genetically Engineered Organisms or Cells. These Rules then mandated the creation of six institutions under the aegis of the MST and MoEF that span the three tiers of governance in India<sup>5</sup>.

#### **INSTITUTIONAL RESPONSIBILITIES OF THE CURRENT INDIAN REGIME**

- Recommend and/or create further guidelines (Recombinant DNA Advisory Committee)
- Ensure adherence to standards of safety in R&D (Institutional Biosafety Committees)
- Restrict field trials and ensure safety upon release (Review Committee on Genetic Manipulation)
- Permit commercial application (Genetic Engineering Approval Committee)
- Monitor and report field level performance (State Biosafety Coordination Committees and District Level Committees)

Since 1989, these institutions have been the most active components of the regulatory regime surrounding GMOs. While the initial creation of the 1989 regime was borne out of domestic concerns and ambitions, these and other frameworks have been amended to ensure compliance to international fora on trade (i.e. the WTO via plant variety protection and patent law) and safety (i.e. the UN via biodiversity and labelling) standards and best practices<sup>6</sup>. In total, the Indian regulatory regime currently spans across six ministries, and is in a continual state of development due to these obligations<sup>7</sup>.

This framework presents a means to regulate the usage GMOs within India. It clearly establishes roles, responsibilities, and an institutional framework, based on scientific principles of inquiry and analysis to control and manage these new technologies. But how does this regime fare in practice? What happens when a regime rooted in the classical formulations of “how to regulate” are contested by a variety of actors due to alleged failures of the technology by users, concerns of whether industry abuses the monopoly power implicit in formally owned technologies, and direct actions by farmers due to lacking state directed interventions to protect their welfare? More specifically, what are these classical formulations, and what is their rationale? While some observers have characterized the emergence of biosafety regulation in India (Ramanna 2005, Sahai 2005, Scoones 2003, Gupta 2002) there is a dearth of analysis of how this regulation actually operates in practice. It is precisely this analysis that will be addressed within this research.

### **3. WHAT IS REGULATION? PERSPECTIVES FROM THE LITERATURE**

Historically, the process of regulation is rooted in the economic literature, with the underlying premise that the market presents a series of economic incentives that may be at odds with the public interest. Consequently, one party, most often the state, would endeavour to implement a series of barriers to trade in an attempt to ensure that the pursuit of these incentives would not result in harm to society.

#### **THREE PERSPECTIVES ON REGULATION<sup>8</sup>**

<sup>5</sup> Refer to Appendix 2 for a more detailed treatment of these institutions.

<sup>6</sup> Specifically, the WTO mandates plant variety protection via Article 27.3(b) or TRIPS, either by a patent or *sui generis* regime. Similarly, the CBD (via UNEP) mandates states to facilitate the fair and equitable sharing of plant genetic resources, along with presenting standards for food labelling via the FAO/WHO Codex Alimentarius Committee.

<sup>7</sup> Refer to Appendix 3 for a diagrammatic outline of these institutions and their relation to one another.

<sup>8</sup> This section draws from a review by a series of earlier reviews undertaken by the author of the three main disciplines that have contributed to an understanding of the process of regulation: economics, international law, and political science. A summary of this review can be found in Appendix 1.

Economics:	Ensuring efficiency via competition and limiting the power of monopolies is the primary catalyst for regulation, and in the face of information asymmetries, government must find a balance between minimizing intrusion and ensuring that efficiency is maintained.
International Law:	International legal regimes are ultimately a function of the efficacy of individual sovereign states, and are primarily determined by a combination of hard (legally binding obligations) and soft (best practices) laws.
Political Science:	The classic firm-state-expert nexus disintegrates when regulation moves into social spheres (i.e. health, environment) and command and control regimes, and as a result, a broader variety of parties (i.e. civil society) becomes involved in the process of creating regulation.

This has all occurred in a post second world war environment where regional integration has become more and more pervasive for both strategic and trade interests, and where the role of multilateralism and the reduction of barriers to trade became the primary doctrine that has determined how representatives of sovereign states interacted. This was both to facilitate strategic interests at the level of international trade, but also to ensure that domestic industry was allowed to develop, grow, and achieve certain goals, driven both by intangible factors, such as national pride, and tangible factors, such as incentives to invest. It is maintaining this balance that has been the primary challenge of negotiators, often in fora that, while democratic in principle, presents inequalities with regards to power and influence.

The diversity of the literature reviewed here clearly points to certain agents as having particular roles and certain mechanisms by which authority is asserted within the context of enforcement. Yet in practice, these formal divisions and responsibilities are encumbered with the challenge of pragmatic application<sup>9</sup>. It is in such a context that processes other than those outlined in these three disciplines find their catalyst.

In practice, and in the context of what has occurred in India with Bt Cotton, the distinction between informal and formal processes is key, as it appears that informal strategies - either via self regulation or the system of economic incentives that firms pursue as a catalyst for informal action - have been particularly effective and influential. In more recent times, some observers have pointed more to the role of informal processes within the context of how regulation operates in practice<sup>10</sup>, and a number of authors have highlighted factors that may determine why these processes arise<sup>11</sup>. In the Indian context of the regulation of GMOs, many of these factors apply with regards to the rise of informal processes, and in practice, informal regulation, most often spearheaded by civil society organizations, has been one of the major catalysts for regulatory reform, either by engaging in formal debates on one hand, or via direct action on the other.

<sup>9</sup> This is particularly relevant when the scope of governance at the central level is directed towards a large population governed by decentralized institutions such as state legislatures and community level representation and governance. These processes are further compromised when the technology subject to regulation is mired in an implicit sense of uncertainty, or where the opinions of scientists and experts, while still considered paramount, are tacitly understood as not sufficient to conclusively provide evidence of complete safety.

<sup>10</sup> There appears to be tacit characterization in the literature of informal regulation being the domain of civil society. de Senarclens (1998) uniquely includes another party: multinational companies. Neoclassical economic behaviour of the firm is in itself "informal" (if not regulated by the state) if the pursuit of profit maximization/cost minimization is accepted to be a key behavioural tenet of the firm. The pursuit of these goals in itself creates an informal dynamic, arguably outside of a government framework.

<sup>11</sup> Afsah (1996), Foulon (2002), and Goldar (2004) characterize the strength and effectiveness of informal regulation as a process facilitated by non-governmental actors due to education levels, the degree of political organization and bureaucracy, the level of environmental awareness, the ability to access information, the availability of legal or political recourse, the level of media coverage lent, the efficacy of formal frameworks in the geographic environment, and community income (both magnitude as well as revenues from those firms that provide employment).

#### 4. BT COTTON IN INDIA

The case of Bt Cotton in India is particularly interesting as it presents an ideal lens to observe how regulation is applied in practice, and which parties truly motivate reform at the centre via actions undertaken by those outside the central sphere; specifically, those who are the end users of these new technologies and those parties that aim to represent them in that context<sup>12</sup>.

Bt Cotton was first approved for commercial use in the US in 1986, with China following suit in 1987 (Scoones 2003:7). India's first experience with Bt Cotton can be traced back to 1990, when Monsanto first approached the DBT for commercial release of Bt Cotton in India<sup>13</sup>. However, in 1995, the DBT granted the Maharashtra Hybrid Seeds Company, or Mahyco, the ability to import 100g of Bt Cotton seed from Monsanto, and in 1996 Mahyco began the process of backcrossing to produce local Bt Cotton varieties. Between 1996 and 1998, Mahyco had developed three strains of Bt Cotton, and in 1998 Monsanto bought a 26% share in the firm, resulting in Mahyco-Monsanto Biotech Ltd (MMB). In June 1998, the Review Committee on Genetic Manipulation (RCGM) had approved forty trials by MMB of Bt Cotton across nine states<sup>14</sup>. It is at this point that the story of Bt Cotton veers into the unexpected.

Later in 1998, public opposition against the trials begins to manifest, first in Karnataka where a farmers' organization sets a trial plot ablaze. Allegations are made by a civil society organization against the central government regarding the legality of the field trial. In 1999 this allegation is formalized as a petition lodged by a civil society organization, and based on this, the state notifies MMB as having violated the law. However, this has only a short-term effect towards hindering the progress of Bt Cotton in India.

In February 2000, the Indian Council for Agricultural Research applies to conduct limited trials of Bt Cotton varieties, and in May, the DBT gives biosafety clearance to Bt Cotton. Civil society groups are critical of this as clearance was given after trial plots were sown in 1998, and it is argued that the DBT is not authorized to give clearance, only GEAC is<sup>15</sup>. In January, farmers' groups burn additional plots of Bt Cotton in Karnataka in protest<sup>16</sup>. In June, further trials of GM food crops are made public by MMB, but in the same month GEAC bans the commercial cultivation of Bt Cotton.

In October, the first instance of the unauthorized plantation of Bt Cotton comes to light. Over 10,000 hectares of illegal Bt Cotton plots are found in Gujarat, though this particular variety (Navbharat 151) was legally registered with the Gujarat government since 1998. In the same month, the DBT announces that Bt Cotton will be commercially released in March 2002<sup>17</sup>. In November, the DBT releases "Biotechnology - A Vision", a document detailing India's ten year plans for the biotech industry. This all occurs parallel to civil society efforts to launch an inquiry into the illegal

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<sup>12</sup> This chronology draws from an extensive review undertaken by the author of the popular press; citations are available on request.

<sup>13</sup> This application was rejected on the basis of the exceedingly high technology transfer fee demanded by Monsanto and concerns relating to the backcrossing of an American variety of cotton with local varieties. (Bharathan 2000: 1068).

<sup>14</sup> Around the same time, Monsanto made statements to the press characterizing Bt Cotton as a "high-yielding" variety, something it later denies. Bt Cotton is genetically engineered to be pest resistant, but is not a high-yielding variety.

<sup>15</sup> As per the Indian regulatory framework, the RCGM should not have given permission as the trial sites were large scale and required GEAC approval. Their argument put forth by civil society is that the entire clearance process is ineffective given that field trials had been occurring for up to two years prior to this decision, thus arguably rendering the governments alleged concerns for biosafety disingenuous.

<sup>16</sup> At the same time however, some industry observers argue that India's current regulatory system is too cumbersome and actually hinders research and investment in India's emerging biotech industries, with some observers pointing to the ease and speed with which China embraced Bt Cotton. January also sees a US delegation meeting with Indian counterparts to illustrate and promote the benefits of biotech.

<sup>17</sup> The illegal Gujarat plots are not destroyed, but are rather left for cultivation with the resultant harvest being destroyed to deter the saving of seed.

leakage of Bt Cotton in Gujarat. As stated in 2001 by the DBT, March 2002 sees the commercial release of the three varieties developed by MMB between 1996 and 1998<sup>18</sup>. Demand for the MMB varieties is massive, with stocks of the seed depleted in Maharashtra.

