

## **IDS Working Paper 197**

### **Regulatory manoeuvres: the *Bt* cotton controversy in India**

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## Summary

This paper asks what regulation actually means in practice in the post-economic reform context of India, taking the case of biosafety regulation and *Bt* cotton as a case. The last few years have been a test case for such regulations, culminating in the formal approval of *Bt* cotton for commercial production in 2002. The paper explores various dimensions of regulation – narrow and broad, “front end” and “back end”, technical and political. With the opening up of the economy and the encouragement of external investment in areas like biotechnology, biosafety regulation is one area retained by the central state. But how effective is this, given the role of powerful commercial players and the highly diverse set of practices found at more local, state levels? By examining the *Bt* cotton story in India – and in Karnataka state in particular – the paper demonstrates how – in practice – regulations emerge through a political process of negotiation between a wide range of actors in multiple sites. The result is usually an uneven, and often diverse, compromise, based on a combination of technical, social, political and, sometimes, moral considerations. It is the process of co-construction of policy, operating in a hybrid world between science, business and policy which is key for our understanding of regulation in practice. A particular focus of this paper is the interaction between national and state level processes in the Indian federal system, and an examination of how regulatory debates – formally located at the national level within national ministries and departments, firmly within the Delhi policy circuit – influence and, in turn, are influenced by what happens at a state level. Across these sites – all under the banner of “*Bt* cotton” – a number of quite different debates are being had: over the efficacy of the technology; over the changing nature of agriculture; over the control of agriculture and food by multinationals; over the role of the state in a federal system; over the relevance of regulation in a post-reform economy, and so on. Different actors, deploying different narratives about regulatory policy, join up with different allies at different times. There is no simple story. Yet the sheer complexity of the policy process, and the way this is embedded in the political and social fabric of India, is revealing and important for any discussion about what appropriate policy responses might be to the regulatory dilemmas presented by agricultural biotechnology in the developing world. Despite the advocacy of uniformity and harmonisation in regulatory policy, this paper shows how there clearly can be no one-size-fits-all solution.



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## Preface

### Biotechnology Policy Series

This IDS Working Paper series emerges from a series of three interlinked projects. They involve collaboration between IDS and the Foundation for International Environmental Law and Development (FIELD) in the UK and partners in China (Center for Chinese Agricultural Policy (CCAP)), India (Centre for the Study of Developing Societies, Delhi; Research and Information Systems for the Non-Aligned and Other Developing Countries (RIS), Delhi; National Law School, Bangalore), Kenya (African Centre for Technology Studies, Nairobi) and Zimbabwe.

Three key questions guide the research programme:

- What influences the dynamics of policy-making in different local and national contexts, and with what implications for the rural poor?
- What role can mechanisms of international governance play in supporting the national efforts of developing countries to address food security concerns?
- How can policy processes become more inclusive and responsive to poor people's perspectives? What methods, processes and procedures are required to "democratise" biotechnology?

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## 1 Introduction

This paper is concerned with how biosafety regulations work in practice in the Indian context. The last few years have been a test case for such regulations, culminating in the formal approval of *Bt* cotton for commercial production in 2002. The paper explores various dimensions of regulation – narrow and broad, “front end” and “back end”, technical and political – and asks what regulation actually means in the post-economic reform context of India. With the opening up of the economy and the encouragement of external investment in areas like biotechnology, biosafety regulation is one area retained by the central state. But how effective is this, given the role of powerful commercial players and the highly diverse set of practices found at more local, state levels?

By examining the *Bt* cotton story in India – and in Karnataka state in particular – the paper explores the validity of different views of regulation. One view would claim a simple, rational, science-based process, whereby guidelines developed centrally by experts are enshrined in law and implemented by bureaucrats with the assent of politicians. An alternative perspective, though, and one that the evidence presented in this paper would support, posits that regulations emerge through a political process of negotiation between a wide range of actors, in multiple sites. The result is usually an uneven, and often diverse, compromise, based on a combination of technical, social, political and, sometimes, moral considerations. In such a view, it is the process of co-construction of regulatory policy, operating in a hybrid world between science, business and policy which is key.

Since 1989, biotechnology regulatory policy has emerged in an incremental, some would say haphazard, way, prompted by a variety of factors and influenced by a range of different actors, both within and outside the formal regulatory arena. The debates over the approval of *Bt* cotton, in particular, offer a useful lens through which to look at the emergence of regulatory policy in practice. The *Bt* cotton debate exemplifies the tensions between the attempted maintenance of a rational, technical, science-based stand focused on issues of risks and potential impacts – where technical and political issues are deemed to be wholly separated – and a more explicitly social and political perspective, which sees the debate as part of a wider discussion about the future of agriculture, technology and society more broadly.<sup>1</sup>

The *Bt* cotton debate also highlights the tensions between different actors – between the public and private sectors, between agriculturalists and new biologists, between arms of the central and state-level bureaucratic machinery, between the Union government and the states, and between formal governmental

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<sup>1</sup> While these two perspectives are not mutually exclusive they do highlight an important contrast between a “back end” risk/impact focus and a “front end” technology choice/societal priority focus. Regulatory arrangements may cover both aspects, but most efforts – including the very significant investments in donor supported “capacity building” efforts by such agencies as USAID, UNEP/GEF, OECD and others – tend to focus on “back end” risk approaches, emphasising impacts on biosafety, and especially health and environmental impacts. The wider issues, such as the socio-economic and political consequences of adopting a particular technology trajectory are, as a consequence, left out of the picture. Thus, the framing of the regulatory debate is key. If it is kept narrow, science-focused and risk oriented, then key elements of the debate are not on the table. If it is broadened and made more inclusive, then the remit of regulatory deliberations widens, with a range of consequences for who participates, what expertises are required and so on. The way such debates are framed internationally, and what “capacity building” support is made available as a result has a major impact on the way regulatory processes are designed and played out in the developing world (see Newell 2002; Scoones 2002a for a discussion of these issues).

authorities and a range of different “civil society” players. As the discussion in the paper shows, these groupings are not watertight, nor are the tensions uniformly played out. Indeed, a close examination of the *Bt* cotton controversy reveals a much more complex scenario than often suggested. Under the banner of “*Bt* cotton” a number of quite different debates are being had: over the efficacy of the technology; over the changing nature of agriculture; over the control of agriculture and food by multinationals; over the role of the state in a federal system; over the relevance of regulation in a post-reform economy, and so on.

Different actors, deploying different narratives about regulatory policy, join up with different allies at different times. There is no simple story. Yet the sheer complexity of the policy process, and the way this is embedded in the political and social fabric of India, is revealing and important for the any discussion about what appropriate policy responses might be to the dilemmas presented by agricultural biotechnology in the developing world. There is no one-size-fits-all solution clearly. As the paper reveals the story is played out in very different ways in New Delhi, Bangalore and Haveri district in Karnataka. A responsive, adaptive, politically attuned, and thoroughly embedded regulatory process is required, one that must emerge organically from the settings it is supposed to serve. What the *Bt* cotton story in India tells us loud and clear is that a simplistic, imposed, technical regulatory formula – along the lines so often touted by development agencies in “capacity building” exercises in response to the Cartagena protocol – simply will not work.

The paper therefore sets out to examine how the regulatory policy governing agricultural biotechnology has been co-constructed by the interaction of scientists, bureaucrats, politicians, farmers, NGO activists, media commentators and others, across a range of sites from the more local to the national level and even to the global arena. A particular focus of this paper is the interaction between national and state level processes in the federal system, and an examination of how regulatory debates – formally located at the national level within national ministries and departments, firmly within the Delhi policy circuit – influence and, in turn, are influenced by what happens at a state level. In order to explore state-level dynamics in some depth, one state – Karnataka – is taken. As a major cotton producing state, Karnataka has a significant interest in the future of cotton production technologies, and biotechnology applications in particular. With its concentration of science institutes and laboratories, the Government of Karnataka is also positioning itself as a future biotechnology centre for India as a whole. As host of the Monsanto Research Centre, based on the Bangalore campus of the Indian Institute of Sciences (IISc), Karnataka is also seen as a key site for multinational R and D investment. This in turn has provoked controversy and protest among NGOs and farmers groups, and many of the significant protests against agricultural biotechnology over the past few years have also been played out within the state.

The paper starts with an overview of the Indian regulatory system for biotechnology, quickly tracing its history and origins. This provides a background for a brief history of the *Bt* cotton controversy, and how the regulatory system has dealt with it. The paper identifies the networks that operate at the central level, responding to the mandated rules, guidelines and committee procedures laid down by the legislation. While there are tensions and fractures, there exists a reasonably stable coalition of actors linking a group of leading scientists (largely molecular biologists) with the Department of Biotechnology (DBT) in Delhi,

and influential commercial companies with biotechnology products, most notably Monsanto/Mayhco in the context of *Bt* cotton. This grouping presents a particular view of the regulations, which upholds a rather narrow view of risk assessment, and a technical vision of how regulations should be implemented in practice. Whether anyone actually believes this is another story, but the guiding narrative is that central government should have the authority to regulate the growing of GM crops and that approvals must be based on impartial, objective, sound scientific information and advice from experts.

Of course in practice nothing is so neat and tidy. The regulations have been intensively contested by individuals and groups outside this core network, and indeed from some who have been only loosely coopted. This dissent – from both within and outside the core network – has taken a variety of forms, and has been played out in a range of different sites: behind closed doors in committee rooms and through informal lobbying; in the market through the illegal distribution of *Bt* seeds; in a variety of courts through legal public interest petitioning; in the media, both print and internet-based; and on the streets and in farmers' fields during demonstrations and direct actions of various sorts. Such contests to the regulations have raised a number of different perspectives, both challenging, and importantly, broadening, the framing of the debate from one of a narrow, “back end” concern with risks and technology impacts to a much wider “front end” discussion about farming, livelihood and societal futures. In Section 4, and later in Section 6, the paper explores this dynamic, and examines how such processes are played out, both at national level, but also more locally, and how in turn these Indian debates both are informed by and inform more global dimensions.

The paper then turns to an examination of how the regulatory process has played out in the southern Indian state of Karnataka. At this level, a new set of actors and networks come into view, and with them a new set of political configurations, offering sometimes very different critiques of the regulations to those dominating at the centre. Such groupings, in turn, may have an influence on what occurs at the centre, mediated through combinations of scientific networks, political connections, industry lobbying or activist protest. Regulations, it is seen, are co-constructed through ongoing interactions between the centre and state in a process of iterative negotiation, where diversity rather than uniformity and dissent rather than consensus is the norm. While a thin veil assuming that the debate is about technical, scientific criteria, rather than essentially political-economic issues, is maintained, this becomes increasingly less credible when regulation in practice is examined. In the end, regulation is a political negotiation which takes on a particular form in the context of the post-reform state operating in a federal setting.

In line with much else in Indian politics and policy, negotiation, bargaining and complex accommodation dominates (cf. discussions from a range of perspectives in Corbridge and Harriss 2000; Jenkins 1999; Rudolph and Rudolph 1987; Bardhan 1984). Biosafety regulatory policy is no exception, although in contrast to other areas more commonly analysed in the more standard political science literature, the mix of actors and interests, the role of technical experts, the high profile presence of influential multinational and Indian business interests and the level of often global activist concern makes the dynamic of biosafety policy particularly interesting, and perhaps reflective of an emerging politics of policy associated with the “new economy” in a post-reform era. The conclusion, then, moves to asking if

such a politics of negotiation understanding of regulatory policy in practice is accepted, and the myth of linear, rational, technical, apolitical process rejected, then how might “regulation” realistically be improved or redefined, given the Indian context, to enhance efficacy, accountability, trust, legitimacy and inclusivity?

## 2 The regulations

In 1989 India established a regulatory system for the import, testing and commercialisation of genetically engineered material, modelled on similar frameworks from elsewhere in the world. An apparently straightforward approach to applications, and assessment is laid out, with a hierarchy of expert committees overseeing the process. Decisions are expected to be guided by assessments based on objective science and expert guidance, using the best experimental and monitoring information available. This regulatory process – argued by a former senior advisor in the Union government’s Department of Biotechnology – to be the most comprehensive and rigorous in the world (Ghosh 1997; Ghosh and Ramanaiah 2000), is supposed to deliver the benefits of agricultural biotechnology to the Indian farming population in an orderly and safe way. Yet it was only in 2002 – nearly nine years after the first application was submitted – that the first approval for commercial release was granted by the Genetic Engineering Approvals Committee (GEAC) under the Ministry of Environment and Forests (see below). Over this period, the application for approval of *Bt* cotton release therefore has acted as the test case for the regulations, sparking controversy, protest, scientific debate and some deep questioning of the regulatory process in its wake.

The Department of Biotechnology was established in 1985, emerging as a separate department from an earlier incarnation as a small unit with the Ministry of Science and Technology. Since discussions around the Environmental Protection Act of 1986 there was a recognition of the need for new regulations to govern the import and use of genetically engineered products. The Ministry of Environment and Forests were already dealing with the import and export of microorganisms under the Hazardous Substances and Management Division, so a ready template existed, it was thought, for the generation of new regulations. A small drafting committee was established which included a senior adviser from the DBT, one university based molecular biologist and an agricultural biotechnologist from the Indian Agricultural Research Institute (IARI). As one of the members of this group commented ‘The earlier regulations leaned towards pharmaceuticals. We had to revise them to incorporate agriculture. It was the drafting group that wrote the regulations. The other officials just signed’.<sup>2</sup> A number of models from elsewhere in the world were looked at. The OECD guidelines were particularly influential, and provided, as with many countries in the world, a standard format for the structure of committees and procedures for approval. The published regulations<sup>3</sup> identify different levels of risk, and authorise the establishment of Institutional Biosafety Committees (IBSC) linked to each lab undertaking transgenic work, the Review

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<sup>2</sup> Interview, DBT official, 28 March 2001.