Towards the end of 2002, the first concrete results of the crop begin to be reported by civil society. These initial reports in September indicate poor performance in three states, with November presenting similar negative experiences in other states. The end of 2002 sees a series of conflicting reports on the performance of the technology, with some observers claiming success (i.e. the MoEF), and others (i.e. Indian Industry Seed Association and farmers/civil society groups) claiming failure. A report released by a civil society organization states GEAC is liable for the apparent poor performance of Bt Cotton<sup>19</sup>. Reactions to Bt Cotton begin to escalate significantly after the end of the 2002 harvest<sup>20</sup>. Concurrently, the Indian Cotton Mills' Federation urges the Indian government to release more varieties of Bt Cotton to increase production, while MMB releases a report stating 30% increase in yields and 65-70% reduction in pesticide use among farmers using Bt Cotton<sup>21</sup>. Yet farmers continue to state their dissatisfaction with the crop due to pest attacks.

In March, the agriculture minister of Andhra Pradesh states Bt Cotton was a “failure” in Andhra Pradesh<sup>22</sup>. More illegal varieties derived from the Navbharat 151 variety are found in Gujarat in May, with farmers in that state calling for the official release of the illegal varieties claiming their higher performance as compared to the MMB varieties<sup>23</sup>. The year progresses with further R&D on Bt Cotton; the state allocates INR 400 million to ICAR to support further R&D into GM food crops<sup>24</sup>.

At this stage, the role of civil society moves from the margins to a much more vocal position. There are two main camps; on the one hand are scientific experts, best characterized by the MS Swaminathan Research Foundation (MSSRF). On the other hand are policy advocates such as Gene Campaign (GC), Deccan Development Society (DDS) and the Research Foundation for Science, Technology and Ecology (RFTSE)<sup>25</sup>. The latter group act more as advocates, presenting independent research results and using legal instruments to ensure adherence to the laws enshrined in the stated regulatory framework<sup>26</sup>. This all occurs in an environment where the MST claims that GM will

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<sup>18</sup> In April, MMB begins to license the Bt technology to three other domestic firms, while further pirated versions of the technology proliferate the Punjab, with the state fully aware of these pirated varieties. This is reflective of other farmers threatening civil disobedience if the government does *not* authorize commercial cultivation.

<sup>19</sup> The RFTSE report cites four parameters for negligence: 1. false claims of pest resistance, 2. false claims of higher yields, 3. false claims of higher incomes, 4. No effective biosafety safeguards (i.e. no refugia).

<sup>20</sup> January 2003 sees the Andhra Pradesh government publicly indicating their “disappointment” with Bt Cotton in that state, and cites the wide acceptance of the technology among farmers due to a “high-decibel and hi-tech campaign” by MMB.

<sup>21</sup> Similarly, an article published in Nature concludes greater yields and lower pesticide use based on field test data provided by MMB, and In February 2003, GEAC begins to allow case-by-case GM food imports, while some (the National Institute of Nutrition) argue there are no means to assess risk or presence of GM in food imports to India.

<sup>22</sup> Similar opinions are cited from farmers in the Punjab sowing illegal varieties of Bt Cotton.

<sup>23</sup> Meanwhile, the government further supports research on the GM vitamin A enriched “Protato”. In June, the DBT announces that the Protato will be available for consumption by schoolchildren within 6 months; GEAC denies any such release and claims never to have received the application for commercial release of the Protato.

<sup>24</sup> For instance, Seven agbiotech firms in India begin to collaborate on producing their own domestic Bt varieties with the stated aim of lessening the dependence on foreign varieties, and GM protein rich rice is developed by state institutions with state support.

<sup>25</sup> This division is presented here to indicate the distinctive nature of these two camps; the MSSRF and Swaminathan himself are highly respected in India. Swaminathan is seen as the “father” of the Indian Green Revolution, and his presence within formal institutional deliberations of policy is consistent. He is named, not without protest from farmers’ groups, as the chairman of the National Commission of Farmers, regardless of his clear position of being a scientist, not a farmer. Correspondingly, his recommendations are generally an attempt at pleasing both industry as well as farmers.

<sup>26</sup> In January 2004, MSSRF submits a report, based on a “consultative” process reflecting the interests of “farmers, industry and the NGOs” arguing that the current regulatory system needs to be “streamlined” and more efficient. Over the course

facilitate the "second green revolution" in India, and that collaboration with foreign entities in setting up joint ventures for R&D should be supported to allow for meeting India's food security needs through GMOs. However, the picture on the ground seems quite distinct. In November, farmers in Andhra Pradesh hold a Monsanto official and seven officials from the state Department of Agriculture hostage (though only for one day), demanding compensation for the failure of Bt Cotton<sup>27</sup>.

More varieties are released over 2005, amidst additional reports by civil society arguing that Bt Cotton is not appropriate for India<sup>28</sup>. Similarly, some scientific reports emerge stating that Bt Cotton is not as effective as argued<sup>29</sup>. The summer also sees further seizure of illegal varieties, and farmers engaging in further aggressive actions such as attacking seed shops and demanding compensation for crop failure. In November, GC states that a lawsuit should be filed against the GEAC for criminal negligence in not providing full access to information regarding Cry1ac immunity.

To date, 2006 has been notable for two events, the efforts by Andhra Pradesh to seek compensation via the Monopolies and Restrictive Trade Practices Committee on the basis of MMB charging an exceeding high technology fee<sup>30</sup> and the enactment of a labelling regime that demands all products containing GM technologies to be labelled. In April, possible cases of Cry1ac poisoning were reported in both the Philippines as well as India among humans and sheep, but these have yet to be conclusively linked to Bt Cotton cultivation.

## 5. RESEARCH OBJECTIVES

The Indian experience with GMOs clearly points to a formal regulatory framework where scientific tenets of analysis, experimentation, and ultimate validation are paramount. However, the preceding section illustrates certain processes outside the state-expert-firm nexus that have been quite influential in determining how these frameworks operate in practice, namely the actions of civil society groups to hold the state accountable to the regulations it has developed, the emergence of unauthorized varieties of Bt Cotton on the market due to the significant financial incentives to supply, and as a reaction to state inactivity in addressing the plight of farmers, kidnapping and arson.

Formal regulation in this context often follows the formulations as depicted in the preceding review of the literature. However, in the Indian context, certain actors (namely civil society and farmers' groups) have undertaken their own activities in shaping regulation in practice, either as a manifestation of their agency as end users and suppliers or as advocacy groups. More specifically, these parties have presented themselves as capable of undertaking specific actions that challenge this nexus and force those within the formal arena to react. As a result of this manifestation, questions arise as to what regulation really means.

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of the year the MSSRF recommendations are deliberated on at length, as are similar recommendations from others (i.e. the Mashelkar report). Similarly, GC files a public interest litigation demanding the government to install an appropriate consultative regime and to instil a moratorium on GMOs until that time.

<sup>27</sup> Similarly, the Minister of Agriculture admits to massive amounts of pirated seed being used by farmers, and a seed firm director says 80% of all Bt Cotton seed in India is pirated. In December, state officials in Gujarat seize 1100 kg of illegal Bt Cotton crop and 67 kg of pirated seed during a raid at a ginning mill.

<sup>28</sup> These reports argue that higher factor input costs distort any yield benefits accrued from Bt Cotton cultivation, participatory elements in the creating of regulation are seriously lacking, there are high incidences of wilt among Bt Cotton crops, the MMB marketing exercises were purposefully misleading, and more biosafety testing is required prior to release.

<sup>29</sup> The reports state that Bt Cotton is susceptible to bacterial blight, alternaria leaf spot and grey mildew, and that the bollworm may develop resistance to over time.

<sup>30</sup> It is worth noting that this was the same reason why Monsanto was initially denied permission to allow commercial use in 1990.



In the face of significant financial incentives to supply either authorized or unauthorized varieties to meet fervent demand among farmers, the inability or refusal of centre and state governments to curtail unauthorized varieties and manage the technology effectively, and a heterogeneous understanding of what biosafety means in practice among the actors involved, how can a regulatory regime operate in practice? Most importantly, how has regulation truly “played out” at the level of end users and in applied practice?

In the context of uncertainty, the true laboratory for the cultivation and corresponding performance of GMOs are farmers’ fields, and as a result, farmers and those that claim to represent their interests have taken on a role that the formal literature does not address. Indeed, this juxtaposition of formal and informal processes is key to understanding how technologies mired in uncertainty are regulated in practice. Given the Indian experience and the juxtaposition of regulatory theory versus practice, a number of questions arise.

### RESEARCH QUESTIONS

1. Who are the key actors in the regulation of GMOs in India, and how do they engage with one another?
2. What is the discursive framing these parties draw upon to interact, and do they facilitate disengagement or dialog?
3. What does regulation initiated at either a multilateral or domestic level ultimately mean in applied practice at the level of farmers, and are these broader frameworks effective?

## 6. METHODOLOGY

This methodology aims to facilitate a treatment of the questions listed in the preceding section via one year of applied fieldwork in four districts of the Vidarbha region of Maharashtra<sup>31</sup>.

GENERAL QUESTIONS	PRECISE QUESTIONS	DATA NEEDS	METHODS
1. Who are the key actors?	1.1 How do these actors interact with one another?	- Evidence of consultative processes - Establishing key actors and fora	- Literature reviews and interviews with policy agents, scientists/experts, civil society groups, and farmers - Video and more traditional means for policymakers, scientists/experts and civil society, and participatory video among farmers
2. What are the cognitive reference points?	2.1 How are the terms that frame the debate defined by these parties?	- The formation of a lexicon of key terms (i.e. risk, uncertainty, and participation) - Corresponding definitions of these terms from policymakers, civil society, scientists/experts, and farmers	- Interviews with policy agents, scientists/experts, civil society groups, and farmers - Video and more traditional means for policymakers, scientists/experts and civil society, and participatory video

<sup>31</sup> Refer to Appendix 4 for an outline of the salient features of the region with regards to this study.

			among farmers
	2.2 Do these terms result in disengagement between these parties?	- An understanding of how these four parties view each other	See 2.1
3. What does regulation initiated at either a multilateral or domestic level mean in applied practice?	3.1 How have those who are allegedly the subject of regulation responded to these frameworks, and how effective have they been?	- An analysis of formal (i.e. court cases) and informal (i.e. civil disobedience, direct actions, advocacy work, and farmer level knowledge) proceedings	See 1.1

This research is stratified among three levels of governance, concurrent with the Indian system of governance; at the centre, state, and village, or *panchayat* level<sup>32</sup>. Accordingly, there are three phases of research that characterize the fieldwork exercise. First, to establish what the expectations are of those actors at the national level in New Delhi in terms of the regulatory regime they administrate and manage. Second, a similar exercise at the state level in Maharashtra, but distinct due to a determination of how state level functionaries negotiate, implement, and undertake directives from the centre. Third, and most significantly for the purposes of this study, at the *panchayat* level in the Vidarbha region. Given that the primary aim of this study is to determine how regulation truly “plays out on the ground”, this final phase will present a series of activities that will comprise the bulk of the fieldwork.

Two villages in Vidarbha will be selected on the basis of one defining feature: the cultivation of Bt Cotton. More specifically, one village will exhibit one or more of the following parameters:

- The existence of Bt Cotton trial plots
- The cultivation of unauthorized varieties of Bt Cotton
- Significant civil society representation on behalf of farmers
- Direct farmer actions (i.e. civil disobedience) in the context of Bt Cotton
- Farmer suicide
- The receipt of government sponsored farmer compensation packages

In comparison, the corresponding village will not. This is to facilitate comparisons between the two, and to judge the primacy of the parameters stated here in terms of the welfare of farmers and the effect of both informal and formal regulation on their welfare.

A number of characteristics at the village level also warrant consideration to facilitate a better understanding of technology acquisition and usage, and will be addressed via the following questions:

- Where is seed acquired? (i.e. seed stalls, farmer to farmer exchange)
- How is seed acquired? (i.e. financed via debt incurred from private moneylenders, formal credit institutions, or other sources)
- What are income levels? (to be estimated via PRA wealth ranking exercises)
- How has Bt Cotton been marketed? (i.e. print/audiovisual media, “caravans”, word of mouth)
- How has cotton lint been marketed (i.e. from field to market and beyond to gauge the spectre of contamination and the possibility of coexistence)

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<sup>32</sup> This also echoes the system of biosafety regulation that currently exists in India, which establishes distinct roles within these three tiers. Refer to Appendix 3 for the schematics of these authorities.

- How does Bt Cotton affect gender relations within farmer households?<sup>33</sup>

While this list is by no means exhaustive, the aim is to outline the nature of the parameters and overarching questions that will be considered in this exercise.

Both quantitative as well as qualitative tools will be utilized here, but of particular note is the application of participatory video (PV) in facilitating a more inclusive attempt at allowing the perspectives of farmers to be considered within policy processes<sup>34</sup>. The rationale for using PV in this research is to allow for those end users of a new technology a medium whereby their perspectives can be offered agency. The benefits of the medium are that they transcend issues such as literacy and barriers present towards the dissemination of perspectives due to the advent of digital video and web based portals that allow anyone with video content to share their content with others<sup>35</sup>. In a more applied context, the aim here is to facilitate a novel qualitative methodological approach to counter those criticisms of fieldwork bias and distortion on the one hand (Geertz 1973, Rosaldo 1986, Denzin and Lincoln 1994), and to address the role of science and citizenship on the other (Leach, Scoones, and Wynne 2005).

## 7. PROVISIONAL TIMELINE (2007-2008)

	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
Phase 1.1: New Delhi <sup>A</sup>	✓																							
Phase 2.1: Mumbai <sup>B</sup>		✓																						
Phase 3.1: Vidarbha <sup>C</sup>			✓	✓	✓																			
Consolidation of findings, possible re-strategizing <sup>D</sup>						✓	✓																	
Phase 2.2: Mumbai <sup>E</sup>								✓																
Phase 3.2: Vidarbha									✓	✓	✓													
Consolidation of findings and initial presentations <sup>F</sup>												✓												
Writing of Thesis <sup>G</sup>													✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

### Notes:

<sup>A</sup> This phase will build on contacts established at the central level throughout 2002-2005 via previous work conducted with Dr. Suman Sahai, and during this time the researcher will be based at the offices of Gene Campaign ([www.genecampaign.org](http://www.genecampaign.org)).

<sup>B</sup> More time may be required for this phase as contacts will have to be cultivated during Phase 1.1, and as such, the precise schedules of those interviewees is not currently known.

<sup>C</sup> Phase 3.1 will be spent primarily among the two villages chosen for this exercise, with the bulk of time divided between conducting interviews (via traditional means as well as using video). The researcher will ideally be based within the villages themselves, depending on the contacts made in Mumbai/New Delhi.

<sup>D</sup> Two months have been allotted here to reflect on the initial fieldwork conducted to date. The rationale here is to write an initial report that will consolidate the findings to date with regards to the objectives of this study.

<sup>33</sup> The role of gender is primarily within the context of post suicide households, where women typically become primary wage earners due to the loss of the male head. Similarly, the marriage of daughters implies a cost burden to families, which compounds the burden of debt due to the acquisition of farm factor inputs. Refer to Appendix 4 for more details.

<sup>34</sup> Much has been written about how the moving image, and more specifically, digital video, can allow for the purity of perspective to be retained. For instance, see Ghose (2006).

<sup>35</sup> For instance, <http://www.youtube.com> offers those who sign up a "channel" that anyone can access via the unique URL assigned to it.

<sup>E</sup> Phases 2.2 and 3.2 draw upon 2.1 and 3.1, but differ in terms of the depth and focus due to the preceding consolidation phase.

<sup>F</sup> This phase marks the end of formal fieldwork. The findings will be presented back to those parties who assisted in the research (i.e. Gene Campaign, IDRC, other parties) and will also allow for a broader range of parties to offer feedback.

<sup>G</sup> The authoring of the final thesis will occur over 2008. At this point, it is envisioned that time will be split between England and India to write, but this is subject to change.

## APPENDIX 1: PERSPECTIVES FROM THE LITERATURE

### A1.1 ECONOMICS

Posner (1974) defines regulation in an economic context as “taxes and subsidies of all sorts [and] explicit legislative and administrative controls over rates, entry, and other facets of economic activity”, while Chang (1997) defines it as “...government activity that is intended to affect directly the behaviours of private sector agents in order to align them with the ‘public interest’”. Both definitions (one implicitly, the other explicitly) casts a role of an agent that enforces control, which broadly can be described as some sort of regulatory authority, either informal or formal. A definition such as this places regulation firmly within the context of a market consisting of parties who, due to the incentives present within a capitalist system, engage in activities that can be characterized via various modes of production, with the end result being a good or service available for consumption in the market.

Along these lines, the neoclassical school of economics posits the following assumptions: that market efficiency is best achieved via competition, fostered by a large number of firms operating in a tacit environment of perfect information which leads to Pareto optimal pricing, and that intervention in this process (by, for instance, the state) will result in distortionary incentives and a resultant misallocation of resources, thus perverting the process of attaining efficiency<sup>36</sup>. If the 1960s were the “age of regulation”, where developed countries emphasized the correction of market failures (in the neoclassical sense) via government intervention and developing countries had more of a focus on “developmental” (i.e. Import-Substitution-Industrialization) objectives, the 1970s saw a shift away from interventionist regulation and classic developmental objectives. In the 1980s, policies appeared to come full circle and were aimed more at deregulation and privatisation.

Yet regardless of these geographic and dynamic dichotomies and characteristics, six elements are common: the possibility of market failure (i.e. where the notion of competitive markets efficiently allocating resources fails due to externalities (Scitovsky 1954), information asymmetries (Akerlof 1970), public goods (Samuelson 1954), merit goods, incomplete markets, monopolies, or income inequalities), state failure (i.e. where the state does not act as a disinterested party and succumbs to influence, or regulatory capture), the challenge of regulating competition, notions of how to characterize risk under information asymmetries, and how policy can be transposed from one country to another (Parker 2005: 6).

### A1.2 INTERNATIONAL LAW

Since the end of the second World War, the mechanisms used by states to establish culpability or to influence state level decision making in the international arena have evolved along the lines of those trends outlined in the preceding section (i.e. economic incentives and deregulation), but have also been influenced by such trends as the growing influence of transnational corporations, changes in production methods, rapid expansion in international trade, and advances in information and communication technologies (Senarclens 1991: 91). The arena of international legal engagement in the context of regulation can be characterized along one main distinction; that of “hard” laws, or legally binding obligations that delegate authority for implementation, versus “soft” laws, or legal arrangements that are less precise in terms of obligation, precision, and delegation (Abbott and Sindal

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<sup>36</sup> With particular reference to the final assumption, some individuals (initially Keynes) have presented arguments for government intervention within this system to address the “excesses and contradictions” of capitalism. His influence was significant in the Bretton Woods conference of 1944, which acted as the catalyst for the World Trade Organization (WTO). However, current trends reflect the opposite, with the widespread implementation of privatisation schemes, the decreasing role of individual states in creating policy, and attempts at the harmonization of trade policy to facilitate the exchange of goods and services across borders (Chang 1997).

2000: 421-422). Institutionally, this is characterized primarily via the WTO and the UN, the catalysts of which both can be traced to the end of the Cold War and movements towards the increased role of regional integration (Lake 2003).

The WTO constitutes hard law due to the process and architecture of dispute settlement (DS) and the treaties that govern interaction within the context of international trade<sup>37</sup>. The legal status of the WTO is made tractable by a series of treaties and a system of dispute settlement (Snyder and Cheng 2005)<sup>38</sup>. Similarly, the UN consists of a number of treaties, some legally binding, others not<sup>39</sup>. However, the concern here is the disaggregation of individual culpability for violations of these treaties, particularly in the context of the transboundary movement of new technologies (Mason 2004:4). Ultimately, the efficacy of an international legal system based on either hard or soft laws is directly a function of the capacity of domestic legal systems, rendering the notion of “international” law somewhat misleading as it is domestic law that ultimately implements international directives (Malanszuk 1997)<sup>40</sup>. Finally, even if these instruments are binding, no guidance is provided on how member states can implement these directives.

### A1.3 POLITICAL SCIENCE

Regulatory reform in the current political context can be traced back to state initiated economic reform efforts in the US; first the Progressive Era of the late 19th century, followed by the New Deal (characterized by the central tenets of “relief, recovery, and reform”) arising from the Great Depression. These initiatives were characterized by state directed intervention, and most of these attempts were focused on economic regulation; to ensure, define and establish the preconditions for “good” (i.e. efficient) market performance (Nichols 2000). In the US at this time, intervention and regulation were almost interchangeable terms.

After 1930, two issues arose: first, the acknowledgment of regulatory capture, rent seeking behaviour and concerns of regulatory independence (Moran 2002), and second, the movement of state sponsored regulation into unprecedented social spheres (i.e. health and safety, environment) during the 1960s and 70s, with a corresponding rise in risk assessment activities. This era is considered by some to be the beginning of the modern regulatory era (Wiener 2004). Movement into these spheres produced litigation and a growing legalization of regulation for maintaining authority, characterized in the literature as command and control (Rhodes 1997). This was distinct from the prior negotiation of outcomes between state agencies and industry (Stewart 1988). As a result of these changes, the notion of the Regulatory State (RS) arose, in contrast with the (Keynesian) Welfare State (WS)<sup>41</sup>. The RS contains more emphasis on the use of authority, rules and standard-setting, and shifting the emphasis of control from traditional bureaucratic mechanisms towards instruments of regulation. This is in contrast to the WS emphasis on public ownership, public subsidies, and directly provided services, often offered via a partnership of local and central government (Hood et al. 1999, Scott 2003, Jones 1998).

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<sup>37</sup> For instance, the Agreement on Trade Related Aspects of Intellectual Property Rights, or TRIPS, presents minimal standards for the formal protection of knowledge that all member states are to adhere to.

<sup>38</sup> However, some observers have noted possible imbalances in this system. Horn et al (1999) state that 60% of all WTO DS complaints have been filed by Canada, US, Japan and the EU, which raises questions as to whether DS is biased towards smaller and poorer countries, who may lack legal capacity, have limited retaliatory power, or be averse to the spectre of negatively influencing aid or unilateral agreements.

<sup>39</sup> The Convention on Biological Diversity, or the CBD, is one example of a legally binding framework, though the wording of the convention is arguably open to a wide variety of interpretations.