<sup>3</sup> Recombinant DNA Guidelines (DBT 1990) and Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity, Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts (DBT, August 1998).

Committee on Genetic Manipulation (RCGM) hosted by the DBT formally dealing with trials, and the cross-ministerial committee GEAC hosted by MoEF dealing with commercial release. DBT also host a Monitoring cum Evaluation Committee (MEC) which oversees the trial process (Ghosh 1997; Ghosh and Ramanaiah 2000; Gupta 2002). The process is supposed to be decentralised, with district biosafety committees overseen by district collectors throughout the country, although these seem to not actually exist in practice.

The development of the legislation took time and many discussions. Someone from the MoEF who was involved observed:

Always when you bring in new regulations there are disagreements and compromises. Amendments are always necessary. You cannot conceive of everything today. It helps if there is an international consensus. But this was absent with biotechnology. The process of consultation is very painful. There are too many people with ideas. Ours is a huge democracy. The problem today is that legislation is much bulkier. People want everything written down. Before people were happy with more flexible guidelines. But with public interest litigation round the corner, we have to be secure.<sup>4</sup>

However, despite the commitment that this was only a first stab at a regulatory framework, as with many initiatives of this sort, the incentives to change things once created are limited, and those changes that have occurred in 1994, and again in 1998, have been largely at the margins.<sup>5</sup> External influences and models were therefore key from the start, appropriated largely to save time and effort in a pressured timetable set for civil servants. Since that time, external influences have continued to play a role in the development and interpretation of the regulations, with visits by key regulators and scientists organised to both Europe and the US. The existing regulations are essentially process based, with the particularities of genetically engineered products recognised, requiring a case by case assessment of each product. The tussle between the US and Europe on regulatory approaches (cf. Newell 2002), and the more general push towards regulatory harmonisation, has certainly been a feature of the Indian debate, with industry lobbyist arguing for a more streamlined, less bureaucratic approach (CII 2002).

The criteria for assessment are indeed extensive, requiring significant amounts of data collection and documentation by the applicants at each stage. For lab and greenhouse work, the regulations specify the containment requirements for experiments. Compliance with these is monitored by the DBT-approved IBSC. Today, there are several hundred approved IBSCs in India, indicating the now significant scale of genetic engineering work ongoing. However, most work to date remains at the lab and greenhouse level

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<sup>4</sup> Interview, MoEF official, 29 March 2001.

<sup>5</sup> The 1998 revisions extended the requirements for assessment to allergenicity/toxicity testing, assessments of long-term environmental safety and economic benefits compared to non-*Bt* crops (Dhar 2002).

and there are far fewer small-scale field trials, although the numbers of these continue to grow, involving both private and public sector research teams.<sup>6</sup> Trials, once approved by the RCGM, are supposed to test the product in “contained” and “controlled” field conditions over a number of years. The regulations specify a range of studies that must be undertaken at the field level, including basic agronomic monitoring, pest incidence, pollen flow and so on. In addition, toxicity and allergenicity tests must be conducted at the government-approved laboratory in Lucknow. Approval for large-scale trials, seed bulking and commercialisation must be sought by the GEAC, once the RCGM have reviewed the field trial data. In the words of P.K. Ghosh, formerly advisor at the DBT: ‘the RCGM brings the science to the GEAC’.<sup>7</sup> Data is compiled and submitted by the applicant, although there is a key role reserved for the Monitoring cum Evaluation Committee who may visit test sites. In addition to fulfilling the range of scientific tests – in relation to gene flow risk, food safety and so on – the applicant must also make the case for the new technology in economic and agronomic terms by showing superior performance against different test crops.

Clearly within this process there is much scope for negotiation and bargaining. While the formal procedures, the field trials and the laboratory tests, and the vast compilations of data dominate the visible process of regulation, there are inevitably other processes going on which are perhaps less tangible. Who are the members of these committees? What forms of expertise are brought to the table? What alliances or conflicts exist between key players? How do bureaucratic or political interests influence the process? In this hybrid world where science, business and the policy bureaucracy interact uncovering what actually goes on is well nigh impossible. However, the next section attempts a preliminary and necessarily incomplete dissection of the *Bt* cotton controversy over the last few years, with a view to understanding a bit more the politics of negotiation surrounding *Bt* cotton regulation.

### **3 *Bt* cotton: a sketch of the regulatory controversy**

*Bt* cotton is an insect resistant transgenic crop with a gene (Cry1a, in the case of the Monsanto/Mayhco application) from the bacterium, *Bacillus thuringiensis*, conferring some degree of resistance to lepidopteran pests of cotton, notably the potentially devastating bollworm. To the proponents of *Bt* cotton, the technology offers a potential solution to some of the key problems of the cotton sector. Genetically modified cotton is of growing importance with some 5.3mha or 16 per cent of the 34m ha of cotton worldwide being either round-up ready or *Bt* or some combination. Globally India is the third largest producer of cotton, producing around 2.86m tonnes on 9m ha, representing around 15 per cent of global

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<sup>6</sup> Transgenic crops are being worked on by at least 25 public and private research groups across India, with over 150 approved Institutional Biosafety committees in operation. Currently work on transgenic tobacco, potato, mustard, cotton, brinjal, tomato, cauliflower, rapeseed is at contained field trial stage, and further work on rice, tomato, cauliflower and cabbage at greenhouse stage. Field trials are being conducted by the Central Tobacco Research Institute, Rajahmundry; the Central Potato Research Institute, Shimla; Pro-Agro (India) Ltd, New Delhi; Mayhco-Monsanto Biotechnology, Mumbai; the Indian Agricultural Research Institute, New Delhi; and Jawaharlal Nehru University, New Delhi (Dhar 2002: Annex Table 15).

<sup>7</sup> Interview, DBT, 28 March 2001.

production. The export revenues generated annually amount to around Rs 25000 crores (Ghosh 2000; Choudhary and Laroia 2001). Yet areas planted to cotton are on the decline, as the returns to farmers shrink with rising costs of inputs and declining world market prices. In Karnataka, historically one of the main cotton producing states, the cotton area has halved since the 1970s to around 6 lakh ha.<sup>8</sup> Both the financial and environmental costs of heavy pesticide applications to cotton were also being widely recognised, both by farmers and other commentators. Of the US\$620m of pesticides applied in India a year, about half was applied to cotton, with an average of 7.3 sprays per year applied.<sup>9</sup> The cotton pest complex includes over 160 species of insects, with 15 recognised key pests. Much damage derives from lepidoptera pests, notably bollworms, including the American bollworm, *Helicoverpa armigera*, and it is these that are the targets of *Bt* toxins which act by blocking mid-gut receptors in such insects resulting in loss of appetite and subsequent death. If genetically engineered cotton can reduce such pesticide inputs applied to combat lepidopteran pests, even with a premium being paid for the seed, it is argued, this will have multiple benefits – for the farmers, the agricultural economy and the environment.

*Bt* cotton was first approved for commercial release in the US in 1996, where Monsanto supplies 85 per cent of the cottonseed. In 1996–97 *Bt* cotton was also released in China, both by Monsanto and the Chinese Academy of Agricultural Sciences. As early as 1990 Monsanto, the US company who patented the Bollgard technology, approached the Indian government through the DBT. This was rejected in 1993 on the basis that the technology transfer fees were too high. In 1995, Mayhco, the long established seed company headed by Dr Barwale, was granted permission to import 100g of transgenic cotton seed as part of an agreement with Monsanto. Between 1996 and 1998, Mayhco developed three backcrossed lines using the imported material with Mayhco cotton varieties (Mech-12, 162 and 184),<sup>10</sup> and started experiments into outcrossing, germination, weediness, food and feed safety, allergenicity, toxicity and pollen escape. In 1998, Monsanto bought a 26 per cent stake in Mayhco creating Mayhco-Monsanto Biotech (India) Ltd (MMB) with a special interest in developing biotechnology products. Later that year, the RCGM approved 40 field trials in nine states.<sup>11</sup> Following the review of the 1998 data the committee requested a further additional ten trials in 1999. The results of all the trials were presented by Mayhco to DBT in April 2000, resulting in RCGM clearance in May and a go-ahead from the GEAC in July for 85ha

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<sup>8</sup> Department of Agriculture, Government of Karnataka website.

<sup>9</sup> MMB (2001). Seeds of Hope. Harnessing Biotechnology for Insect Protection and High Yield in Cotton. MMB: Mumbai. Spraying is estimated to be up to 15 in AP and 9 per season in Karnataka.

<sup>10</sup> These varieties were destined for the central-southern cotton region, but not the north, where Mech-915 was deemed more suitable. This was to be tested in 2002, although this was delayed as ICAR had not been fully informed by GEAC. See *Business Line*, 2 April 2002 for a report.

<sup>11</sup> Field trials were approved formally by DBT on 27 July (25 trials) and 5 August (a further 15), 1998, although in practice they were ongoing at least from mid June and early July according to Shiva *et al.* (1999). In 2001 there were 400 trial locations in six states, including Maharashtra (180), Karnataka (89), Gujarat (23), Madhya Pradesh (23) Andhra Pradesh (49) and Tamil Nadu (11), alongside a further 11 locations overseen by ICAR (see *Asia Intelligence Wire*, 20 June 2002).

of large scale field trials and 150ha of seed production.<sup>12</sup> Following the review of the results of these trials on 29 June 2001, the GEAC failed to give approval for commercialisation on the basis of a number of conditions and requirements for on-going monitoring.<sup>13</sup> At this stage, the GEAC requested that the Indian Council of Agricultural Research (ICAR) be involved to provide independent advice on the product. ICAR, working with agricultural universities conducted trials in 11 locations in six states in 2001, comparing Mech variety *Bt* and non-*Bt* together with a high performing check hybrid (NHH-44 in many trials). They concluded that *Bt* cotton was both economic and effective.<sup>14</sup> As is shown later, the involvement of the ICAR and the agricultural universities was a key move, and ended several years of internal wrangling within the regulatory committees.

While being presented as a straightforward technocratic process of decision-making, the committee processes were, not surprisingly, given the stakes, more complex than this. Ever since the refusal to allow Monsanto to import GM material in 1993 and the failure of the joint effort with government, there has been a general suspicion of Monsanto and its role. In part this comes on the back of the company's disastrous PR tactics both in India and Europe during the 1990s, and the highly effective activist stance developed around fears of "terminator" technologies and environmental and health risks (see below). But the antagonism towards Monsanto – and even the alliance with Mayhco – came from other quarters too. Some commentators with a more conspiratorial bent argued that the regulatory delays were being orchestrated by the chemical pesticide companies who had a vested interest in maintaining high and growing pesticide sales to cotton growers.<sup>15</sup> Others saw delays emerging more as a result of nationalist competition with a foreign multinational. The national research system prides itself as the organisation that delivered to India the Green Revolution. Although this was done with the help of the philanthropic foundations, the nascent CGIAR system and foreign experts such as Norman Borlaug, it was largely a home-grown effort, with Minister Subramaniam working alongside scientists such as Pal and Swaminathan, being the Green Revolution heroes (Seshia and Scoones 2003). Why shouldn't the national public research system deliver the biotech revolution too some people ask? After all *Bt* cotton was under development in the ICAR system at the Cotton Research Institute at Nagpur, at IARI in Delhi, at Tamil Nadu Agricultural University in Coimbatore and at Dharwad in Karnataka. The Ministry of Agriculture

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<sup>12</sup> 'Monsanto's *Bt* cotton gets biosafety clearance' (*Financial Express*, 14 May 2000); 'Govt gives biosafety clearance to Monsanto cotton' (*Express Textile*, 18 May 2000); 'Monsanto allowed field trials for cotton' (*Times of India*, 13 May 2000). Press release, MoEF, MSD Division 20 July, 2000. See 'Extensive field trials of *Bt* cotton cleared' (*Business Line*, 21 July 2000). Earlier reports indicated production increases ranging from 14 to 88 per cent from the trial data, see *Business Line* (19 January, 27 June 2000).

<sup>13</sup> See *Frontline*, 18, (July 7–20, 2001). Also see commentary by Chengal Reddy proclaiming June 19<sup>th</sup> 'Farmers' Betrayal day'.

<sup>14</sup> Director General Panjab Singh confirmed that *Bt* cotton turned out superior to non-*Bt* across a range of criteria in the ICAR trials, with an economic advantage of Rs8-10000 per acre (*Business Standard*, 25 June 2002). In April, Mangala Rai, then Deputy DG of ICAR (Crop Sciences) was quoted as saying 'nobody can raise a question on the authenticity and comprehensiveness of our field investigations which indicated yield superiority of the *Bt* hybrids and their tolerance to bollworm damage in the central and southern zones' *Business Line* (2 April 2002).

<sup>15</sup> Kiran Muzumdar sees the KRRS as 'leading a pesticide lobby' – see 'Monsanto blamed for giving biotechnology a bad name', *Times of India*, 15 September 2000 (see below also, footnote 92).



was represented by ICAR on the GEAC, and some of the delays and requirements can possibly be seen in this light. As one senior university scientist involved in DBT committees put it: 'If developed by Indian scientists, transgenics may have seen the light of day much earlier'.<sup>16</sup>

Alongside these negotiations within the formal regulatory process, which has cost Monsanto/Mayhco a significant sum, not counting the market foregone during the period, other things were going on. As the GEAC deliberated on the final decision in 2001–2002, with a further deferral in June 2001,<sup>17</sup> news broke that illegal *Bt* cotton had been planted over several years in Gujarat. In 2002 some 10000 ha were reported planted to *Bt* cotton in Gujarat alone, with other areas in Maharashtra, Madhya Pradesh, Andhra Pradesh and Karnataka also having unspecified areas under *Bt* cotton. The seed had been supplied through an Ahmedabad company, Navbharat Seeds, and had gone out to distributors in a number of states. A section of the vast, largely unregulated network of seed bulking, supply and distribution outfits had made good use of an apparently good new product and, to the delight of many farmers, had sold it at a reasonable, if slightly marked up, price. While the regulators were deliberating in Delhi, the farmers of the cotton belt were reaping the benefits of *Bt* cotton across large areas.