<sup>40</sup> Thus while hard laws do imply culpability, establishing culpability in practice is often difficult. Moreover, international law (i.e. the International Court of Justice) differs from (common) law as it does not recognize past legal precedence (*stare decisis*) (Shahabudeen 1996).

<sup>41</sup> The core assumptions of the RS are that regulation is instrumental and standardized in character, that the state is necessarily central to regulatory governance, and that state law is a central instrument of regulatory governance.

More recently, the 1990s have seen movement away from the assumptions that underpin these notions, as some critics have viewed them as overly theoretical (MacLeod 1997, Moran 2002). The Post RS shifts the focus of analysis from state law to the wider range of norms and mechanisms to assert or achieve control due to tensions between the *social* and *economic* goals of regulatory politics<sup>42</sup>. Starting from Foucault (1979)<sup>43</sup>, Parker (2002) and Morgan (2003) present the notion of metaregulation, characterized as an instance of non judicial legality, situated at the intersection of two trends – an increasing legalization of politics and a growing reliance on non judicial mechanisms of accountability.

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<sup>42</sup> Scott (2003) characterizes the Post RS as where the capacity of law to exert control is limited (Autopoiesis: Teubner 1987), where control based on law is marginal to processes of ordering (Foucault 1991), and where state law is most effective when linked to other ordering processes (Braithwaite 1992).

<sup>43</sup> Foucault (1979) argued that the “state” is just one site of managing the “conduct of conduct”.

## APPENDIX 2: INDIAN REGULATION ON GMOS WITH REGARDS TO PGR

The management of GMOs in Indian agriculture via regulation reflects ambitions within two spheres. First, an almost nationalistic fervour to lead, be recognized as a leader, and to be self sufficient; *to become a regional player in the biotech industry by providing incentives for domestic innovation via intellectual property rights*. Second, to ensure “biosafety”; *ensuring scientifically sound best practices within a system of stringent checks and balances for the “safe” management of the technology in the context of commercial release and R&D*. These ambitions manifest themselves via a regulatory framework that is both ambitious in scope as well as technically comprehensive.

India’s regulatory framework spans science and technology, the environment, agriculture, food and health, and trade<sup>44</sup>. With the exception of the Patent Act, Biological Diversity Act, and Plant Variety Protection and Farmers’ Rights Act (which are not expressly concerned with GMOs but are still linked), all the existing frameworks refer back to the **Environmental Protection Act (1986)** as the basis for all regulation surrounding GMOs<sup>45</sup>.

The objective of this appendix is to characterize and summarize all the relevant mechanisms within the management of GMOs in agriculture in India. They are presented in three sections: Rules and Policies, Guidelines, and Acts and Bills. This distinction does not indicate that some are legally binding and others not; with the exception of bills, all are legally enforceable. It should be noted that in what follows, only those domestic frameworks that have implications on agriculture are considered; pharmaceuticals and aquaculture are not considered, nor are the international fora that have often (but not always) acted as a catalyst for domestic regulation.

### A2.1 RULES AND POLICIES

#### A2.1.1 The 1989 Rules

In 1989, the Ministry of Environment and Forests (MoEF) notified the **Rules for Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells (1989)**<sup>46</sup>. The stated rationale for the 1989 Rules are to protect “...the environment, nature and health, in connection with the application of genetechonology and micro-organisms”, and to address activities involving the manufacture, use, import, export, storage and research of GMOs including microorganisms, plants and animals (Damodaran 2005, MoEF 2006)<sup>47</sup>.

<sup>44</sup> Refer to Appendix 3 for a chart outlining the relevant ministries, departments, and regulatory frameworks.

<sup>45</sup> Refer to <http://dbtindia.nic.in/policy/act1.html> for the text of the EPA 1996. Briefly, the relevant sections of the EPA in the context of GMOs are sections 6 (relating to environmental pollution), 8 (adherence to safety standards in the context of hazardous substances), and 25 (the power of the Indian government to enforce).

<sup>46</sup> Hereafter referred to as the “1989 Rules”. Refer to <http://dbtindia.nic.in/policy/rules.html> for the text of the 1989 Rules. More recently, there appear to be moves to amend the 1989 Rules within the context of importation and GEAC approval. A recent public notice by the GoI has suggested that GEAC import approval would only be required in the context of LMOs, and that some GMOs (i.e. Round up Ready Soybean oil) would not require GEAC approval (MoEF 2006b).

<sup>47</sup> The approvals and prohibitions of the rules can be summarized along twelve points: 1. No person shall import, export, transport, manufacture, process, use or sell any GMOs, substances or cells except with the approval of the GEAC. 2. The use of pathogenic organisms or GMOs or cells for research purpose shall be allowed under the Notification (1989) of the EPA (1986). 3. Any person operating or using GMOs for scale up or pilot operations shall have to obtain permission from GEAC. 4. The ISBC is the contact for experiments on GMOs for the purposes of education, as per the guidelines of the Government of India. 5. The deliberate or unintentional release of GMOs is not allowed. 6. Production processes in which GMOs are generated or used shall not be commenced except with the approval of GEAC. 7. GEAC supervises the implementation of rules and guidelines. 8. GEAC carries out supervision through SBCC, DLC or any authorized person. 9. If these orders are not complied to, the SBCC/DLC may take suitable measures at the expenses of the person who is responsible. 10. In the context of immediate interventions to prevent damage, the SBCC and DLC can take suitable measures and the expenses incurred will be recovered from the person responsible. 11. All approvals shall be for a period of 4 years at first instance, renewable for 2 years at a time. 12. The GEAC shall have powers to revoke approvals in case of: a)



In practice, two ministries are responsible for the implementation of these rules, the MoEF and the Ministry of Science and Technology (MST) via the Department of Biotechnology (DBT)<sup>48</sup>. The 1989 Rules mandate and characterize the role of six competent authorities for the management of GMOs.

#### MOEF AND MST AUTHORITIES AS MANDATED BY THE 1989 RULES

<b>Authority &amp; Accountability (Policy)</b>	<b>Primary Role</b>
Recombinant DNA Advisory Committee (RDAC) <b>MoEF→DBT</b>	Presents recommendations for upholding safety regulations for GMO research and management; authored the Recombinant Safety Guidelines (1990) (RSG 1990) <sup>49</sup>
Review Committee on Genetic Manipulation (RCGM) <b>MoEF→DBT (RSG 1990)</b>	Provides guidelines to parties interested in GMO R&D, use, and application; reviews and permits all high risk rDNA experiments; restricts GMO import/sale/use; authorizes field trials up to 20 acres in size; visits trial sites and ensures safety measures are met as per RSG 1990
Genetic Engineering Approval Committee (GEAC) <b>MSE (EPA 1986)</b>	Permits GMO commercial products and applications; authorizes large scale GMO production and release, authorizes punitive action under EPA 1986
Institutional Biosafety Committees (ISBC) <b>MST→DBT→GEAC, RCGM</b>	The nodal point within the DBT for all parties intending on GMO R&D; alerts SBCC, DLC, and GEAC about experiments; reports to and seeks approval from RCGM for category III risk or above experiments; ensures experimentation occurs on mandated areas based on protocol
State Biosafety Coordination Committees (SBCC) <i>Chief Minister→Relevant State Ministries</i>	Inspects and takes punitive action if policy violation occurs via state ministries; periodically reviews institutional safety/control measures, acts as the nodal agency within the state in case of damage caused by GMOs, is the main link to Centre Ministries in the GMO context, can nominate state representatives for GMO field inspection
District Level Committees (DLC) <b>DISTRICT COLLECTOR→SBCC→GEAC (EPA 1986)</b>	Monitors safety regulations in installations; reports to SBCC or GEAC in case of violations, acts as nodal agency at the district level to assess potential damage

Source: MoEF 2006a

The IBSC, RCGM, and GEAC are the primary agencies involved in the approval of new transgenic crops in the context of biosafety; in general, the ISBC acts as the nodal point for receiving the initial application submitted by any party interested in research activities, with the final decision being made by the RCGM, except in “large-scale” experiments where the application is directed towards and considered by the GEAC<sup>50</sup>. With regards to monitoring and safety concerns, the Monitoring and Evaluation Committee (MEC) acts under the RCGM to visit small-scale field sites and to recommend safe and viable crops to the GEAC and RCGM.

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Any new information on harmful effects of GMOs. b) GMOs causing damage to the environment not envisaged when approval was given. c) Non-compliance of any conditions stipulated by GEAC. Refer to Ahuja and Jotwani, p. 3.

<sup>48</sup> While two ministries are directly involved, in total six ministries are indirectly involved, along with a host of other committees and agencies. Refer to Appendix 3. Note that this chart does not include aspects of transgenic technologies in pharmaceuticals or aquaculture.

<sup>49</sup> Refer to [http://dbtindia.nic.in/policy/guidelines\\_90.pdf](http://dbtindia.nic.in/policy/guidelines_90.pdf) for the text of the RSG 1990.

<sup>50</sup> In terms of size, the RSG states that experiments above 20 L for research and industrial purposes and above 20 acres for agricultural purposes is considered large-scale, and require approval from the GEAC. Large-scale agricultural trials are conducted by the Indian Council for Agricultural Research (ICAR), who the report their results and findings to the GEAC. Refer to Chapter 7 of the RSG 1990.

### A2.1.2 The Seed Policy

India's **Seed Policy (2002)** has seen a number of amendments since 1988, with the catalyst being both the advancement of transgenic technologies and the need for regulatory frameworks as well as the prescriptive commitments that India is bound to as a member state of the World Trade Organization. The salient aspects of the Seed Policy (SP) with regards to GMOs are found in Chapter 6 under "Transgenic Plant Varieties", where linkages are made to the EPA 1986, and thus the 1989 rules.

- All transgenic seed will be tested prior to commercial release as per the EPA 1986.
- The importation of transgenic seed into India must be received only by the National Bureau of Plant Genetic Resources (NBPGR), and only after GEAC approval.
- Transgenic seed must be labelled as such, and must be tested for at least 2 years by the Indian Council for Agricultural Research (ICAR) in coordination with all other tests as stated in the EPA 1996. After commercial release, the Ministry of Agriculture and State Departments of Agriculture will monitor transgenic crops for five years.
- Transgenic varieties are afforded the same IPR protection as non-transgenic varieties as stipulated in the Protection of Plant Varieties and Farmers' Rights Act (2001).

It should be noted that the Seed Policy (2002) is distinct from the Seed Act (1966) and the proposed successor to the Seed Act, the Seed Bill (2004)<sup>51</sup>. The Policy is primarily of interest to those firms involved in commercial R&D as a procedural indication of what the Centre will require of them as suppliers, whereas the Act covers all aspects and users of seed.

### A2.1.3 The Prevention of Food Adulteration Rules

The Prevention of Food Adulteration Act (PFA) was enacted in 1954 for ensuring the quality and safety of food marketed in the country. It is managed by the Ministry of Health and Family Welfare (MoHFW) under the central PFA Division, and has seven salient features.

1. Enhance the availability of safe and wholesome food.
2. Consumer protection from deception, fraud and food-borne diseases.
3. Risk analysis, risk management and risk communication.
4. Ensure safety of genetically modified food.
5. Enhance the involvement of NGOs and Home Science Institutes.
6. Educational authorities to ensure better consumer protection.
7. Promote a voluntary management system, the Code of Ethics, through principles of Good Manufacturing Practices and the Hazard Analysis and Critical Control Points<sup>52</sup>.

Of particular interest here are the third, fourth, and fifth points. In May 2006, the PFA notified the **Prevention of Food Adulteration Rules**, which amended the PFA act<sup>53</sup>. There are two relevant

<sup>51</sup> Refer to <http://agricoop.nic.in/seedsact.htm> for the 1966 act and [http://agricoop.nic.in/seeds/seeds\\_bill.htm](http://agricoop.nic.in/seeds/seeds_bill.htm) for the 2004 bill. Initial preparation for the 2004 Bill began in 1998; refer to Sharma (2005) for a useful review of this process.

<sup>52</sup> GMP and HACCP are standards and guidelines developed by the US Food and Drug Administration. Refer to <http://www.fda.gov/oc/guidance/gmp.html> for an overview of GMP and <http://www.cfsan.fda.gov/~lrd/haccp.html> for an overview of HACCP.

<sup>53</sup> Refer to <http://pib.nic.in/release/release.asp?relid=17941> for the text of the PFA Rules. The PFA Rules appear to be a direct consequence of the best practices detailed in the Codex India Procedural Manual, prepared by the National Codex Committee under the PFA as a consequence of membership to the Codex Alimentarius Commission, created by FAO/WHO in 1963 to develop food standards, guidelines and related texts (i.e. codes of practice) under the Joint FAO/WHO Food Standards Programme. Refer to [http://codexindia.nic.in/Codex%20\(India\)%20Procedural%20Manual.pdf](http://codexindia.nic.in/Codex%20(India)%20Procedural%20Manual.pdf) for the Indian Procedural Manual and [http://www.codexalimentarius.net/web/index\\_en.jsp](http://www.codexalimentarius.net/web/index_en.jsp) for the Codex Alimentarius website.

additions that relate to the labelling of GM food products. Rule 37(e) states that:

GM food [...] whether it is primary or processed or any ingredient of food, food additives or any food product that may contain GM material shall be compulsorily labelled without any exceptions.

Similarly, rule 48(f) has been added, which states that:

No person shall, except with approval of and subject to the conditions that may be imposed by the Genetic Engineering Approval Committee (GEAC) constituted under the Environment Protection Act, 1986, manufacture, import, transport, store, distribute or sell raw or processed food or any ingredients of food, food additives or any food product that may contain GM material in the country: Provided that in case of imported genetically modified foods, the importer shall submit documents supporting the purported clearance at the time of import.

The GoI press release that released this information also stated that “the draft rules in the notification will be taken into consideration after the expiry of 60 days. [O]bjections or suggestions in respect of draft rules may be addressed to the Secretary, MoFHW.

#### **A2.1.4 The Plant Variety Protection and Farmers Rights Rules**

The 2003 Rules manifest a framework for undertaking the provisions of the Plant Variety Protection and Farmers Rights Act (2001)<sup>54</sup>. Refer to section A.3.3 for the salient features of the 2001 Act.

### **A2.2 GUIDELINES**

#### **A2.2.1 The Recombinant Safety Guidelines**

The DBT formulated the **Recombinant Safety Guidelines** (RSG) to address risk and safety concerns in light of research activities undertaken by Indian institutions and industry. The 1990 guidelines were then revised in 1994 “...to cover R&D activities on GMOs, transgenic crops, large-scale production and deliberate release of GMOs, plants, animals and products into the environment, [and the] shipment and importation of GMOs for laboratory research” (Ahuja and Jotwani, Undated)<sup>55</sup>. The guidelines are classified into three categories based on the level of the associated risk and requirement for the approval of competent authority.

#### **EXPERIMENT CATEGORIZATIONS WITHIN THE RSG**

<b>Category</b>	<b>Characterization</b>
I	Experiments involving self cloning and interspecies cloning belonging in organism in the same exchanger group; exempt from approval
II	Containment levels II, II, IV
III	Toxin gene cloning, gene cloning for vaccine production.

Source: Ahuja and Jotwani

These guidelines draw from principles of “good laboratory practices” as noted in the World Health Organization laboratory safety manual on genetic engineering techniques involving

<sup>54</sup> Refer to <http://agricoop.nic.in/seeds/farmersact2001.htm> for the text of the PPVFR Rules.

<sup>55</sup> Refer to [http://dbtindia.nic.in/policy/guidelines\\_90.pdf](http://dbtindia.nic.in/policy/guidelines_90.pdf) and [http://dbtindia.nic.in/policy/guidelines\\_94.pdf](http://dbtindia.nic.in/policy/guidelines_94.pdf) for the RSG 1990 and 1994 respectively.

microorganisms<sup>56</sup>. Specifically, the RSG requires those parties involved in GMO R&D to evaluate risk in terms of “...possible interaction with other disease causing agents and infected wild plant species” and that an independent review be conducted to assess risk on a case by case basis prior to release (MoEF 2005).

### A2.2.2 The Guidelines for Research in Transgenic Crops

In 1998, the DBT established the **Guidelines for Research in Transgenic Crops (GRTC)** 1998 due to the “...enormous progress that has been made in rDNA research and its widespread use in developing improved microbial strains, cell lines, and transgenic plants for commercial exploitation” (DBT 1998). While similar in scope to the RSG, the GRTC has a specific focus on transgenic PGR, unlike the RSG which also covered animals. Specifically, the GRTC addresses areas of rDNA research on plants including the development of transgenic plants and their growth in soil for molecular and field evaluation. The guidelines also deal with import and shipment of genetically modified plants of research purposes (Ahuja and Jotwani, Undated). In this context, the GRTC outlines three categories of experiments on plants.

#### EXPERIMENT CATEGORIZATIONS WITHIN THE GRTC

Category	Characterization
I	Routine cloning of defined genes, defined non-coding stretches of DNA and open reading frames in defined genes in <i>E. coli</i> or other bacterial/fungal hosts which are generally considered as safe to human, animals and plants.
II	Lab and green house/net house experiments using defined DNA fragments non-pathogenic to human and animals for genetic transformation of plants, both model species and crop species.
III	Experiments where the escape of transgenic traits into the open environment could cause significant alterations in the biosphere, the ecosystem, plants and animals by dispersing new genetic traits which cannot be judged precisely. This also includes experiments having risks conducted in green houses and open field conditions.

Source: Chapter 4, GRTC (1998)

### A2.3 ACTS AND BILLS

Aside from Rules, Policies, and Guidelines, there are also exist a number of legally binding acts and not yet enacted bills that exist within the context of GMOs.

#### A2.3.1 The Food Safety and Standards Bill

In 2005 the Ministry of Food Processing Industries introduced the **Food Safety and Standards Bill (FSSB)** to facilitate scientific standards for food articles and regulate their manufacture, storage, distribution, sale and import. As per the provisions of the Bill, no person shall manufacture, process, export, import or sell genetically modified articles of food, organic foods, functional foods, nutraceuticals, health supplements etc. except in accordance with the regulations made under the FSSB. Moreover, the salient aspects of the PFA 1954 (and presumably the 2006 PFA Rules) and the EPA 1996 are to be considered in tandem with the FSSB, thereby implying testing and labelling.

#### A2.3.2 Plant Quarantine (Regulation of Import into India) Order

<sup>56</sup> Refer to <http://www.who.int/entity/csr/resources/publications/biosafety/en/Biosafety7.pdf> for the manual.

The Destructive Insects and Pests Act (1914) was notified in 2003 via the **Plant Quarantine (Regulation of Import into India) Order**, and has been amended several times to meet the SPS guidelines of the WTO<sup>57</sup>. The relevant portions of the order are in section 8, which assigns the role to the National Bureau of Plant Genetic Resources (NBPGR) as the sole party that can receive GMOs via importation, conditional on RCGM approval and the 1989 Rules.

### A2.3.3 The Plant Variety Protection and Farmers Rights Act

As a response to the WTO mandated prescriptions of plant variety protection under Article 27.3(b) of TRIPS, India introduced the Plant Variety Protection and Farmers Rights Act (PPVFR) in 2001, which was notified in 2005<sup>58</sup>. The salient aspects of the PPVFR with regards to GMOs can be found in section 29.2, which disallows the formal registration of Gene Use Restrictive, or “Terminator”, Technologies (GURTs). Moreover, section 39.1(iv) details Farmers’ Rights provisions, and disallows farmers to sell seed that is “branded”. However, Indian farmers are allowed to save formally protected seed under the PPVFR, regardless of the protection conferred to that seed in other countries. This has implications on the saving of formally protected transgenic varieties of seed by Indian farmers, which, according to the PPVFR, is allowed, provided the farmer does not sell it. Yet the stipulation of “branded” is unclear and seems to imply that farmers are free to repackage branded seed and sell it as “non-branded” with no legal implications.

### A2.3.4 The Seed Bill

The 2004 **Seed Bill** forms the basis for the revised Seed Act, which is expected to replace the existing 1966 Seed Act<sup>59</sup>. In terms of GMOs, the bill has two relevant aspects. First, section 12.1 details the modalities of a Registration Subcommittee, whose primary role is to maintain a National Register of Seeds encompassing “...all kinds and varieties of seed”<sup>60</sup>. Second, section 15.1 states that “...no seed of any transgenic variety shall be registered unless the applicant has obtained clearance in respect of the same as required by or under the provisions of [the] EPA (1986)”. Third, as in the PPVFR (2001), GURTs are banned under section 18.2. Fourth, farmers are provided with an accountability mechanism in Section 20, whereby if “...such registered seed fails to provide the expected performance under such given conditions, the farmer may claim compensation from the producer, distributor or vendor under the Consumer Protection Act, 1986”. Fifth, it establishes culpability for those parties supplying spurious seed in Section 38.2 by stating that “...[i]f any person furnishes any false information relating to the standards of genetic purity, misbrands any seed or supplies any spurious seed or spurious transgenic variety, [or] sells any non-registered seeds he shall, on conviction, be punishable with imprisonment for a term which may extend to six months or with fine which may extend to fifty thousand rupees or both.”

<sup>57</sup> Refer to [http://plantquarantineindia.org/PQO\\_amendments.htm](http://plantquarantineindia.org/PQO_amendments.htm) for the 2003 order and successive amendments.

<sup>58</sup> Refer to <http://agricoop.nic.in/PPV&FR%20Act,%202001.pdf> for the text of the PPVFR 2001. While the PPVFR opts for a plant breeders/farmers’ rights regime on plants and seeds as opposed to a patent regime, patents on PGR are admissible under the Patents Act (2005).

<sup>59</sup> Refer to [http://agricoop.nic.in/seeds/seeds\\_bill.htm](http://agricoop.nic.in/seeds/seeds_bill.htm) for the text of the Seed Bill.