The exposure of this put the central regulatory authorities in a difficult position. The Ministry ordered the destruction of the illegal crop, but the farmers and the state government argued for compensation. This of course was not forthcoming and following a few visits by some inspectors from Delhi, some burning of cotton in full view of the press, and the arrest of Patel the Managing Director of Navbharat Seeds, the issue was pushed aside. There was of course nothing the central state could do. And many in the pro-*Bt* cotton lobby were quietly delighted that the farmers of Gujarat had proved the market demand for the product and pre-empted the 2002 decision by the GEAC.<sup>18</sup>

On 26 March 2002, the GEAC formally approved the commercial release of MMB *Bt* cotton for a three-year trial period in six states, alongside a number of conditions.<sup>19</sup> The conditions included the growing of a refuge area of five rows surrounding each *Bt* cotton plot, early removal of the cotton crop following harvest, and continuous scouting through the season. Since the approval was on a trial basis, ongoing monitoring of production and pest control results was required by the GEAC, prompting a huge explosion of studies, each vying for press attention and demonstrating different "results" (see below).

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<sup>16</sup> Interview, Delhi University South Campus, 3 April 2001.

<sup>17</sup> 'GEAC defers proposal to market *Bt* cotton; resolves to undertake fresh large-scale trials' (*Financial Express*, 23 June 2001); 'Panel on genetic engineering extends field trials of *Bt* cotton' (*Business Standard*, 22 June 2001); 'GEAC withholds clearance for *Bt* cotton cultivation' (*Economic Times*, 21 June 2001).

<sup>18</sup> See numerous press reports, including: 'Fate of illegal *Bt* cotton uncertain' (*Financial Express*, 29 October 2001); 'Agri ministry, biotech dept disagree on *Bt* cotton issue' (*Economic Times*, 29 October 2001); 'Controversy over *Bt* cotton deepens' (*Business Standard*, 22 October 2001); 'Navbharat seeds may have to cough up Rs11crore' (*Economic Times*, 24 October 2001); 'Gujarat govt in dark on *Bt* cotton issue' (*Economic Times*, 13 October 2001); 'GEAC orders destruction of *Bt* cotton crops in Gujarat' (*Economic Times*, 19 October 2001).

<sup>19</sup> See review in *Frontline*, 13–26 April 2002: 'Green signal for *Bt* cotton' by R. Ramachandran. See also *Times of India*, 26 March 2003. However, the conditions were being questioned by Monsanto and others. T.M. Manjunath, research head of Monsanto-India commented 'land holdings in some cotton growing pockets is so small that the mandatory refuge would make *Bt* cotton cultivation uneconomical' (*Financial Express*, 23 June 2002). Farmers were similarly sceptical in an Indian Express report one AP farmer was quoted as saying 'next year I may not plant it [the refuge area] as it is a complete waste', 12 November 2002.

During the season *Bt* cotton was marketed at Rs1600 per packet, which comprised a 450g packet of *Bt* cotton (with Mech backgrounds), and a 120g packet for a non-*Bt* refuge crop. Packets intended to cover 1.05 lakh acres were produced, intended, including 21000 packets allocated to Karnataka, which ended up in the planting of 16950 acres of *Bt* cotton in the state.<sup>20</sup> 80 per cent of these packets were sold to those in cluster areas surrounding trial sites, both through Mayhco and a number of other sub-licensed partners including Rasi, Ajeet, Krishi Dhan, Ankur and India Seeds Holdings.<sup>21</sup>

The significance of the GEAC decision was not lost on commentators. The Bangalore-based industry advocate of biotech, Kiran Muzumdar-Shaw, commented: ‘With the right policy signals such as stem cell research and the commercialisation of *Bt* cotton, global venture capitalists will now be more inclined to invest in the Indian biotech industry’<sup>22</sup> C.S. Prakash, the non-resident Indian scientist and biotech commentator (see below), stated that: ‘India should shed its conservative stand on the entry of transgenic crops into the country’.<sup>23</sup> Recalling the symbolism of the Green Revolution, Dr Barwale, MD of Mayhco, reminisced about the parallels between the release of transgenics and the great achievements of the 1960s.<sup>24</sup>

Whether the first season of *Bt* cotton growing has been a success or not has been the source of much heated debate. Literally dozens of “surveys” have been carried out, each proclaiming a result.<sup>25</sup> There have

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<sup>20</sup> See ‘Monsanto cotton seeds a sell out’ (*Hindu*, 17 July 2002). See also *Business Line*, 6 July 2002. The sale price drew much comment, it being four times the price of comparable non-*Bt* hybrid cotton seed. In Gujarat the illegal *Bt* cotton had been sold at Rs500 per packet.

<sup>21</sup> See *Business Line* (16 July 2002) who asks whether the ‘highly fragmented cotton seeds market is headed for some sort of consolidation, with the underlying “software” (gene construct) being provided by Monsanto?’ See also news on Rasi seeds in *Financial Express* (24 May 2002).

<sup>22</sup> *Hindu*, 28 March 2002.

<sup>23</sup> Monsanto India, 12 April 2004. See also *Economic Times* interview, 26 March 2003.

<sup>24</sup> *Hindustan Times* (28 March 2002).

<sup>25</sup> For example in AP a Deccan Development Society-organised survey in 11 villages in Warangal was released by P.V. Sateesh (*Business Line*, 9 December 2002). Press reports in AP also reported poor performance, see for example: ‘*Bt* cotton dashes hopes of ryots’ (*Hindu*, 29 December 2002). In Maharashtra a team led by Dr R.B. Thakare editor of Farmers’ Forum reported low yields (AgBioIndia, 10 December 2002). Similarly in MP, extensive spraying against sucking pests was reportedly required (AgBioIndia, 10 December 2002). Yet in often the same places, more positive results were reported following the first pickings, with farmers reporting for example a 20–30 per cent yield increase in parts of AP (*Indian Express*, 12, 14 November 2002), and good results in Karnataka (C.K. Rao on [www.bio-scope.org](http://www.bio-scope.org), 14 November 2002). See also ‘The verdict is in – *Bt* cotton works just fine’ (*Financial Express*, 20 November 2002); ‘The cotton club’ (*Indian Express*, 14 November 2002). The Environment Minister, Baalu to the Rajya Sabha in December that the yields were satisfactory (see *Times of India*, 14 December 2002). Earlier in the season problems with leaf curl virus in north India, wilting and root rot in Maharashtra were reported and widely circulated in the anti-GM internet lists (see *Business Line*, 19 August 2002; Hitavada, Nagpur, 4 September 2002, IPS, 6 September 2002). By early 2003, MMB were claiming great successes. See, for example: ‘Sweet harvest of *Bt* cotton, says firm’ (*Times of India*, 21 January 2003), ‘*Bt* cotton yields rich dividends’ (*Tribune India*, 13 January 2003). However, reports from state departments of agriculture were more circumspect (see reports of a Sun TV interview with the AP Minister of Agriculture in AgBioIndia, 5 March 2003, while the Karnataka minister for agriculture, V.S. Kougali, was quoted as saying that ‘growing *Bt* cotton has not yielded the desired results in Karnataka’, *Times of India* (14 December 2002). The Indian Seed Industry Association president, Prabhakar Rao argued that the results were ‘not up to the mark’, in part because the *Bt* gene had been inserted into an inappropriate variety (see UNI, 18 December 2002; *Hindu*, 18 December 2002). Greenpeace in turn claimed that ‘*Bt* cotton a 95 per cent failure’ (AgBioIndia, 5 March 2003), and on 10 March 2003 Gene Campaign sent a letter to the Union Agriculture Minister demanding compensation under the newly passed Plant Variety Protection and Farmers Rights Act of 2001 (see AgBioIndia, 11 March 2003). The Standing Parliamentary Committee attached to the Union Ministry of Agriculture reportedly found ‘little merit’ in the *Bt* cotton seed, finding that farmers who

been many claims and counter-claims, and a certain amount of back-tracking by the pro-*Bt* cotton advocates as the results of the first year's crop proved less positive than hoped for. The drought that struck large parts of the cotton zone was partly to blame, resulting in a very limited pest problem. Instead other diseases and pests struck, against which *Bt* had no effect. Those opposing *Bt* cotton were quick to jump on this, often making highly tendentious claims about how *Bt* cotton was an unmitigated disaster. But it was not only the opponents of transgenic crops who were perhaps stretching the truth a bit far. A huge row broke out following the publication of an article in *Science*, also reported in *Nature*, in February 2003 (Qaim and Zilberman 2003). This used a series of somewhat dubious extrapolations to claim that *Bt* cotton could offer an 80 per cent economic advantage over non-*Bt*. When Monsanto in their more generous PR gambits were only suggesting the gain might be 20–30 per cent,<sup>26</sup> this seemed to stretch credibility too far. An Indian Syngenta employee currently based in Switzerland, Shantu Shantaram, argued that poorly peer reviewed articles of this sort in publications like *Science* only undermine the case for crop biotechnology: 'It is unfortunate', he said, 'that both *Science* and *Nature* are making very serious errors in judgement in this most controversial of all technologies by hastily publishing such premature manuscripts based on seemingly not so rigorous data. By doing so, these journals are doing a great disservice to science and technology development'.<sup>27</sup> He goes on to argue that all the available data should be made available on the company website. Others argued that, given the controversy, 'there is no such thing as an independent review in India. Anyone can manipulate the data'.<sup>28</sup> Thus, as of mid-2003, the controversy is far from resolved.

While the reviews were on-going, the farmers were planting *Bt* cotton, much of it illegal. Some estimates suggest that 90 per cent of the market share in Gujarat was "pirated" *Bt* cotton. In May 2003, *The Indian Express* was referring to the 'transgenic chaos in Gujarat's cotton belts' and the 'Robinhoods of Biotechnology', supplying the farmers with the seed they wanted at a fraction of the price that of the now formally approved seed. The paper observed that: 'The state is now virtually one big laboratory for a variety of hybrids of genetically modified cotton seeds – none of them cleared by government, but most of them sought eagerly by farmers keen on reducing pesticide consumption and increasing yields'.<sup>29</sup>

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grew it did so at a loss in most places (*Hindu*, 26 April 2003). The GEAC meeting on 25 April 2003 did not approve further cultivation of *Bt* cotton in northern India, as the proposed variety Mech-915 was susceptible to leaf curl varieties, and demanded that the states provide full reports of the performance across the country to date (see *Financial Express*, 25 April 2003). Meanwhile in Gujarat the state government claimed that the illegal Navbharat variety was superior to the Mayhco-Monsanto one (see *Indian Express*, 26 April 2003).

<sup>26</sup> See Manjunath quoted by *Financial Express*, 23 June 2002.

<sup>27</sup> See postings on AgBioview, 21 February 2003 (special: *Bt* cotton in India: how successful is it?), and AgBioIndia, 26 February 2003. See extended discussion of the article by Devinder Sharma, AgBioIndia (14 February 2003); 'A scientific fairytale: providing a cover-up to the *Bt* cotton fiasco in India', and Sharma's reply to the *Science* authors' comments on 24 February 2003. See also press commentary, 'Yields of discontent', *Business World* (26 March 2003).

<sup>28</sup> Interview, Chair Foundation for Biotechnology Awareness and Education, India, February 2003.

<sup>29</sup> 'Bales of red tape', *Indian Express* (29 May 2003).

## 4 Actors and networks

So who are the key players in the formal regulatory process, and how are they linked? As already mentioned, much of the regulatory oversight falls to the Department of Biotechnology in the Ministry of Science and Technology. The most senior civil servant, the DBT Secretary has, since the establishment of the Department, been a technical appointment, drawn from the professional ranks of the wider ministry, rather than from the Indian Administrative Service. As a result the highest civil service appointment has the benefits of a technical understanding of the issues, but, because of personal and professional links in the area, there are dangers that this may result in the undermining of impartiality. The current secretary, Dr Manju Sharma, has been in post since 1996, and has overseen much of the regulatory approval process for *Bt* cotton. However, on a day to day basis the secretary relies on a number of advisors who are allocated to different tasks within the Department. In respect of regulation, the key advisor has been Dr P.K. Ghosh for much of this period who, among other things, acted, until he left DBT in 2002, as the Member Secretary to the RCGM committee. He has been a key figure in arguing the case for the current regulatory framework – in numerous articles, workshops, newspaper articles, media interviews and in submissions to the Supreme Court. As principal architect of the current revised regulations drawn up in 1998, he is a firm believer in the principles laid out and the validity of the process. As a former Monsanto scientist conceded: ‘Ghosh oversees the process. He knows the system well. He has been part of it for a long time. He must cover his back. One negative press report and it takes three months to calm down. It is always slow.’