<sup>60</sup> At this stage, it is unclear which parties the Registration Subcommittee will be comprised of. Some critics have noted that registration in the context of the subcommittee could subordinate the registration process detailed in the PPVFR via the Protection of Plant Varieties and Farmers’ Rights Authority outlined in section 3.1 of the PPVFR, namely the registration activities outlined in section 8.2 (Kuruganty 2005). Moreover, the PPVFR Authority is mandated to contribute to a Register of Plant Varieties, which appears to be distinct from the National Register of Seeds mandated in the Seed Bill. The spectre of duplication requires consideration. Similarly, while the PPVFR allows for anyone (i.e. farmers or public/private sector breeders) to intimate registration (as per Section 16), the Seed Bill does not contain this explicit provision. Essentially, critics consider the Seed Bill to be directed towards those seeking to register GM seeds (i.e. private sector firms) as opposed to the PPVFR which has a broader mandate of plant variety protection, and there are concerns as to how the two frameworks will interact in tandem (Shiva 2005).

### A2.3.5 The Patents Act

Under the Ministry of Commerce and Industry, the 1970 Patent Act (PA) has been amended in 1999 and 2002<sup>61</sup>. The 2002 amendments removed the term “plants” from section 3(i), which previously disallowed patents on “...any process for the medical, surgical, creative, prophylactic or other treatment of human beings or any **process** for a similar **treatment** of animals or plants or render them free of disease or to increase their economic value or that of their products.” Further, section 3(j) was added, which disallows patents on “...plants or animals or any part thereof other than **microorganisms** but including seeds, varieties and species and essentially **biological processes** for production or propagation of plants and animals”<sup>62</sup>. These amendments are reflected in the current 2005 **Patent Act**.

While the PA 2005 still disallows patents on plants, animals, and seeds, a precise definition of “microorganism” and “biological process” is not defined<sup>63</sup>. Moreover, it has been argued that only those microorganisms that are the result of human invention, or due to an “inventive step” as opposed to those commonly found in nature, can be patented (Sharma 2005). In light of the amendments to 3(i) and the addition of 3(j), it could be argued that patenting of processes such as the insertion of the Bt gene into Cotton are now admissible, though the actual resultant seed (i.e. Bollgard) is not.

The other salient feature of the 2005 Act is the move from a process to product patent regime; India was mandated to ensure their IPR policy was fully TRIPS compliant by January 1, 2005<sup>64</sup>. The two amendments addressed plant variety protection; the only other TRIPS compliant measure was the enactment of a product patent regime, which the 2005 act now addresses<sup>65</sup>.

### A2.3.6 The Foreign Trade (Development and Regulation) Act

Aside from patents, the Ministry of Commerce and Industry also regulates export/import (EXIM) activities, and as such, notified the 1992 **Foreign Trade (Development and Regulation) Act** (FTDR) in April 2006 to amend Chapter 1A in the context of the import of GMOs<sup>66</sup>. The salient aspects of the notification are:

- imports are governed by the EPA 1986 and the 1989 Rules
- import approval can only be given by the GEAC
- parties wishing to import must submit their proposal to the RCGM
- imported goods must be declared (but not necessarily labelled) as a GMO

<sup>61</sup> Refer to <http://www.patentoffice.nic.in/ipr/patent/patAct1970-3-99.html>, [http://www.patentoffice.nic.in/ipr/patent/patact\\_99.PDF](http://www.patentoffice.nic.in/ipr/patent/patact_99.PDF), and <http://www.patentoffice.nic.in/ipr/patent/patentg.pdf> for the original 1970 Act and the two amendments respectively.

<sup>62</sup> Note that this language is almost a verbatim transfer from article 27.3(b) of TRIPS, where these terms are similarly left undefined. Apart from WTO obligations, the amendments also reflect obligations to the WIPO Patent Cooperation Treaty (PCT). Briefly, the PCT aims to facilitate a process whereby parties wishing to invoke a patent in many countries can do so with one application, though WIPO itself cannot grant protection.

<sup>63</sup> Refer to [http://www.patentoffice.nic.in/ipr/patent/patent\\_2005.pdf](http://www.patentoffice.nic.in/ipr/patent/patent_2005.pdf) for the 2005 act. The Technology Information, Forecasting & Assessment Council (TIFAC), an autonomous authority under the Department of Science and Technology, recently released a report titled “Patenting of Microorganisms”. This report states, inter alia, that bacteria does constitute a microorganism (i.e. Bacillus Thurengensis) and patents have been allowed on them in other countries. Refer to <http://www.tifac.org.in/discus/dispcf.htm>.

<sup>64</sup> A process patent allows the same products to be produced by different producers with different processes, whereas a product patent does not allow other firms except the patent holder to produce a particular product.

<sup>65</sup> This has serious implications for the pharmaceutical industry in the context of the production of generic drugs, or treatment regimes based on drugs that are, in essence, domestic “copies” of drugs developed elsewhere but made in a slightly different manner so as to avoid litigation under a process patent regime.

<sup>66</sup> Refer to <http://dgftcom.nic.in/exim/2000/not/not06/not0206.htm> for the text of the amendment.

- penal action as outlined in the FTDR can be taken against those to parties who knowingly export GMOs to India without the proper declaration

### A2.3.7 The Biological Diversity Act

The **Biological Diversity Act** (BDA) was enacted in 2002 in light of the best practices outlined by the CBD in the context of access to PGR and details the procedural hierarchy that exists for those parties interested in doing so<sup>67</sup>. The objectives of the Bill are:

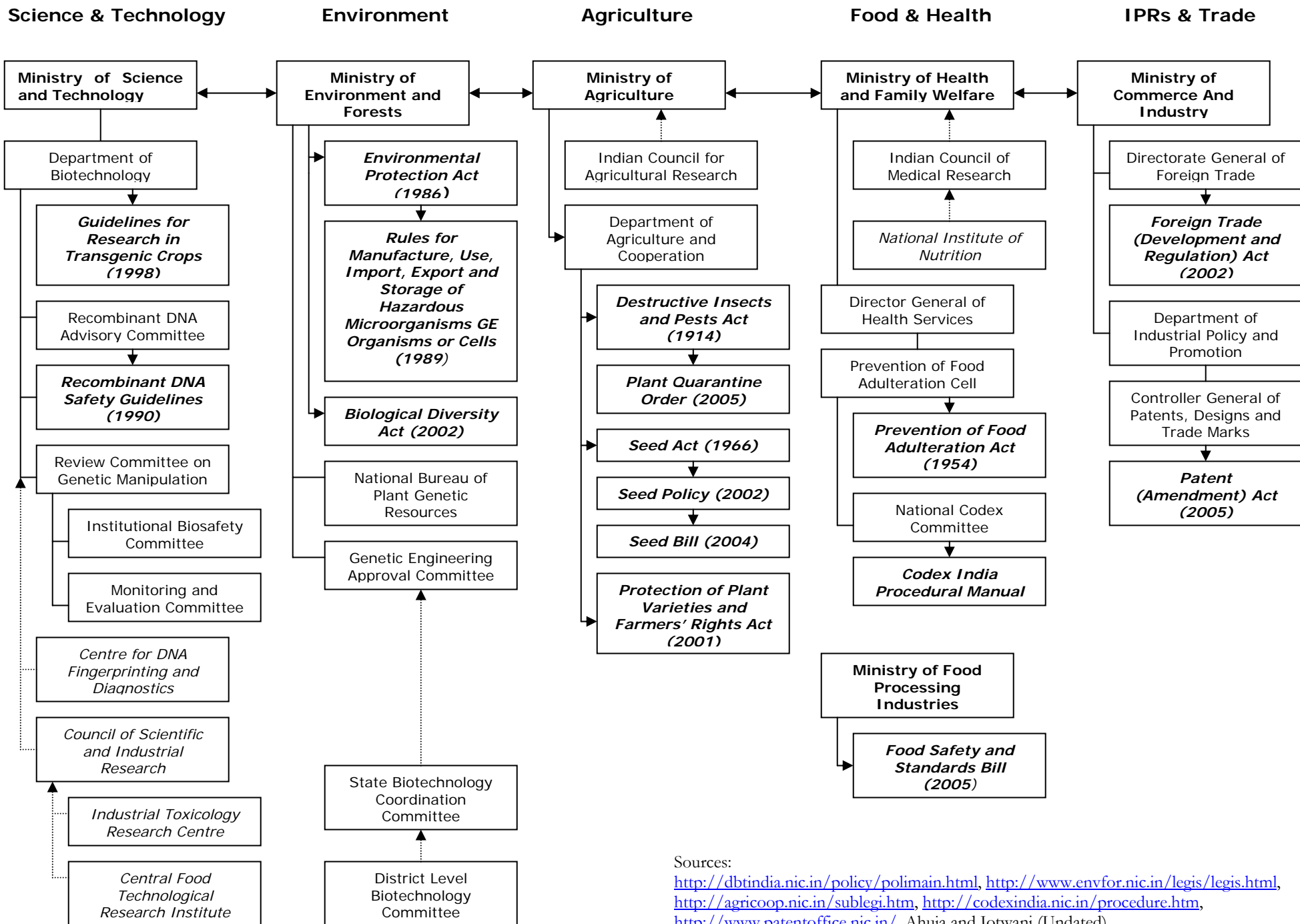
- The conservation of biological diversity
- The sustainable use of its components
- The equitable sharing of benefits arising out of the use of biological resources.

These are precisely the three objectives of the CBD, with one small change; rather than genetic resources, the third objective refers to biological resources. The Bill defines biological resources as “plants, animals and micro organisms and parts thereof, and their genetic material and by-products, with actual or potential use or value, but does not include human genetic material.” The stated objective of the act is to provide for conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources and knowledge. In the context of GMOs, section 36.4 outlines the duties of the central and state governments in the context of the act, and states that the central government shall undertake an environmental impact assessment of any project “... which is likely to have adverse effect on biological diversity, with a view to avoid or minimise such effects and where appropriate provide for public participation in such assessment”. More specifically, the central government will “...regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology likely to have adverse impact on the conservation and sustainable use of biological diversity and human health.

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<sup>67</sup> Refer to <http://grain.org/brl/?docid=322&lawid=1378> for the text of the BDA.

**APPENDIX 3: THE INDIAN REGULATORY FRAMEWORK FOR GM PLANT GENETIC RESOURCES IN AGRICULTURE**



Sources: <http://dbtindia.nic.in/policy/polimain.html>, <http://www.envfor.nic.in/legis/legis.html>, <http://agricoop.nic.in/sublegi.htm>, <http://codexindia.nic.in/procedure.htm>, <http://www.patentoffice.nic.in/>, Ahuja and Jotwani (Undated)



## APPENDIX 4: DESCRIPTION OF VIDARBHA



52% of all cotton grown in Maharashtra is grown in Vidarbha (Narayanamoorthy and Kalamkar 2006). The region is somewhat heterogeneous with regards to agro climatic features, but overall the region can be characterized as arid. There are three distinct agro climatic areas; the east (upwards of 1500mm of rain pa, with paddy being the principal crop), the west (650-850mm pa, with sorghum, pigeonpea and cotton being principal crops), and the centre (900-1300mm pa, principal crops being cotton, paddy, red chillies, sorghum, and pigeon pea) (Phansalkar 2005).