In order to gain credibility and legitimacy, the DBT must rely on its network of science advisors who are coopted into an enormous array of committees, advisory groups and working parties.<sup>30</sup> As a major funder of biotechnology research across the country, scientists are reliant on the DBT, especially with the squeeze in core funding for research labs, even in the prestige relatively well funded institutions. Being in favour with the DBT, despite many complaints about its operations, is seen as important, and so serving on a committee of the DBT is, according to many informants, necessary and desirable in order to be “in the loop”. While some argue that, with DBT being a benefactor of so many in the biotechnology science community, the possibility of independence is limited, others disagree. One senior plant scientist argued: ‘There is no conflict of interest. I am an authority on the subject: that’s what matters’.<sup>31</sup>

In terms of biotechnology regulation, the RCGM is the key DBT committee, although the Scientific Advisory Committee may offer guidance in some matters. The RCGM has been headed by Professor Assis Datta, a reknowned molecular biologist with a successful lab at JN University, where he is also Vice-Chancellor. The RCGM is composed of scientists, mostly molecular biologists or biochemists, operating in their individual capacity as “experts” in the field. As a senior committee member commented: ‘We are

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<sup>30</sup> See DBT website: [www.dbtindia.nic.in](http://www.dbtindia.nic.in). In addition to the RCGM, there are two scientific advisory committees, a research promotion committee and a total of 17 task forces on different themes (DBT Annual report, 2000–2001).

<sup>31</sup> Interview, Bangalore 10 April 2001.

all scientists on the committee. We can mould DBT policy'.<sup>32</sup> Another agreed: 'The regulatory system is dominated by informed scientists. This is a good thing. But it puts a lot of pressure on us to get things right'.<sup>33</sup> Another observed: 'I go to the advisory group meetings at DBT. Everyone has the same view as me. Agreeing is easy'.<sup>34</sup>

Much of the committee time in the last few years has been allocated to the *Bt* cotton case, although of late there have been a number of other field trials in place.<sup>35</sup> But despite the relatively small number of cases presented to it committee members privately agree that it is impossible for them to deal with all the paperwork, and all the minute details of the cases being made against all the varied criteria. Committee meetings are held in Delhi usually over one day with a late start and early finish to allow for travel, and all those who commented observed that the details were handled by the Member Secretary, with the members and the chair being adjudicators of broad fair play, rather than scrutinisers of regulatory detail. As one committee member put it: 'Of course we can't look at the detail. What do you expect? People go to Delhi for a meeting. The committee sits for half a day. They get the job done, sign the forms and go. We can complain but nothing changes much'.<sup>36</sup> However, where concerns were raised there has been, according to informants, vigorous debate, but always apparently arriving at a consensus.

Over the past nine years, Mayhco and Monsanto have had close interaction with the RCGM, and more particularly the civil servants from DBT overseeing the process. From the application to import genetically engineered cotton seed in 1993 and then again 1995 through to the submissions for commercialisation approval in 2001 and 2002, the company has had to submit thousands of pages of material, making presentations at each stage. The company has approached this task on a number of fronts. Mayhco-Monsanto Biotechnology (MMB) has been formally the applicant at each stage from 1995. Mayhco's director, Dr B.R. Barwale, winner of the 1998 World Food Prize and well respected member of the Indian agricultural industry scene has been an important player. As a member DBT committees he has good links with the Department, as well as long-standing personal connections with other Ministries and key officials. At the height of the protests against Monsanto (see below), the presentation of Mayhco and Barwale in particular as the acceptable, Indian faces of *Bt* cotton were key. As one commentator put it 'Monsanto was clever linking up with Mayhco. It is a big and well established company, and Barwale is well respected'.<sup>37</sup> The close relationship between the applicant and the regulator has, however, raised sceptical voices. As one leading NGO campaigner asked rhetorically: 'Will Monsanto monitor Monsanto?'<sup>38</sup> Others instead regard a close working relationship a good example of public-private partnership and a consensus-based negotiation of regulations.

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<sup>32</sup> Interview, Department of Biochemistry, IISc Bangalore, 18 January 2001.

<sup>33</sup> Interview, IISc, Bangalore 8 February 2001.

<sup>34</sup> Interview, NCBS Bangalore 13 February 2001.

<sup>35</sup> Currently eight different crop field trials are on-going (Dhar 2002: Annex Table 15).

<sup>36</sup> Interview, NCBS Bangalore, 13 February 2001.

<sup>37</sup> Interview, IISc, 26 February 2001.

<sup>38</sup> Interview, Gene Campaign, 2001 (PN).

In terms of preparing materials for submission, the Mayhco-Monsanto technical teams followed the ever-expanding guidelines, documenting in detail results from the range of required tests. The presence of the Monsanto Research Centre in Bangalore, and extensive back up from Monsanto in the US, made the task more feasible, although nevertheless time-consuming and cumbersome. Many industry informants noted that Monsanto was really the regulatory guinea pig, jumping all the hurdles and, hopefully, smoothing the way for other applications. As the MRC head put it: 'Monsanto as the pioneer has paid the price. We were the first and regulations had to evolve'.<sup>39</sup> It is not surprising that Pro-Agro, an applicant for GM mustard, has kept its head down, as its potentially more controversial application (given that mustard oil is widely consumed as a food) has not drawn the same publicity as *Bt* cotton.<sup>40</sup>

In parallel to the accumulation of evidence for presentation to the regulatory authorities, Monsanto engaged in a broader public relations effort. The news reporting service offered by the company through the email and by fax kept media people abreast of developments, and with a most definite pro-GM spin. Newspaper adverts, public opinion surveys, open-days, workshop talks, video presentations were all part of a well orchestrated approach to win over a generally hostile public mood coordinated by the Mumbai "government and public affairs" department of Monsanto, with heavy backing from head office in St Louis Missouri. In addition to these more up front approaches, behind-the-scenes lobbying has also been part of the approach adopted. Monsanto has informally funded a range of different activities, events and groups which are aimed at promoting biotechnology and *Bt* cotton in particular,<sup>41</sup> as well as visits to India by articulate advocates of biotechnology.<sup>42</sup> Monsanto has also been an active participant in the US government's study visits to the US, aimed at showcasing US biotechnology experience, including the benefits of its regulatory approach. Through funding offered by the US Embassy in Delhi, a number of scientists, DBT officials and others have travelled on such study tours.

It is difficult to gauge how Monsanto/Mayhco influenced the regulatory decision process and through what means. Of the informants who were RCGM committee members, the general view was that the committee "worked well" and maintained its "independent" stance. Its efficient functioning was essentially because it was managed by a competent, informed civil servant, and was composed of like-minded people, who concentrated on "the science". By providing the DBT legitimacy and authority, the scientific community (or more particularly the biotechnology/molecular biology community) ensured that

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<sup>39</sup> Interview, TM Manjunath, Monsanto Bangalore, 22 February 2001.

<sup>40</sup> Although see press commentary in November 2002 when a decision by GEAC was delayed, and March 2003 when the application was rejected pending further trials. See 'GM mustard put on hold' (*Times of India*, 8 November, 2002); 'ICAR calls for more trials on GM mustard' (*Financial Express*, 17 November 2002); 'Mustard mess' (*Times of India*, 3 December 2002), for example.

<sup>41</sup> For example, the Foundation for Biotechnology Awareness and Education, founded in 2001 by Dr Kameswara Rao and based in Bangalore.

<sup>42</sup> C.S. Prakash, professor in plant molecular genetics from Tuskegee University in Alabama, in particular has been especially vocal. He is a member of the US Department of Agriculture's Biotechnology Advisory Committee and he also sits on the DBT Government of India's Scientific Advisory Committee (Overseas). His website AgBioWorld ([www.agbioworld.org](http://www.agbioworld.org)) and newsletter AgBioView carry regular pro-GM crop commentaries. He has also organised a global petition or declaration of support of agricultural biotechnology signed by 3,200 scientists including Norman Borlaug, James Watson and Gurdev Khush. Both his website and his trips to India to promote biotechnology are reportedly sponsored by corporate interests.

the regulations could be upheld as based on a rational, objective and scientific approach. While there were disputes about what data was needed, how rigorous the trials were and whether more extended tests were needed, the fact that the RCGM was dealing with “research” and not commercial release meant that things never got too heated. Certainly there was concern raised about the potential bias of data only produced by the commercial applicant, and the apparent side-lining of the agricultural universities and ICAR did become an issue (see below). This in particular raised some hackles, and in 2001 seemed to be jeopardising the credibility of the process. A University of Agricultural Sciences (Bangalore) researcher commented then on the trial monitoring process:

How competent are these M and E committees? You visit for a day or an hour, with briefcase in hand. The pure scientists in these groups may know the plant system, but not the crop and certainly not the farmers. The company provides everything. Hospitality, transport is organised by Monsanto. What can be learned? People just sign and approve. What can you tell from visual inspection – the crop is there, the plot size is such and such. What use is this?<sup>43</sup>

However, it was only when the commercialisation decision came close and the issue was referred to the GEAC did these issues become really hot topics. The GEAC of the MoEF operates outside the rather more cosy confines of the DBT-centred networks of the RCGM, and is the interministerial committee which must approve any environmental releases. This includes any permissions for large scale field trials, seed multiplication and commercial release. Unlike the RCGM, the GEAC is an inter-ministerial committee with representatives from a wide range of ministries and departments.<sup>44</sup> As a senior DBT official complained: “This results in constant reshuffles. Twelve secretaries in twelve years. And they are not necessarily technical people. We need more scientists, otherwise we have to reeducate people continuously”.<sup>45</sup> The GEAC is seen to fulfil the necessary bureaucratic function of ensuring safety and acceptability across a range of ministerial concerns and mandates, to ensure that all government players become committed to the decision. In the view of the DBT, the RCGM provides the necessary technical and scientific advice for the GEAC to formally make the decision, making the GEAC the formal, bureaucratic rubber-stamping body, with the key decisions and advice emerging from the expert-led, science-based RCGM.

However, once the decision enters the melee of departmental rivalry and bureaucratic politics at the central governmental level, simple rational scientific criteria are less of a concern. A major division has

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<sup>43</sup> Interview, UAS, 12 March 2001.

<sup>44</sup> The current chair (from early 2003) is Shushma Choudhary who replaced A.M. Gokhale. If applicants are aggrieved by the GEAC decision they can appeal to the Appellate Authority under the former Union Environment Secretary, Vishanath Anand. Members include representatives from the Ministry of Industrial Development and Department of Science and Technology, Ocean Development and Biotechnology. Other members are drawn from the Indian Council for Agricultural Research (ICAR), the Indian Council for Medical Research (ICMR), the Council for Scientific and Industrial Research (CSIR), and the Central Pollution Board. A Health Services member from the Ministry of Health and Family Welfare is also included, along with a Plant Protection Adviser and three experts in the relevant fields (Dhar 2002).

<sup>45</sup> Interview, DBT, March 2001.

already been hinted at between the Ministry of Science and Technology/DBT – strong proponents of biotechnology as a key driver of the new economy and the supporters of a large and influential group of molecular biologists across the country, many with strong industry connections – and the Ministry of Agriculture/ICAR – with their comparable commitment to biotechnology, but with different funding streams and more scepticism about how the new technology should fit with more conventional approaches to agricultural research and development, and particularly the role of the public sector effort. The ICAR representative on the GEAC reportedly regularly made it clear that a gung-ho private sector led approach was not wise, and that there should be more reliance on the public sector, both in terms of regulatory approval and technology development.<sup>46</sup> Ministry of Agriculture officials have made it clear on a number of occasions that they believe that agricultural technology approvals should be under their ministry, rather than under MoEF. There were also questions raised by the Ministry of Health who at times had felt side-lined by the process. This was partly because of the lack of concrete data on health effects one way or the other, meaning that health matters were seen not to be fully considered. Shortly before he resigned, former Union Health Minister, C.P. Thakur commented: ‘GM products could have long-term environmental and health effects. It is essential that the Health Ministry is involved more in such decisions’.<sup>47</sup> But despite this wrangling internally on the committee between different arms of the bureaucracy, the recognition that any decision was ultimately a political one was acknowledged by a senior DBT official: ‘For approval there will have to be wide political consultation beyond the GEAC. Even if the scientific community approves, there will still be a delay as consultations occur, with eminent people like Swaminathan and politicians’.<sup>48</sup>

Others have asked whether the GEAC should exist as currently constituted at all. The CII, for example, in its high profile launch of its White Paper on biotechnology argued for a fast track single window approval process to speed up investment in biotechnology – and particularly the pharma/medical sector – and argue for the separation of functions, with regulatory approval being granted by different bodies depending on the type of product (CII 2002; Newell 2003). As a CII official noted: ‘We are trying to sell India as a biotech location. But government needs to do more. It’s the bureaucratic process that’s important. It is an ad hoc system, with lack of clarity and delays. We need an industry friendly single agency with all the experts in one place’.<sup>49</sup> Noting the regulatory furore created by agricultural products, many in the biotech industry feel frustrated that this is holding back the development of the industry as a whole and so argue for the separation off of the agricultural sector, and with this the bad publicity, public anxiety and regulatory attention associated with Monsanto and others.

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<sup>46</sup> Following the rejection of Pro-Agro’s GM mustard application, Deputy DG of ICAR, Mangala Rai was quoted as saying ‘ICAR is a responsible public sector research institution having international reputation. ICAR cannot just abide by the dictates of GEAC for no further trials . . .’ (*Financial Express*, 17 November 2002).

<sup>47</sup> IPS press release, 6 September 2002. See AgBioIndia archive, September 2002. The recognition that conflicts between ministry positions was proving problematic was highlighted by the convening of a ‘high level interministerial meeting’ in early 2003, with the aim of ‘fixing the responsibilities of the various ministries and ironing out interministerial differences’ (*Deccan Herald*, 27 February 2003).

<sup>48</sup> Interview, DBT, 28 March 2001.

<sup>49</sup> Interview, CII, March 2001 PN.