For the purposes of this study, the districts of Akola, Amravati, and Buldhana in the west and Yavatmal in the centre will be the geographic focus, and for three primary reasons.

1. **Lacking Press and Scholarly Coverage.** While the centre and the east have begun to receive more attention in the literature, it is relatively (i.e. in comparison to the Warangal district of Andhra Pradesh) rarely mentioned in both the popular press as well as scholarly discourse within the context of Bt Cotton. This is regardless of the fact that the area has grown cotton for well over a century, was one of the first regions to adopt Bt Cotton in India, and has been subject to many of the same biotic (i.e. pests) and abiotic (i.e. limited access to irrigation) stressors that affect other cotton growing areas such as Warangal (Phansalkar 2005, Mishra 2006)<sup>68</sup>.
2. **Farmer Suicides and Gender Dynamics.** Vidarbha has witnessed a relatively dramatic increase of cotton farmer suicides over the last season. Sainath (2006) and Parsai (2006) note that since 2001, as many as 981 farmers have committed suicide in Maharashtra, with 828 in Vidarbha alone since June 2005. In August 2006 alone, 111 farmers in Vidarbha have taken their own lives. Mishra (2006) outlines three primary reasons for farmer suicides: indebtedness, crop failure, and change in social status due to these challenges. This has distinct implications on the gender dynamics of households that derive their livelihoods from farming as typically it is men who commit suicide, leaving women with the burden of debt incurred from the purchase of Bt Cotton<sup>69</sup>.
3. **Secessionist Movements and Civil Society.** Efforts towards attaining state autonomy for the Vidarbha region have a long history. Immediately after independence in 1947, parts of present day Maharashtra, Gujarat, and Madhya Pradesh were part of the state of Bombay. The States Reorganization Act of 1956 was the initial catalyst for the formation of Maharashtra as a state in 1960 along linguistic (Marathi) lines. A 1953 study undertaken by the central government appointed States Reorganization Commission recommended state autonomy for Vidarbha and a larger Marathi state that would balance the Gujarati and Maharashtrian Marathi communities. However, the Maharashtrian Marathi community rejected the recommendation due to the

<sup>68</sup> While the gross output of cotton has risen since 2002 and the crop is still extensively grown (particularly in the central and western regions), profitability is declining, and as a result of both this and farmer suicides, the central government has embarked on a compensation and rehabilitation package, encouraging, *inter alia*, a shift away from cotton monocultures (Parsai 2006).

<sup>69</sup> Faleiro (2005) states that widows, who are often illiterate, become the sole wage earner and are responsible for the repayment of all debts. Moreover, the marriage of daughters presents an additional cost, and ultimately debt, burden on families. While the government has established compensation packages for these families, as of November 2005 only 168 families had received any funds, arguably complicated by the 42 conditions that must be met in order to be eligible for compensation.

Vidarbha region being a “revenue surplus area” (i.e. richly endowed with natural resources), while those in Vidarbha were suspicious of inclusion due to the strain it would put on their natural resources and their ability to assert their own control over development priorities (Windmiller 1956). Ultimately, statehood was not granted to Vidarbha at that time. Yet, political and popular movements favouring autonomy have continued, based on the premise that western Maharashtra treats the east, and Vidarbha in particular, in a “stepmotherly” fashion, which has resulted in the relative underdevelopment of the region (Phansalkar 2005). More recently, farmers organizations and political parties have argued that the dismantling of the Maharashtra State Cotton Monopoly Procurement Scheme and the lowering of the Minimum Support Price (MSP) for cotton has been of severe detriment to farmers due to rising factor input costs, particularly those in Vidarbha as the region grows half the cotton in the state<sup>70</sup>. It is this that has characterized demands for autonomy in recent times, with the primary agents for secession being civil society groups motivated by the plight of cotton farmers in the state.

#### DESCRIPTIVE STATISTICS OF THE REGION

##### Maharashtra

State Population (% of India)	96752247 (9.4%)
% of Population BPL (Rural/Urban)	17%/15.2%
Literacy (2001, Male/Female)	86.3%/67.5%
Precipitation (mm: monsoon withdrawal, monsoon, summer, winter)	28, 923, 32, 46
Area of Cotton sown in state (2000-1, 1000's of hectares) (National Ranking)	3077 (1/20)
Yields of Cotton (2000-1, bales of 170kg) (National Ranking)	1803 (1/22)
Proportion of Cotton grown as % of other crops (Statewide, 2002-3)	10.0%
Proportion of Cotton grown in State compared to National yield (2004-5)	22.4%
Area of land sown with Bt Cotton (2002-2005, Hectares)	30699, 54000, 399000, 1256961
Proportion of Bt Cotton sown by state compared to national levels (2002-5)	42.2%, 23.5%, 32.9%, 50.1%
Productivity (kg per hectare, 2002-3) (National Ranking)	141 (13/16)
State wide consumption of pesticides (2004-5, Metric Tonnes) (National Ranking)	3724 (5/34)

##### Vidarbha

	Akola	Amravati	Buldhana	Yavatmal
Population (% Rural)	1630239 (61.5%)	2607160 (65.5%)	2232480 (78.8%)	2458271 (81.4%)
Proportion of land sown under irrigation (2003-4)	4.2%	8.6%	13.4%	6.7%
Proportion of state Cotton yield by district (2000-1)	10.8%	22.3%	7.1%	14.6%

Source: IndiaStat.com

<sup>70</sup> Until 2004, and under the Maharashtra Raw Cotton Monopoly Procurement Act, 1972, Maharashtra was the only state in India that had offered state monopoly procurement of cotton at a price that was fixed at a 20% premium above the national MSP, which itself was fixed historically at an interventionist rate above global market prices. The rationale for this was twofold: to ensure farmers did not suffer due to global price fluctuations, and to redistribute monopoly profits in the form of subsidies to farmers (Mohanty et al 2002). However, recent trends have seen global prices consistently above the MSP, rendering intervention irrelevant. This, compounded with systemic corruption that rendered the subsidy program ineffective, the firm incurring significant losses, and the resultant withdrawal of financing from creditors, resulted in the termination of the monopoly in 2004 (Mishra 2006). These factors, combined with the centre reducing the MSP from INR 2500/100kg to INR 1750 and the increase in factor input costs due to Bt Cotton, have presented distinct challenges to cotton farmers, and have resulted in civil society actions to counter what is often argued as state and central regulatory failure.

## BIBLIOGRAPHY

- Abbott, K. and D. Snidal. (2000). "Hard and Soft Law in International Governance." *International Organization*. (54:3) 421-456.
- Afsah, S. et. al (1996). "Controlling Industrial Pollution: A New Paradigm." World Bank Policy Research Paper 1672.
- Ajuha, V. and G. Jotwani. (undated). "The Regulation of Genetically Modified Organisms in India." AgBios South Asia Biosafety Program Resources. Retrieved May 24, 2006 from <<http://www.agbios.com/docroot/articles/05-097-002.pdf>>
- Anonymous. (undated). "Internet Self-Regulation: An Overview." <<http://www.selfregulation.info/iapcoda/030329-selfreg-global-report.htm>>
- Barcelo, J. (2005). "The Status of WTO Rules in U.S. Law". Cornell Legal Studies Research Paper No. 06-004.
- Bharathan, G. (2000) "Bt-cotton in India: Anatomy of a Controversy." *Current Science*. 79:8 1067-1075.
- Blackman, A. (1999). "The Economics of Technology Diffusion: Implications for Climate Policy in Developing Countries." Resources for the Future Discussion Paper 99-42.
- Burand, D. (2001). "How does Consumer Protection Relate to Microcredit?" <[http://microfinancegateway.com/resource\\_centers/reg\\_sup/consumer\\_protection](http://microfinancegateway.com/resource_centers/reg_sup/consumer_protection)>
- Chandrashekhar, G. (2005). "No Case for Cotton, Sugarcane Price Hike." Business Line, October 24. Retrieved September 20, 2006 from <<http://www.thehindubusinessline.com/2005/10/25/stories/2005102501481200.htm>>
- Chang, H. (1997). "The Economics and Politics of Regulation". Cambridge Journal of Economics (21) 703-728.
- Cloghesy, M. (2001). "Hard Choices, Soft Law: Combining Trade, Environment, and Social Cohesion in Global Governance". November 9, 2001, Presentation at University of Toronto. <[www.cpeq.qc.ca/apropos/HardChoices.pdf](http://www.cpeq.qc.ca/apropos/HardChoices.pdf)>
- Curtis, K. (2005). "The Importance of Self-Regulation in the Implementation of Data Protection Principles: The Australian Private Sector Experience." Address to the 27th International Conference of Data Protection and Privacy Commissioners. <[http://www.privacy.gov.au/news/speeches/spp09\\_05.pdf](http://www.privacy.gov.au/news/speeches/spp09_05.pdf)>
- Damodaran, A. (2006). "Re-engineering Biosafety Regulations in India: Towards a Critique of Policy, Law, and Prescriptions." *Law Environment and Development Journal*. 1:1. Retrieved May 24, 2006 from <<http://www.lead-journal.org/content/05001.pdf>>
- Denzin, N. and Y. Lincoln. (1994). "Introduction: Entering the Field of Qualitative Research." in Handbook of Qualitative Research. Thousand Oaks: Sage.

- Department of Biotechnology, Ministry of Environment and Forests, Government of India (1998). "Revised Guidelines for Research in Transgenic Plants". Retrieved May 26, 2006 from < [http://dbtindia.nic.in/policy/guidelines\\_98.pdf](http://dbtindia.nic.in/policy/guidelines_98.pdf)>
- de Senarclens, P. (1998). "Governance and the Crisis in the International Mechanisms of Regulation." *International Social Science Journal*. (50:155) 91-104.
- De Soto, H. (1989). The Other Path. New York: Harper & Row.
- Faleiro, S. (2005). "Death Among the Famished Road." Sonia Faleiro. Retrieved September 10, 2006 from < <http://soniafaleiro.blogspot.com/2005/12/death-along-famished-road.html>>.
- Foulon, J. et. al (2002). "Incentives for Pollution Control: Regulation and Public Disclosure." World Bank Policy Research Working Paper 2291.
- Geertz, C. (1973). "Thick Description: Toward an Interpretative Theory of Culture." in The Interpretation of Cultures. New York: Basic Books.
- Ghose, J.R. (2006). "Digital Video as a Tool for Participatory Development Communication and Poverty Reduction: The ENRAP Experience." Paper Prepared For The World Congress On Communication For Development, October 25-27, 2006.
- Giddens, A. (1990). The Consequences of Modernity. Cambridge: Polity.
- Goldar, B. and N. Banerjee (2004). "Impact of Informal Regulation of Pollution on Water Quality in Rivers in India." *Journal of Environmental Management* (73) 117-130.
- Gupta, A. (2002). "Ensuring 'Safe Use' of Biotechnology in India: Key Challenges." *Economic and Political Weekly*. July 6: 2762-2769.
- Hahn, R. (1998). "Government Analysis of the Benefits and Costs of Regulation". *Journal of Economic Perspectives* (12:4) 201-210.
- Holmes, P. and A. Young (undated). "Emerging Regulatory Challenges to the EU's External Economic Relations". SEI Briefing Paper Number 7. Sussex European Institute.
- Hood, C. et al. (2001). The Government of Risk. Oxford: Oxford University Press.
- Hopf, T. (1998). "The Promise of Constructivism in International Relations Theory." *International Security*. (23:1) 171-200.
- Horn, H. et al (1999). "Is the Use of the WTO Dispute Settlement System Biased?" CEPR Discussion Paper No. 2340.
- Huq, M. and D. Wheeler (1993). "Pollution Reduction Without Formal Regulation: Evidence from Bangladesh." World Bank Environment Department Divisional Working Paper 1993-39.
- Jessop, B. (1997). "Capitalism and its Future: Remarks on Regulation, Government and Governance." *Review of International Political Economy* (4:3) 561-581.
- \_\_\_\_\_ (2001). "State Theory, Regulation, and Autopoiesis: Debates and Controversies." *Capital and Class*. (75) 7-16.