Thus in the context of the different committees and stages of the regulatory process, different actors and interests and so associated tactics and strategies of negotiation, become important. While the RCGM is less overtly political compared to the GEAC in terms of (semi)public contestations over roles and influence, nevertheless the move of framing the regulations in a particular narrow way, with science-based risk assessment at the centre, must be seen in a political light. By removing certain debates from regulatory purview, the way the regulations are discursively framed and in turn institutionalised in particular scientific-administrative procedures has unquestionably political effects.

Defending the line between this narrow, technical, risk assessment approach and the wider debate within which the regulatory approval process is set has been an important task for the DBT, and particularly P.K. Ghosh, the former advisor. At the same time, along with the DBT Secretary and other department officials, he had to fulfil the DBT mandate of “promoting biotechnology”<sup>50</sup> through articles, speeches and press interviews making the case for *Bt* cotton, pointing to its potential economic and environmental benefits, and, at the same time, he was having to defend the thoroughness and probity of the regulatory procedure to increasingly vocal critics. That he and the DBT in general was not always believed is perhaps not surprising. As the person on the front-line for press comment and public defence of governmental action, he was unquestionably in a difficult position, and clearly resented the fact that many other scientists preferred to keep quiet and avoid comment. As the protests against *Bt* cotton rose to a head in 1998–99, he commented that ‘I was sitting on top of a volcano. Now we have faced the volcano and somehow we survived’.<sup>51</sup> It was this more general loss of trust in the legitimacy and authority of the regulatory process – and DBT in particular – that became critical as we shall see in providing opportunities for challenging the framing and procedural institutionalisation of the regulations in this period.

The management of the regulatory process has been characterised by a relatively tight grouping of people, with few opportunities for wider deliberation. There has been a marked absence of open discussion and sharing of information on the details of the regulatory deliberations. The DBT has also had limited interaction with opposition groups and the broader public, except through a limited number of public events and media briefings. In private, and sometimes in public, DBT officials deem opposition groups to be rabble-rousers, unscientific, emotional, political and therefore not worth engaging with. One DBT official described the debate as constructed around ‘superstitions, mystical threats and hypothetical risks’.<sup>52</sup> The broader public is seen as unduly influenced by dramatic media stories, and essentially ignorant of complex scientific issues, and in need of education. A senior IISc biotech scientist put it this way: ‘Public understanding is key. We need to educate the public. The scientific community need to come up

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<sup>50</sup> Promotion as well as regulation are both part of the formal mission of the DBT. This ambiguous role was confirmed by the current DBT Secretary who was quoted as saying ‘*Bt* cotton is only released commercially after convincing farmers about its benefits . . .’ (*Deccan Herald*, 19 November 2002).

<sup>51</sup> Interview, DBT, 28 March 2001.

<sup>52</sup> Interview, DBT, March 2001 PN.

with a statement of the facts'.<sup>53</sup> Others argue that, rather than the urban-based activist groupings becoming involved in the regulatory process, it must be the farmers themselves. In the end, they argue, it will be the market that decides, not the “experts”. As Ghosh himself commented ‘Science will not find us all the answers . . . In the end society has to find the answers. Ultimately the debate will be decided in the fields by the farmers themselves’.<sup>54</sup>

The DBT, and the regulatory authorities more generally, certainly seem to play by the rules. But these are rules that have been developed by them, and a close-knit coterie of advisors and others. And, increasingly, these rules are being questioned, both on their own terms and in relation to a broader debate about technology and development policy. While this questioning may be dismissed as emotional, irrational and unscientific, it is important not to ignore the wider implications of this broader debate. Even if such perspectives are primarily emanating from a relatively small grouping of people, with no justifiable claim to be speaking for a wide constituency, the reverberations of the debate may have implications elsewhere, galvanising others to develop their own (often very different) positions, and encouraging a diversity of views and voices to enter the discussion – sometimes, as with the very vocal and visible protestors, in the public eye, but sometimes more subtly and behind the scenes. The next sections, then, turn to the way the expertise of those at the centre of regulatory authority is being challenged on a number of fronts, and how such dissent is manifested in the emergence of new coalitions of actors, presenting alternative perspectives on the regulation of *Bt* cotton specifically, and the future of biotechnology in India more generally.

## 5 Contesting the regulations

Outside the formal regulatory committees, the regulatory process surrounding *Bt* cotton has been marked by much controversy and debate. For some, *Bt* cotton has become symbolic of a much wider struggle against the dominance of multinational capital, particular forms of technological modernisation, and globalisation more generally. Thus alliances are potentially forged between those concerned with the protection of indigenous crop varieties in dryland farming areas, different styles of nationalists interested in protecting the Indian economy and culture outside depredation, and from anti-globalisation protestors, linked to an international network of activists. Clearly, such debates go far beyond the regulation of technological risk that is overseen by the DBT and the MoEF. As a MoEF official put it: ‘Thanks to the NGOs, half our time is spent in the courts!’.<sup>55</sup>

Soon after *Bt* material was imported, objections were raised and presented as a court petition by the Research Foundation for Science Technology and Ecology (RFSTE) headed by Vandana Shiva disputing the form and content of the regulations on. But things really started to heat up in 1998, sparked in

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<sup>53</sup> Interview, IISc, 8 February 2001. This commentary is very similar to that observed in Europe where the public shows a much more sophisticated understanding of risks and uncertainties than is conventionally assumed (Marriss *et al.* 2001).

<sup>54</sup> Interview, DBT, 28 March 2001.

<sup>55</sup> Interview, MoEF, 29 March 2001.

particular by the controversy about the “terminator gene”.<sup>56</sup> Monsanto, as potential purchaser of Delta Pine, the co-owner of the terminator patent (with USDA), became implicated by association. The press commentary, fuelled by plenty of carefully pitched briefings from international groups such as RAFI (Rural Advancement Foundation International, now ETC group) and GRAIN (Genetic Resources Action International), elided the issues, such that *Bt* cotton (already synonymous with Monsanto) became linked to terminator technology. Despite strenuous denials by Monsanto PR officials,<sup>57</sup> questions in parliament, and much media commentary, the issue had been raised, and the links made.

By mid-1998 a public relations battle was on. Monsanto launched a series of adverts in the press. At the same time, NGO groups also launched the Monsanto Quit India campaign, symbolically choosing 9 August, the day Gandhi launched the Quit India struggle against British occupation.<sup>58</sup> Although it was well known that field trials had been established, details of field trials became public only in November, following formal approval at the end of July and early August. State governments were furious at the lack of coordination with them.<sup>59</sup> In Karnataka the Agriculture minister, Byre Gowda, established an expert panel to discuss the issue.<sup>60</sup> Through pressure from the media, the four locations of the field sites in the state were also made public. Immediately following this, the KRRS (Karnataka Rajya Ryota Sangha, perhaps the most famous Karnataka farmers’ movement) announced the ‘Cremate Monsanto’ campaign in November 1998. KRRS leader, Professor Nanjundaswamy identified the following slogans ‘Stop Genetic Engineering’, ‘No Patents on Life’, ‘Cremate Monsanto’ and ‘Bury the WTO’. He gave notice that all trial sites in Karnataka would be burned the following Saturday under media scrutiny.<sup>61</sup> The US embassy in turn requested police protection for US companies in Bangalore, and the High Court of Karnataka ruled to protect sites and the property of Mayhco seed firm.<sup>62</sup> In Bellary and Raichur districts the trial farmers

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<sup>56</sup> See, for example, ‘Patent for terminator technology filed in India, experts worried’ (*Indian Express*, 29 December 1998). Also see the articles by Gail Omvedt ‘Terminating choice’ and Vandana Shiva, ‘Terminating freedom’ (*Hindu*, 26 December 1998). See also: ‘Terminator seeds not permitted in India: agric minister’ (*Economic Times*, 3 December 1998); ‘Terminator gene is not being used, says MNC’ (*Indian Express*, 3 December 1998); ‘Seeds of conspiracy’ (*Hindustan Times*, 3 December 1998); ‘Terminator seed tech will be banned: Som Pal’ (*Indian Express*, 2 December 1998); ‘Terminator seeds not allowed’ (*Hindu*, 2 December 1998); ‘Gene terminator creates panic’ (*Times of India*, 28 November 1998); ‘Terminator gene row a fabrication: Monsanto’ (*Times of India*, 26 November 1998); ‘India gears up to face the threat posed by the terminator gene’ (*Indian Express*, 10 September 1998); ‘Stop entry of terminator into India, urge scientists’ (*Indian Express*, 28 July 1998); ‘The demon seeds’ (*Hindu*, 24 July 1998); ‘Infamous invention’ (*Hindu*, 19 July 1998); ‘Farmers count seedlings as Terminator gets canned’ (*Economic Times*, 18 July 1998).

<sup>57</sup> See ‘Monsanto releases educative ads’ (*Financial Express*, 8 December 1998).

<sup>58</sup> See ‘Indians fight biotechnology giants: implement “operate cremate Monsanto”’, ‘Monsanto quit India’ campaign, press release RSFTE, New Delhi. See also: ‘KRRS threatens nationwide agitation against Monsanto, 24 October 1998; ‘KRRS threatens to throw out Monsanto’ (*Times of India*, 23 November 1999).

<sup>59</sup> For example, Karnataka Agriculture Minister, Byre Gowda indicated he had been informed of the presence of trials, but had no idea where they were (‘Seeds of controversy’, *Indian Express*, 18 November 1998). Only on 24 November did he release details of where the four locations were in Raichur, Bellary and Haveri.

<sup>60</sup> ‘Panel to check field trials of terminator gene technology’ (*Hindu*, 25 November 1998).

<sup>61</sup> The first burning took place on 28 November 1998 with the consent of the farmer. Activists from KRRS along with the (little known) ‘Progressive Front’, ‘Action Front for the Untouchables’, ‘Karnataka Liberation Front’ and the ‘Organisation of the Landless’, according to a press release from KRRS, Bangalore. The burning was also attended by a five member team from the Geneva based ‘Global People’s Action Group’ according to *Indian Express*, 30 November 1998.

<sup>62</sup> See ‘Police protection to all American companies in Bangalore city’ (*Samyukta Karnataka*, 25 November 1998); also ‘HC orders security to seed firm’ (*Times of India*, 4 December 1998).

agreed to the demands of the protestors and their crops were burnt. However Mr Sankarikoppa of Haveri district resisted and sought police protection, with the police deploying ‘a van load of constables to stand guard in his field’<sup>63</sup>. This stand against KRRS put Sankarikoppa at the forefront of the pro-GM movement in the state, and from that time on he regularly appeared at Monsanto events proclaiming on the benefits of *Bt* cotton. In a move which preempted further protests, and in a sign of annoyance that they too had not been adequately informed, the Andhra Pradesh government banned the trials at the end of the year, and requested that they be moved to an agricultural university to allow more thorough state level scrutiny.<sup>64</sup> By December, the KRRS threatened to launch a criminal case under the Union Seed Act in magistrates courts where the trials were underway against Monsanto, as well as the state and central government, on the basis that trials in Karnataka were illegal.<sup>65</sup>

The media debate continued into the following year, with plenty of opportunity for coverage prompted by a number of workshops and conferences.<sup>66</sup> By this time, the debate had become more sophisticated, and the coverage offered greater depth and commentary, compared with the earlier discussions around terminator technology. Monsanto, though, were still in the spotlight, particularly following their attempts to import plasmids for transgenic crop research at their Bangalore research centre.<sup>67</sup> With the flurry of anti-GM protest occurring in late 1998, there were also some more concerted counter moves by the pro-GM lobby, with interventions from non-resident Indian scientists (most notably C.S. Prakash from Tuskegee University, USA who made several visits to India and managed to place a wide range of articles in the press), other farmer leaders (including Sharad Joshi of Shektari Sanghatana, and Chengal Reddy of the Andhra Pradesh Farmers’ Association)<sup>68</sup> and industry commentators (including a more measured, less brash contribution from Monsanto which had commissioned a public opinion survey which, rather unsurprisingly, showed how farmers were in support of biotechnology).<sup>69</sup> With the exception of a few regular commentators from the scientific community

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<sup>63</sup> ‘Anti-Monsanto campaign runs into dry ground’ (*Pioneer Press Service*, 5 December 1998); ‘Haveri farmers will resist KRRS destruction trail’ (*Times of India*, 5 December 1998); ‘Haveri farmers have not asked for protection: police’ (*Times of India*, 1 December 1998). See also ‘Join us in burning cotton crop, KRRS chief urges Byre Gowda’ (*Times of India*, 6 December 1998).

<sup>64</sup> ‘Monsanto told to stop field trials’ (*Indian Express*, 3 December 1998); ‘Seeds of controversy’ (*Times of India*, 4 December 1998).

<sup>65</sup> ‘KRRS to file criminal case against Monsanto’ (*Deccan Herald*, 18 December 1998); ‘KRRS threatens to destroy Monsanto crops’ (*Deccan Herald*, 2 December 1998); ‘KRRS will destroy *Bt* cotton crop in Bellary today. Says it will file criminal cases against Monsanto, state and central govts’ (*Times of India*, 2 December 1998).

<sup>66</sup> For example, the TERI “stakeholder dialogues” (see *Economic Times*, 26 November 1999); the National Science Summit in Bangalore (*Times of India*, 9 August 1999); the 86<sup>th</sup> Science Congress in Chennai where James Watson spoke alongside Manju Sharma who gave the Presidential address (*Indian Express*, 1 February 1999); the MSSRF national consultation on GM plants also held in Chennai (*Business Line*, 13 January 1999); and the UAS-Bangalore seminar on ‘Environmental and Health risks associated with transgenic plants’ at which various DBT officials and other scientists spoke (*Times of India*, 23 December 1998).

<sup>67</sup> See ‘Monsanto proposal to genetically alter rice draws flak’ (*Economic Times*, 6 August 1999); ‘Monsanto raises more dust in Indian fields’ (*Economic Times*, 6 August 1999); ‘Monsanto turns to food crops’ (*Hindu*, 6 August 1999).

<sup>68</sup> ‘Farmer leader pleads for immediate release of GM crops in India’ (*Financial Express*, 24 April 2000). See ‘Yielding positive results: gene revolution as farming aid’ by Chengal Reddy, *Financial Express*, December 2000.

<sup>69</sup> ‘Farmers support biotech use for increasing yield – Monsanto study’ (*Financial Express*, 31 August 1999).

(including Professor G. Padmanaban, former director of the Indian Institute of Science<sup>70</sup> and former CCMB director Dr Pushpa M. Bhargava)<sup>71</sup> there remained very few local Indian scientists prepared to enter the fray, although the likes of Norman Borlaug were not shy of offering their opinion in pieces placed in the Indian press.<sup>72</sup>

The anti-GM groupings, always on the look out for good media opportunities, also had their share of exposure during 1999. For example, the caravan to Europe, part of a protest about globalisation and the WTO more generally, occurred in May and June, with KRRS leader, Nanjundaswamy, as ever, ready for media comment.<sup>73</sup> Through 1999 and 2000 there were also further court case cases lodged by public interest petitions by the Research Foundation for Science, Technology and Ecology (RFSTE) with the Supreme Court, with much media exposure for Vandana Shiva, the internationally well-known activist.<sup>74</sup> The cases contested the legitimacy of the field trials on the basis of alleged technical failings of trial procedure according to the regulations. At the same time, issues around the patenting of local materials were raised effectively on various occasions highlighting the dangers of biopiracy by large, foreign (usually US) companies. The big industry gathering for the Asia Seed conference in September 2000 in Bangalore provided an excellent opportunity for a counter-protest, and the “seed tribunal” offered both testimonies by farmers from across the country and a “judgement” by a leading judge on biotechnologies, and an associated call for a moratorium on testing. As one journalist commented of this period: ‘there was no problem getting good copy. Monsanto would send sometimes several faxes a day, and all I needed to do was ring up one of the anti-GM groups and get a response’.<sup>75</sup> Thus dissent, protest and questioning of biotechnology was a constant feature of the daily media (at least in the English press, but also to a lesser extent the vernacular press too).

In the last three years, this pattern of activist protest has become well established. International events – whether the Social Forum in Porto Allegre, Brazil, the World Summit on Sustainable Development in Johannesburg, South Africa or major international meetings on biotechnology across Europe, North America and elsewhere in Asia – have been used to provide a platform (or a site of protest) for the raising of local issues which in turn have been picked up by the international and local press. At home the courts have seen much continued action, with public interest litigation following thick and fast. The RFSTE petition involved extensive hearings at the Supreme Court and vast amounts of evidence submitted. Others have followed suit, including a Delhi High Court action by Gene Campaign in

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<sup>70</sup> See for example ‘Bt cotton trials harmless, aver experts’ (*Indian Express*, 24 December 1998); ‘India definitely needs transgenic technology’ (*Economic Times*, 24 August 2001).

<sup>71</sup> Bhargava has maintained a sceptical tone, including critical comments at the People’s Science Congress held alongside the annual Science Congress in New Delhi in January 2001 (*Press Trust of India*, 2 January 2001).

<sup>72</sup> For example: ‘We need biotechnology to feed the world’ (*Financial Express*, 13 December 2000).

<sup>73</sup> ‘Indian farmers take the war to Europe’ (*IPS*, 25 May 1999). See also an article by Sharad Joshi: ‘Indian peasants on European jaunt’ (*Business Line*, 10 March 1999).

<sup>74</sup> The public interest petition sought judicial intervention to check alleged violation of the regulations, and the Supreme Court issued notices to federal ministries of science and technology, agriculture and environment and forests in February 1999. The Supreme Court rejected Monsanto’s plea for the dismissal of the litigation, and the case was heard on a number of occasions (see *Economic Times*, 19 November 2000). RFSTE have claimed the 2002 decision to allow commercialisation as illegal as the PIL was still pending.

<sup>75</sup> Interview, *Financial Express* journalist, Chennai, February 2001.

2001 claiming that the illegal sales of GM seeds in Gujarat were done with the knowledge of the government.<sup>76</sup> A further petition by the Gene Campaign arguing for the right to information disclosure on trial results under the Freedom of Information Act.<sup>77</sup> Other forms of litigation have occurred in other courts, for example farmers' groups from Vidharba region threatened action in the Mumbai High Court demanding compensation for the failure of the *Bt* cotton crop in Maharashtra in 2003.<sup>78</sup> Similarly, the Gene Campaign has demanded compensation for farmers under the terms of the 2001 Plant Varieties and Farmers' Rights Act.<sup>79</sup>

Other more direct forms of protest have continued, with the KRRS being active in crop burning media events, and arguing for a five-year moratorium on GM seeds.<sup>80</sup> Protests have occurred in a variety of places, including, following the commercial release of *Bt* cotton in 2002, at the research headquarters of Monsanto in India at the IISc, Bangalore.<sup>81</sup> Events such as the citizen juries in Karnataka in 2000 and in Andhra Pradesh in 2001 have also provided foci for activists to denounce GM crops and the associated future vision for agriculture assumed to go with them.<sup>82</sup> Media interest has remained high and the continuous briefing and counter-briefings have occurred, with competing internet-based services providing alternative views on the Indian scene.<sup>83</sup>

A new politics of dissent around *Bt* cotton had been manufactured, where the debate was taken beyond the technical specifics of *Bacillus thuringiensis* and effectiveness or otherwise of mid-gut receptor interactions, to a wider set of anxieties about corporate control, farmers' rights and livelihoods. The NGOs and farmer movements in India drew very explicitly on their international connections. RAFI, GRAIN and other international networks and activist organisations provided a continual stream of press briefings to counter the Monsanto PR campaign. Attempts by influential scientists to intervene, and impose what they saw as the need for rational debate were by-passed. The frustration from the core grouping associated with the formal regulatory procedures was tangible. P.K. Ghosh resignedly commented 'it is like a first pregnancy, there are always more problems',<sup>84</sup> while leading Indian scientists, echoing the comments made by the Nobel laureate James Watson in Chennai in early 1999

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<sup>76</sup> *Business Line*, 23 November 2001.

<sup>77</sup> Gene Campaign president Suman Suhai wrote to the National Academy of Agricultural Sciences head, V.L. Chopra, requesting that they oversee the release of the trial data for public scrutiny. She claimed that the current situation contravened the Freedom of Information Act (see *Deccan Herald*, 8 August 2002). However, reports in early 2003 suggest that this pressure has had some effect. A high level inter-ministerial meeting was held in February 2003 and a commitment made to make the field trial results available to the public. This however would be limited by commercial confidentiality considerations, such that key data such as the level of *Bt* expression in cotton plants would not be made available (*Deccan Herald*, 27 February 2003).

<sup>78</sup> Details of the Maharashtra farmers movement action is covered in [www.agbioindia.org/archive](http://www.agbioindia.org/archive), see posting 11 March 2003.

<sup>79</sup> See text of letter to Union Minister of Agriculture at [www.agbioindia.org/archive/](http://www.agbioindia.org/archive/), posted 11 March 2003.

<sup>80</sup> 'KRRS opposes commercial release of *Bt* cotton seeds' (*Economic Times*, 20 June 2001).

<sup>81</sup> See 'Demand for Monsanto's ouster picks up. Karnataka bans Monsanto's *Bt* cotton seeds', AgBioIndia, 11 August 2002, and *Deccan Herald*, 9 August 2002.

<sup>82</sup> See ActionAid (2000); Pimbert and Wakeford (2002).

<sup>83</sup> For example, AgBioIndia ([www.Agbioindia.org](http://www.Agbioindia.org)), supported by Delhi based activist Devinder Sharma, and more international lists (including [bio\\_activists@iatp.org](mailto:bio_activists@iatp.org)) with a more sceptical crops stance, and AgBioWorld, supported by C.S. Prakash and Monsanto India ([www.monsantoindia.com](http://www.monsantoindia.com)) taking more pro-biotech positions.

<sup>84</sup> Interview, DBT, 28 March 2001.

(MSSRF 1999), saw the dangers of excessive caution being introduced on the basis of irrational, non-scientific debate. Leave it to us, we are the experts, was their view. But, in the meantime, and partly in reaction to this arrogant style, the argument was pushed to a different level.

## 6 Citizens and activists

This was therefore becoming a struggle against not just the *Bt* technology, but the whole vision of agriculture and technological control that, according to the critics, the adoption of biotechnology would imply. There was therefore a questioning of the narrow, technical, rational discourse on which the regulatory process was based, through the demand for a wider debate. Symbolic links to deeper, cultural and political associations were also explicitly made in order to embed the dissent in a wider and longer running politics. Thus Vandana Shiva, director of RFSTE refers to the “second cotton colonisation”<sup>85</sup> and makes links to struggles over rights to land, seeds and the body; protest marches commemorate Ghandi’s struggles against the British, and Professor Nanjundaswamy, the leader of the KRRS, makes rhetorical links to struggles against globalisation and the need for a “khadi curtain” to protect Indian peasants against foreign capital.<sup>86</sup> While such rhetorical flourishes can easily be dismissed (and indeed are by many), what is important is that they are part of the debate, reported, discussed and responded to. As one agricultural university scientist commented: ‘Whatever you think about them [the anti-GM protestors], the important thing is that *Bt* cotton is being debated. Otherwise it would not be talked about. This is the good thing about democracy’.<sup>87</sup>

So who are the protestors? The Research Foundation for Science, Technology and Ecology, led by Vandana Shiva has perhaps been involved in the biotechnology debate for the longest, and has pursued an approach which has combined activist writing (including regular newspaper/magazine articles, and books (e.g. Shiva 2001, 1993), legal challenges to the Supreme Court of India (dates,) involving the production of voluminous quantities of case material, and the hosting of events (e.g. seed tribunal etc.). Vandana Shiva has a long history as an environmental activist, and is particularly well known internationally. She presents herself as a scientist, but also at the same time as someone who is linked to the grassroots and particularly rural women. An earlier ally was the KRRS, and particularly its President Professor M.D. Nanjundaswamy, one time lawyer and aspiring party politician in Karnataka, but also the leader of the KRRS, based in Bangalore. He again claims expertise (‘these people used to be my students’ referring to Karnataka

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<sup>85</sup> ‘Monsanto’s bollgard: poison or panacea?’, *Times of India* (3 January 1999).

<sup>86</sup> Rhetorical links to Ghandian struggles, such as “khadi curtain” (referring to the struggle against British cotton imports and the Ghandian vision of making locally manufactured alternatives (khadi cotton), are all part of the debate.

<sup>87</sup> Interview, University of Agricultural Sciences, Bangalore, February 2003.

ministers), and local connections through a mass membership movement.<sup>88</sup> A Monsanto official commented with some resignation: ‘For Nanjundaswamy, it’s a way of life – biotech, fashion shows, whatever. He gets quoted and gets a profile’.<sup>89</sup> Other key players include Suman Suhai, founder of the Gene Campaign, and Devinder Sharma, of the Forum for Biotechnology and Food Security and editor of the influential AgBioIndia website.<sup>90</sup> Both these organisations and individuals are seen as more “moderate”, but essentially develop a similar argument about agricultural biotechnology. Although their tactics involve less direct protest and more engagement, the basic message is the same: *Bt* cotton should be stopped.

All have impressive international links, through the global network of NGOs and other groups working on biotechnology and farmers’ rights. Canada-based RAFI and Spain-based GRAIN have been important in supporting campaign against “terminator” technology for example, while organisations such as Via Campesina have joined up with KRRS (with their South Asia coordinator being KRRS president, Prof. Nanjundaswamy). The anti-globalisation group, Global People’s Action, have been present at a variety of actions, including GM-crop burnings in Karnataka. In early 1999, KRRS and Via Campesina organised a four-day international conference in Bangalore focusing on agrarian reform issues.<sup>91</sup> In September 2000, to coincide with the major Asia Pacific Seed Association conference, the RFSTE organised a “seed tribunal” in Bangalore attended by farmers from the US, Canada and France, while Greenpeace staged demonstrations outside the conference venue.<sup>92</sup> A few days later the annual Via Campesina meeting provided a focus for more protests, and further threats from Nanjundaswamy to destroy field trials in Karnataka.<sup>93</sup>

The degree to which such “movements” “fora” and “campaigns” represent a wider constituency is open to debate. Much commentary on “farmers movements” in India has noted how they are represented by very sectional interests, largely of middle income farmers, keen to preserve the privileges of subsidy and state support, in the face of an increasingly organised urban middle class and increasingly bankrupt state governments (Brass 1995; Corbridge and Harriss 2000). The KRRS in particular has come in for much

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<sup>88</sup> Interview, Bangalore, February 2001. The KRRS and Nanjundaswamy in particular have been involved in activist politics in Karnataka, south India for many years. Of late the *Bt* cotton issue has attracted attention, but in the past protests have been directed against Kentucky Fried Chicken outlets in Bangalore, as well as a Miss World competition. The anti-GM focus emerged through connections with a wider network of global activists, including Via Campesina and various anti-globalisation groups. KRRS once attempted to gain a foothold in electoral politics but failed dramatically and since then their attentions have been focused on both lobbying for particular farmers’ needs and engagement in wider, more global issues such as WTO membership, GM crops and so on. The move to this wider agenda was criticised by some members, particularly as Nanjundaswamy spent time travelling the globe as farmer representative and activist. The result has been a split in the movement, with the Nanjundaswamy faction being associated with a support base in northern Karnataka and the so-called Puttaniah faction be linked to southern Karnataka groups (see McHattie 2000 for more details).