- Jones, M. (1998). "Restructuring the Local State: Economic Governance or Social Regulation?" *Political Geography*. (17:8) 959–988.
- Jordana, J. and D. Levi-Faur (eds.) (2003). The Politics of Regulation in the Age of Governance. Manchester: CRC.
- Joshi, S. (2003). "Vidarbha: A Model Farmers' State?" Business Line, December 10. Retrieved September 20, 2006 from <<http://www.thehindubusinessline.com/2003/12/10/stories/2003121000030800.htm>>
- Kathuria, V. (2003). "Does Informal Regulation of Pollution Work? Empirical evidence From Gujarat." 39th Annual Conference of The Indian Econometric Society Working Paper.
- Kerf, M. and D. Geradin (2000). "Post Liberalization Challenges in Telecommunications: Balancing Antitrust and Sector-Specific Regulation". *World Competition* (23) 27-77.
- Kiely, R. (2005). The Clash of Globalizations. Boston: Brill.
- Klein, D. (1996). "Economic Regulation of Water Companies". World Bank Policy Research Working Paper 1649.
- Kuruganty, K. (2005). "This Seeds Bill Must Go." India Together, August 16, 2005. Retrieved May 30 from <<http://www.indiatogether.org/2005/aug/agr-seedbill.htm>>
- Lake, D. (2003). "The New Sovereignty in International Relations". *International Studies Review*. (5) 303-323.
- Leach, M., I. Scoones and B. Wynne. (2005). Science and Citizens: Globalization and the Challenge of Engagement. London: Zed.
- Loayza, N. (1996). "The Economics of the Informal Sector: A Simple Model and Some Empirical Evidence from Latin America." *Carnegie-Rochester Conference Series on Public Policy*. (45) 129-162.
- MacLeod, G. (1997). "Globalizing Parisian Thought-Waves: Recent Advances in the Study of Social Regulation, Politics, Discourse and Space." *Progress in Human Geography*. (21:4) 530-553.
- Malanczuk, P. (1997). Akehurst's Modern Introduction to International Law. Routledge: New York.
- Marsh, D. and M. Smith (2000) "Understanding Policy Networks: towards a Dialectical Approach." *Political Studies*. (48:1) 4-21.
- McGovern, E. (2005). International Trade Regulation. Globefield Press: Exeter.
- Milner, H. (1997). Interests, Institutions, and Information. Princeton University Press: Princeton.
- Ministry of Environment and Forests, Government of India. (1986) "The Environment (Protection) Act". Retrieved May 20, 2006 from <<http://dbtindia.nic.in/policy/act1.html>>.
- \_\_\_\_\_ (2006a). "About DBT". Retrieved may 24, 2006 from <<http://dbtindia.nic.in/aboutdbt/overviewmain.html>>.

- \_\_\_\_\_. (2006a). "Capacity Building on Biosafety: Training Needs Assessment." Project Coordinating and Monitoring Unit Report, January 2006. Retrieved May 24, 2006 from <<http://envfor.nic.in/divisions/csurv/biosafety/default.htm>>.
- \_\_\_\_\_. (2006b). "GEAC Approves Proposals". May 25, 2006. Retrieved May 30, 2006 from <<http://pib.nic.in/release/release.asp?relid=18042>>.
- \_\_\_\_\_. (2006a). "About DBT". Retrieved May 24, 2006 from <<http://dbtindia.nic.in/aboutdbt/overviewmain.html>>.
- Mishra, S. (2006). "Long Yarn." *Down To Earth*. March 31. Retrieved September 14 from <[http://www.downtoearth.org.in/cover.asp?FolderName=20060331&FileName=news&sid=30&sec\\_id=9](http://www.downtoearth.org.in/cover.asp?FolderName=20060331&FileName=news&sid=30&sec_id=9)>
- Mohanty, S., C. Fang and J. Chaudhary (2002). "Assessing the Competitiveness of Indian Cotton Production: A Policy Analysis Matrix Approach." Iowa State University, Center for Agricultural and Rural Development Working Paper 02-WP 301. Retrieved September 12, 2006 from <<http://www.card.iastate.edu/publications/DBS/PDFFiles/02wp301.pdf>>
- Moran, M. (2002). "Review Article: Understanding the Regulatory State." *British Journal of Political Science*. (32) 391-413.
- Morgen, B. (2003). "The Economization of Politics: Meta-Regulation as a Form of Nonjudicial Legality." *Social & Legal Studies*. (12:4) 489-523.
- Newbery, D. (2002). "Regulatory Challenges to European Electricity Liberalisation". CMI Working Paper 12, The Cambridge-MIT Institute.
- Niskanen (1989). "Economic Deregulation in the United States: Lessons for America Lessons for China". *Cato Journal*, Vol. 8, No. 3.
- Pargal, S. and D. Wheeler (1996). "Informal Regulation of Industrial Pollution in Developing Countries: Evidence From Indonesia." *Journal of Political Economy*, (104:6) 1314-27.
- Pargal, S. et. al (1997). "Formal and Informal Regulation of Industrial Pollution: Comparative Evidence from Indonesia and the United States." *World Bank Economic Review*. (11:3) 433-450.
- Parker, D. (2001). "Economic Regulation: A Preliminary Literature Review and Summary of Research Questions Arising". Centre on Regulation and Competition, Working Paper 6, University of Aston.
- Pasrai, G. (2006). "Package for Farmers in 31 Districts Proposed." *The Hindu*, June 27, 2006. Retrieved July 12, 2006 from <<http://www.hindu.com/2006/06/27/stories/2006062716140100.htm>>.
- Peters, G. (2005). "Forms of Informal Governance: Searching for Efficiency and Democracy." XIV Nordic Political Science Association Conference Paper. <<http://registration.yourhost.is/nopsa2005/papers/ICELAND2.rtf>>
- Pierre, J. and B.G. Peters (2000). Governance, Politics, and State.: London: Macmillan.
- Pierson, C. (1996). The Modern State. London: Routledge.

Portes, A. and L.A. Benton (1989). The Informal Economy: Studies in Advanced and Less Developed Countries. Boston: John Hopkins University Press.

Purcell, M. (2002). "The state, Regulation, and Global Restructuring: Reasserting the Political in Political Economy." *Review of International Political Economy* (9:2) 298–332.

Ramanna, A (2005). "Bt Cotton And India's Policy on IPRs." *Asian Biotechnology And Development Review* (7:2) 43-51.

Rodrik, D. and A. Subramanian (2004). "From 'Hindu Growth' to Productivity Surge: The Mystery of the Indian Growth Transition". NBER Working Paper No. 10376.

Rosaldo, R. (1986) "From the Door of His Tent: The Fieldworker and the Inquisitor." in Writing Culture: The Poetics and Politics of Ethnography. edited by James Clifford and George Marcus. Berkeley: University of California Press, 77-97.

Sahai, S. (2005). "The National Biotechnology Development Strategy: Present Version Unacceptable." Gene Campaign Press Release. Retrieved May 12, 2006 from <<http://www.genecampaign.org/Publication/Article/biotechnology/Biotech%20policy%20-epw-27.11.05.pdf#search=%22THE%20NATIONAL%20BIOTECHNOLOGY%20DEVELOPMENT%20STRATEGY%20sahai%22>>

Sainath, P. (2006). "What The Heart Does Not Feel." India Together, September 10, 2006. Retrieved September 14, 2006 from <<http://www.indiatogether.org/2006/sep/psa-heartfeel.htm>>.

Scoones, I. (2003). "Regulatory Manoeuvres: The Bt Cotton Controversy In India." Institute of Development Studies Working Paper 197. Retrieved January 14, 2005 from <<http://www.ids.ac.uk/ids/bookshop/wp/wp197.pdf>>

Scott, C. (2003). "Regulation in the Age of Governance: The Rise of the Post-Regulatory State." National Europe Centre Paper No. 100, Australian National University.

Shahabudeen, M. (1996). Precedent in the World Court. Cambridge University Press: Cambridge.

Sharma, A. (2005). "New Amendments to Patents Act, 1970 to Affect Farm Sector in India." *Financial Express*, January 3, 2005. Retrieved May 25, 2006 from <[http://www.financialexpress.com/fe\\_full\\_story.php?content\\_id=78652](http://www.financialexpress.com/fe_full_story.php?content_id=78652)>

Sharma, D. (2005). "India's New Seed Bill." Seedling, July 2005. GRAIN. Retrieved May 28, 2006 from <<http://www.grain.org/seedling/?id=338>>

Shiva, V. (2005) "The Indian Seed Act And Patent Act: Sowing The Seeds Of Dictatorship." Znet, February 14, 2005. Retrieved May 30, 2006 from <<http://www.zmag.org/content/showarticle.cfm?SectionID=56&ItemID=7249>>

Slaughter, A.M. et al (1998). "International Law and International Relations Theory: A New Generation of Interdisciplinary Scholarship." *The American Journal of International Law*. (92:3) 367-397.

Smith, M. (1991). "From Policy Community to Issue Network: Salmonella in Eggs and the New Politics of Food." *Public Administration* (69) 235-55.

Stewart, R. (1988). "Regulation and the Crisis of Legalisation in the United States", in Terence Daintith, ed., Law as an Instrument of Economic Policy: Comparative and Critical Approaches. Berlin: de Gruyter. 97–133.

Vignon, J. (2001). "Governance and Collective Adventure" in de Schutter, O. et. al (eds.), Governance in the European Union. Luxembourg: Office for Official Publications of the EC.

Vogel, D. (2003). "The Hare and the Tortoise Revisited: The New Politics of Consumer and Environmental Regulation in Europe". *British Journal of Political Science*. (33) 557-580.

Wendt, A. (1992). "Anarchy is What States Make of it: The Social Construction of Power Politics." *International Organization* (46:2)

White, L. (undated). "Technological Change, Financial Innovation, and Financial Regulation: The Challenges for Public Policy". Centre for Financial Institutions Working Papers 97-33, Wharton School Centre for Financial Institutions, University of Pennsylvania.

Wiener, J. (2004). "The Regulation of Technology, and the Technology of Regulation". *Technology in Society*. (26) 483–500.

Windmiller, M. (1956). "The Politics of State Reorganization in India: The Case of Bombay." *Far Eastern Survey*. 25:9 129-143.