<sup>89</sup> Interview, MRC, Bangalore 22 February 2001.

<sup>90</sup> Sharma has deemed the *Bt* cotton approval ‘the biggest scientific fraud since independence’ and demanded a criminal enquiry into the process (see AgBioIndia, 22, 28 April 2003).

<sup>91</sup> ‘Global farmers meet demands “just” agrarian reforms’, *Times of India* (8 January 1999).

<sup>92</sup> ‘Asian seed meet opens today amid controversy’, *Times of India* (26 September 2000); ‘Tribunal on corporate control over seeds’, *Deccan Herald* (25 September 2000); ‘Greenpeace to disrupt Asia Pacific Seed Association meet’, *Times of India* (13 September 2000).

<sup>93</sup> ‘Campesina strengthens anti-WTO agriforce’, *Financial Express* (7 October 2000).



criticism, with the claims made by its leaders of mass support being questioned (e.g. Assadi 1997; McHattie 2000). The brief foray into electoral politics in Karnataka did not result in significant gains, and the KRRS soon rejected that route in favour of organised activism outside the electoral arena. In the same way, RFSTE and its allies in the NGO movement such as Greenpeace, while making much of the rhetoric of peasant voices, have little authority to speak for the vast rural masses, given their limited membership base. As with many activist NGOs, in India as elsewhere, personal jealousies, rivalries and competition, have plagued both the internal operations of the groups concerned and the relations between them. While there have been some dramatic fall outs, with accusations flying in the media, there remains a consistency of position, however. And it is probably this that has allowed the sense of an alternative vision to emerge, held together by a particular set of commitments, and some common international connections, rather than bonded by regular and close connections on a day-to-day basis.

While strenuously denying any direct connection, the anti-biotechnology groups, some argue, serve other interests too. And the anti-GM discourse provides a suitable cover for others. In particular, it is argued, that the quite large and powerful pesticide industry has no interest in the advent of *Bt* technologies, which would potentially cut significantly into their market share of pesticide sales.<sup>94</sup> In the same way some local biotech companies fear early multinational domination of the biotech product market, and are quite happy to have regulatory delays for them to catch up. While not wanting to present themselves publicly in the debate as a particular, identifiable network of interests, behind-the-scenes lobbying offering a “moderate” and “cautious” stance has been noted.

The controversy generated by *Bt* cotton has therefore gone far beyond the narrow technicalities framed by the regulations and their associated risk assessment approaches. The issue has galvanised a wide array of different groups and individuals, and with them a range of different arguments deployed against the pro-GM line. This has not been a coherent, unified opposition. Indeed much energy has been invested in in-fighting and competition between groups. But the diversity of approaches – from court cases, to street demonstrations, to crop burning direct actions, to media and internet information campaigns – have perhaps been a contribution to the effectiveness of these efforts in raising a bigger, broader debate.

Some argue that much of this debate has been based on appropriations of a foreign, European discourse, and that such groups have no base or legitimacy in India. The Karnataka Chief Minister, S.M. Krishna, identified a ‘diabolical conspiracy by some organisations and vested interests outside India. They don’t want a strong nation or a strong scientific community to come up’.<sup>95</sup> In the same vein, in an op-ed piece, Professor Padmanaban, former IISc director and member of key DBT committees comments:

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<sup>94</sup> See, for example, report by the Pesticide Manufacturers Association of India arguing against GM crops, *Business Line* (29 May 2001). See also commentary by Sharad Joshi claiming anti-GM protests are sponsored by the industry, *Business Line* (10 March 1999).

<sup>95</sup> ‘CM warns of plot against biotechnology’, *Hindu* (8 September 2000).

The state and federal governments have been unnerved by the propaganda, and the response of the regulatory agency to government approvals of GM crops is obviously conditioned by the negative environment . . . The net result is that all the laboratory marvels remains so and do not make it to the field, despite the heroic efforts of scientists and the DBT . . . I do not believe a few more or less trials can answer the environment question. Transgenes are a drop in the ocean and nature has its own way of equilibration . . . Misused democratic traditions, miscredited liberalism and misinterpreted religious sentiments have unfortunately led to endless debates in India without contributing much to the alleviation of human suffering.<sup>96</sup>

While in part he has a case, he and others miss the point that in the democratic context of India, such a cacophony of perspectives must be responded to, lest the formal regulatory process be undermined. Those overseeing the regulatory process in government, as well as the industry advocates, are well aware of this, and have spent considerable time and resources arguing for the efficacy and trustworthiness of the regulatory process. That not everyone quite believes them, or even cares about the formal process, becomes more evident when we examine what happens at a more local, state level.

## **7 Karnataka perspectives**

The earlier sections have looked at how the debate over *Bt* cotton has been played out at a national level. Some actors – such as Professor Nanjundaswamy – have been part of the national, even global, drama, but to this point, the concentration has been on how these players and the unfolding of events has influenced the regulatory process at the centre, and how different national level discourse coalitions have emerged. But how is this played out at state level, and how does the interaction between the states and the centre affect the politics of negotiation around regulatory policy?

When we move to a state level, a complex picture emerges, one that certainly includes many of the same actors as at the national level, but in more complex configurations, and with more variations in plot lines. While the core network at the centre has held together through the process of “facing the volcano”, as Ghosh put it, with stolid determination, this has been more difficult to maintain at state level, at least in Karnataka. Here more fractures, and fault lines are evident, and more locally based coalitions and networks – which have little chance of finding a foothold in the national context – can have major influences over policy positioning and debate. So who are the players in Karnataka? This section identifies some of the key players in the debate, and reflects on interviews held with different groups between 2000 and 2003.

The cotton farmers of the state will either be the beneficiaries or the victims, depending on one’s view of the new technology. In Karnataka cotton is grown largely in the drier part of the state, particularly in the central and northern districts. In the 1990s around 6 lakh hectares was planted to cotton each year, down from 11.5 lakh hectares in the mid-1950s. Due to yield increases, however, total production in the

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<sup>96</sup> *Deccan Herald* (19 April 2002).

state has risen to around 9 lakh bales per annum in the 1990s.<sup>97</sup> While many farmers grow some cotton, those who make a significant proportion of their income from cotton tend to be more prosperous farmers, able to afford the often expensive inputs. They also tend to have relatively larger field sizes, and employ labour on their farm for basic agricultural operations. The *Bt* cotton trial sites were located where seed companies have long had seed multiplication facilities, and, according to Shiva *et al.* (1999), the chosen trial farmers included those who had had previous associations with Monsanto in this regard. The relatively richer, “middle class” farmers are also the core supporters too of the KRRS, and the dryland belt of these districts is the area where Nanjundaswamy’s faction of the KRRS gains most of its support. Thus in the attempts to burn the trial site crops in 1998–99, the KRRS leaders were able to persuade farmers in Bellary and Raichur to comply with their demands.

On GM crops there is clearly no uniformity of position among such farmers. Illegal *Bt* cotton was available in the state during 2001–02 and some estimate that around 10 per cent of the cotton area was planted to *Bt* cotton acquired through informal trade.<sup>98</sup> Much of this planting was done by relatively rich farmers – ironically the main constituency of the KRRS.<sup>99</sup> Unlike the big expose in Gujarat this was quietly ignored by the authorities, in the hope that a more formal approval would come the following year. This indeed did occur and MMB supplied *Bt* cotton in 2002–03 to cover nearly 20000 acres. This was supplied mainly to clusters around the earlier Monsanto trial sites. Monsanto were clear that the trials were a prelude to the commercial release and that they afforded the opportunity to educate the farmers about *Bt* cotton during that period.

The release of *Bt* cotton in the state provoked more protests from KRRS and Nanjundaswamy. A major rally at the Monsanto Research Centre in Bangalore was held in August 2002, and the Minister of Agriculture was called to address the protestors. He banned the sale of *Bt* cotton seed for a period and proclaimed that full scale commercial release had not occurred, and that it remained only on a trial basis.<sup>100</sup> Attempts at crop burning during 2002 had mixed results as before, with some farmers accepting compensation from KRRS protestors for the public destruction of their *Bt* cotton crop, while others firmly refused such advances and called in the police. The degree to which *Bt* cotton will have a major impact on the cotton farming economy of the state will only be known in a few years time, however, when more farmers, beyond the trial clusters have tried the product under a variety of conditions, including high bollworm infestations (which did not occur in the first season due to widespread drought).

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<sup>97</sup> Government of Karnataka (2000). Karnataka Agricultural Profile, April 2000. Karnataka State Department of Agriculture: Bangalore.

<sup>98</sup> Interview, Karnataka Seed Association, Bangalore, February 2002.

<sup>99</sup> This contradiction is often pointed to by critics of KRRS. The high profile anti-GM campaign they argue is more for international consumption and about Nanjundaswamy’s international profile as farmer activist than local concerns. Farmers in the core KRRS districts have been the main purchasers of Monsanto’s (Cargill) maize hybrids for years. They are not surprisingly also potentially key consumers of *Bt* cotton. Outside the anti-GM activism, however, the KRRS focuses more on conventional farmer demands, pushing government to maintain subsidies, ensure electricity for pump sets and so on.

<sup>100</sup> For example Koujalgi banned the sale of *Bt* cotton seeds in response to a KRRS rally in August 2002 (see *Deccan Herald*, 9 August). He was also reported as saying that ‘Government has not given an official go-ahead for growing genetically modified *Bt* cotton’ (*Deccan Herald*, 15 December 2002).

In state electoral politics the views of the farming community, or at least that relatively privileged sections of it, cannot be ignored. The KRRS indeed built its support on that basis, arguing the case for the farmers in the face of threats for what they deemed were “anti-farmer” policies of the state government, both in its Janata Dal incarnation and with the return of the Congress in 1999. The fine balance of electoral politics in the state is determined critically by the rural vote, and in particular by the influence of the farmer lobby. Many Members of the Legislative Assembly identify themselves as farmers (as well as being lawyers, business people and so on), and are keenly aware that their economic and political advancement has been on the back of generous support from successive governments in terms of subsidies on irrigation water, electricity, fertiliser and so on. Even a decade after the formal announcement of the economic liberalisation policy in 1991, the agriculture sector remains relatively untouched,<sup>101</sup> and the relatively well-off sector of the farming population continue to reap the benefits. How the biotechnology debate is seen in this regard is complex and is beyond the scope of this discussion. Until recently in Karnataka successive Ministers of Agriculture have been circumspect about supporting *Bt* cotton, usually hedging their bets and deferring to expert panels (as with Byre Gowda in November 1998) and commissions (as with Jayachandra in 2000). Only since the forthright support of *Bt* cotton offered by the Karnataka Agricultural Commission in late 2000, has the tide turned, and the then Minister of Agriculture advocated *Bt* cotton as a solution for the state’s ailing cotton economy.<sup>102</sup> However, this has again shifted as the populist Minister, Koujalgi, from 2002 has proved more circumspect in his statements.<sup>103</sup>

This reticence about outwardly supporting *Bt* cotton and biotechnology more broadly derives not only from the sensitivity towards the electorally important farming community, but also in relation to the confusion over responsibilities for biotechnology regulation between the centre and the states. On several occasions Ministers in Karnataka have vented their anger publicly at what they have regarded as the inappropriate – and potentially unconstitutional – way that the DBT at the centre has gone about the regulatory process, without engaging the states in any substantive discussion or involvement in the decision process, despite agriculture being a “state subject”. For example, the Minister of Agriculture for Karnataka claimed he had only learned of the approval of the trials from the media. Although he had been informed by letter, this had been filed and not brought to any senior officer’s attention. This is put down to, variously, ‘bureaucratic incompetence of a useless department [DBT]’ or ‘typical Delhi arrogance’ or ‘the usual antagonism between the BJP [at the centre] and the Congress [in the state]’. As many

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<sup>101</sup> Although budget speeches in the period from 2001 have increasingly chipped away at the agricultural subsidy regime. The degree to which state governments are able to respond to these suggestions from the centre is of course another matter.

<sup>102</sup> ‘*Bt* cotton trials launched in state: following suggestion of Karnataka Agricultural Commission’, *Hindu* (29 October 2000). Also ‘Karnataka allows field trials of *Bt* cotton by Mayhco’, *Economic Times* (31 August 2000) [in 85 ha in 14 sites in districts of Bellary, Devangare, Koppal, Raichur and Shimoga]. See also reports on the Commission findings: ‘Farm panel submits reports’, *Hindu* (27 December 2000); ‘Agro panel favours state *Bt* cotton trials’, *Asian Age* (27 December 2000).

<sup>103</sup> See *Deccan Herald* (15 December 2002); *Times of India* (14 December 2002).

commentators have observed, the Indian federal system is a complex, and often fragile, political balancing act, plagued by bureaucratic and administrative complexity (Jenkins 2002; Harriss 1999).

It is not only the politicians who feel such frustrations, but also Department of Agriculture civil servants and scientists based at the state agricultural universities, who equally feel that their valid, local expertise and practical experience has been by-passed by a high-handed, detached, Delhi-centred regulatory process, dominated by a closed clique of scientists and bureaucrats, with few links to field realities. Thus one University of Agricultural Sciences (Bangalore) scientist commented:

DBT is under a lot of pressure. Monsanto is putting pressure as are others. This is why they don't want the state agricultural universities involved in the biosafety regulation process. They feel we might be too thorough. We have experts in many fields. It is easier to get past bureaucrats as they don't have the relevant scientific expertise.<sup>104</sup>

With the intervention of the ICAR in the process at the centre, however, the dynamic changed somewhat from 2002 when the University of Agricultural Sciences (UAS) at Dharwad became involved in the trials, and there was more of a sense of inclusion in the process, as certain sections of the state-level agricultural science community became coopted.<sup>105</sup> As a Monsanto official put it: 'Before there was confusion. DBT thought they should manage everything . . . DBT learned the lesson the hard way. Now they are playing safe'.<sup>106</sup>

Others are more sanguine, arguing that, in practice, despite all the hot air about the regulatory process, it will be the practitioners on the ground who will have to see all this through. When the dust has settled, they can get on with their job. The DBT has no field capacity at all, they point out, and with staff in every district, the Department of Agriculture in Karnataka has a much more substantial influence on what actually happens on the ground. Others point out, particularly in the light of the widespread adoption of *Bt* cotton seed prior to formal regulatory approval, that the possibilities of regulating the highly complex seed bulking and distribution industry in India is effectively impossible. Farmers know the brands they like and will pay appropriate premiums and it is through the market that quality is regulated. However, intervening in this market on wider issues of biosafety and so on is seen to be pie in the sky. A representative from the Karnataka Seed Association put it bluntly: 'There are hundreds of seeds sellers in Karnataka. Regulation is an impossibility'.<sup>107</sup>

A certain scepticism about the trial process is also regularly voiced (see above). In the end, the argument goes, policies and regulatory decisions only matter in relation to what can be done on the ground, and that will be down to those who are in the field – the farmers, the department and the input supply companies. For many the trials are essentially symbolic, part of the ritual of the regulatory process

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<sup>104</sup> Interview UAS Bangalore, 22 February 2001.

<sup>105</sup> UAS Dharwad received a Rs5crore grant from the Karnataka government in 2001, while the UAS Bangalore received a hefty US\$40000 grant from Monsanto in 2002 (*Deccan Herald*, 30 September 2002).

<sup>106</sup> Interview, MRC Bangalore 22 February 2001.

<sup>107</sup> Interview, Bangalore February 2002.

designed by the centre, essentially to respond to the bureaucratic and political requirements of the centre. At the state level, these were less relevant, and carried less bureaucratic or political importance. The issue would be resolved, informants suggested, not through a highly contested trial process, but by the acceptance or otherwise by farmers. Many saw the whole issue being blown out of proportion. As a senior Department of Agriculture official argued: ‘*Bt* will not be a big thing here. Yes, some will adopt it, others will not. We have other more important things to get on with’.<sup>108</sup>

However, there are problems with this *laissez faire* approach. As the same commentators pointed out, what is problematic is that despite the large staff complement, the capacity for overseeing biosafety regulations by the department is very limited, and presents the major problem which seems to have been little addressed. A similar viewpoint was expressed by a number of faculty at UAS (Bangalore) who, during 2001, were furious that they had not been involved in the design and monitoring of the field trials: ‘How do they expect us to believe their trials if we are not allowed to be involved?’, one said. Another went on to complain about how local scientists are coopted by DBT into the monitoring of existing trials, and asked ‘What can you say about a trial which you visit for a few hours, under the close guidance of a company official? You can’t say anything. It is a waste of time’. Another commented: ‘You are well treated when you go to see these trials. In a group of seven who is going to complain? We sign the paper and go. It’s not an effective or transparent process’. Another observed: ‘The trial programme deliberately avoided the University. They feared a more rigorous experimental approach’.<sup>109</sup>

Other scientists in the more basic science institutions – notably the Indian Institute of Sciences (IISc) and the National Centre for Biological Sciences (NCBS) – have less to say about the regulatory process and *Bt* cotton in particular. Most work at the molecular and biochemical level and generally are somewhat confused about all the furore about genetic engineering, it being what they do on a day to day basis in their labs. At IISc in particular there was a sense that the debate had got out of hand, and that there was little that a scientist could offer to it. The best thing to do was to lie low and keep out of it all, and hope that it would blow over without any too damaging consequences for their research funding. The whole controversy about the siting of the Monsanto Research Centre on the IISc campus had put many off stepping into the fray.<sup>110</sup> With a few exceptions (notably former IISc director Professor G. Padmanaban and his colleague Professor Sharat Chandra), there has been little commentary from the elite Bangalore science community on the crop biotechnology issue. Yet many of that same group are engaged in other ways, particularly in the extensive committee structure of DBT at the centre, and some can be seen as key members of the core network highlighted above. Their silence on *Bt* cotton in the Karnataka context is telling therefore, given their broader commitment to biotechnology developments.

One scientist, however, who has not been shy of providing a fairly relentless commentary has been C.S. Prakash, previously of the UAS, Bangalore and now of Tuskegee university in the US. Through his website, regular contributions to the Indian press, and during his visits to Bangalore he has kept up a

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<sup>108</sup> Interview, Bangalore February 2003.

<sup>109</sup> Discussion UAS Bangalore, 22 February 2001.

<sup>110</sup> ‘Monsanto-IISc deal shrouded in mystery’, *Indian Express* (26 December 1998).

committed, single-minded evangelical position in support of biotechnology, and *Bt* cotton in particular.<sup>111</sup> As a non-resident Indian (NRI) he holds a particular status – at one time insider at another outsider, at one time revered and respected, and at another easily dismissed as out of touch. Sceptical views are often expressed about C.S. Prakash, but one cannot deny his commitment and enthusiasm. He is joined, but perhaps with lesser zeal, by other NRIs, including Ganesh Kishore (ex of IISc and subsequently with Monsanto in the US and more recently an independent consultant in the US linked to the Bangalore start-up company, Metahelix), Shantu Shantaram (formerly University of Bangalore, latterly with Syngenta in Switzerland and with links to IFPRI); all of whom on various occasions have presented their views on biotechnology, both to senior state level policymakers, and to a broader public through the media. This NRI connection has been formalised through the efforts of Prakash who has attempted to convene a grouping of such people, under the K-GANGA umbrella, launched by the Chief Minister in August 2000, and recognised in the Millennium Biotechnology Policy of the state (March 2001) as a key advisory group.

While presenting their position as progressive, industry friendly and in line with the pro reform, investment oriented policies of the state government, the NRI players remain regarded with some suspicion by elements of the more local business and industry elite. In the Bangalore context at least, the division is not simply between those who are pro- or anti-GM crops (read *Bt* cotton), as at the national level, and as in much of the international debate, but a more varied set of options are presented. Many influential local business players simply do not trust the likes of Monsanto. They are seen certainly as serious competitors, and ones who have the capital might and global reach to eliminate any smaller player at a stroke. But they also have been seen as a public relations disaster area, undermining real potentials for the sustained growth of a biotechnology industry and associated inward investment into the state (and indeed into their own companies) by fomenting what is seen as an unnecessary and misdirected furore, in the pursuit of their single product. These commentators, then, do not frankly care about *Bt* cotton, but worry seriously about the repercussions that a negative image of biotechnology might have on commercial prospects for biotechnology more broadly. As one leading Bangalore-based biotech entrepreneur put it: ‘We need to distance ourselves from Monsanto. They have really muddied the waters. Monsanto has messed it up for a lot of people’.<sup>112</sup> A Seed Association official argued that ‘Monsanto put back biotech by a decade’.<sup>113</sup> While this view is shared by some of the other multinationals – who also have a fairly dim view of Monsanto – they are seen to have other options, and what happens in Karnataka – or to some extent even India – is relatively unimportant in a global multi-billion dollar business. It is the more local industrialists and entrepreneurs who are building new concerns, through complex negotiations with

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<sup>111</sup> See, for example, ‘Expert endorses *Bt* cotton decision’, *Business Standard* (12 April 2002); ‘Biotechnology and agricultural research’, 10 June 1999; ‘Huge potential of genetically improved plants outweighs hypothetical risks’, *Financial Express* (31 May 1999).

<sup>112</sup> Interview, Bangalore 14 March 2001.

<sup>113</sup> Interview Seed Association of India, March 2001 PN.

venture capitalists and private loans who see the long term risks to their commercial futures of getting swamped by the *Bt* cotton controversy. For them, delinking from that debate is seen as key.<sup>114</sup>

In Bangalore such local industry players have significant – and increasing – political clout and influence (Scoones 2003). While they may not have the electoral base, and solid party connections of the farming lobby, they are part of an emerging policy elite that cuts across industry, government, and the civil service. An alliance between such local industrialists and the “new breed” of politicians and civil servants can be discerned in Karnataka, particularly in the post-1999 period of the S.M. Krishna administration, where the projection of a modern, forward looking, business friendly state is very much part of the political image. The appointment of Kiran Muzumdar Shaw, MD of BioCon a successful Bangalore biotech business to chair the Chief Minister’s Vision Group on biotechnology was no surprise. Building on the success of Bangalore in the IT revolution, so the rhetoric goes, the biotech revolution must follow. Following closely in the footsteps of the earlier IT kings, Narayan Murthy and Premji, Muzumdar Shaw combined the right qualities of good connections, a successful business track record, and is an articulate and influential policy player, increasingly on the national and international stage through her work with the CII as chair of their biotechnology committee. Ensuring the IT to BT connection was part of the Karnataka model was confirmed with the location of the policy development in the Department of Information Technology (now IT and Biotechnology), under the capable hands of a civil servant known for thoroughness and effectiveness, as well as close connections with the Chief Minister.

The Karnataka state biotechnology Vision Group had no representatives from the agricultural sector, and the whole process distanced itself from any association with agriculture, *Bt* cotton and all the difficult controversy that had been raging for several years. The only concession in the final policy document was a Rs5 crore grant to the University of Agricultural Sciences at Dharwad for a new crop biotechnology unit. Dharwad being in northern Karnataka is as one person put it ‘far enough away from Bangalore’.<sup>115</sup> Rather than locating state biotechnology efforts across the conventional line ministries (agriculture, health etc.), where particular bureaucratic politics prevail, a relatively new, nimble, unfettered department was chosen – one that identifies itself as a facilitator of business interventions rather than an implementor itself. This signalled a new style of bureaucratic politics for biotechnology in the state, one based on a discourse coalition very different to that found at the centre. As a member of the Vision Group put it ‘The process was steered to focus on business opportunities, not agriculture. The policy is for corporates and business’.<sup>116</sup>

Thus the core network and the formal regulatory process looks quite distant from the standpoint of Bangalore, rather than in Delhi. Indeed an emergent network in Bangalore seems to be taking a different tack, one based on getting investment rolling, contracts secured, product development processes up and running and worrying about regulation later, or if at all – perhaps through avoiding the thorny issues of

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<sup>114</sup> See ‘MNC-Swadeshi battle in biotech: MNCs are resisting the entry of Indian companies’, *Business Standard* (15 February 2002).

<sup>115</sup> Interview Bangalore, February 2002.

<sup>116</sup> Interview Bangalore, 14 March 2001.



field trials and environmental release altogether through a focus on bioinformatics, genomics and a lab or silicon-based contract research approach (Scoones 2002b). In the words of perhaps the leading local advocate of the biotech industry and chair of the Vision Group, Kiran Muzumdar Shaw: ‘There are no ifs and buts in the race to biotech. India must be a global biopower in the next ten years, and Karnataka the showcase’.<sup>117</sup> Many in Bangalore regard the Delhi bureaucracy as a major hurdle to this vision. One senior Government of Karnataka civil servant argued: ‘DBT is a problem. The regulatory process is too cumbersome. We should be able to deal with things here: we have all the requisite expertise’.<sup>118</sup>

The lack of outward support for the DBT and its regulatory approach introduces more complexity and uncertainty into the process. Implementation becomes delayed, and so more measured and tentative, as other voices of doubt and caution come into view. Despite the formal authority that the centre has over the regulatory process, there is little that they can do to prevent such alternative directions developing at the state level. Court orders, police protection, media rebuttals are all perfectly legitimate responses. But in the end what appears to have happened is that in the Karnataka setting, where contexts, actors and interests – and so politics – are different, the constrained, delineated and highly technical response to the regulatory challenge has been deemed, from a variety of angles, and from a variety of perspectives, to be inadequate, and inoperable.

## **8 Questioning regulatory expertise and procedure**

The debates about *Bt* cotton have raised, then, a series of questions about both the content of regulatory decisions, and the process by which they have been made. Three almost parallel debates have occurred, each highlighting different, but equally fundamental, questions. The first lies within the domain of scientific discourse, and focuses on facts, data and measurement issues surrounding the risk assessment procedures. The second debate is far broader in scope, and goes beyond the more narrow questions of assessing risk, to raise broader political, economic and moral questions about the nature of the technology in question. Third, questions are raised about the use of expertise as part of regulatory procedure, pointing to issues of transparency and inclusion in the process. This questioning has come from a range of different quarters. While the vocal opposition groups have pushed the debate into the media, others have raised similar issues in other fora, and in somewhat more measured tones. This section examines the specifics of this questioning, and asks whether this adds up to a broader challenge to the regulatory process as a whole.

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<sup>117</sup> Speech at Asia Society Conference, Bangalore 13 March 2001. See also *Financial Express* (15 April 2002): ‘Bangalore all set to become biotech hub’, *Economic Times* (15 April 2002); ‘Karnataka biotech sector worth Rs 700 crore’, *Hindu* (16 April 2002), and report of joint survey by Karnataka Vision Group and CII which estimates that Karnataka was likely to attract Rs300 crore in 2002–03 as biotech investment. The report also claims that the state employs 5,000 people in the sector, of whom 3,500 are scientists (*Business Standard*, 16 April 2002).

<sup>118</sup> Interview Bangalore, 6 March 2001.

## **8.1 Contests over science**

As we have seen the regulatory process over the past eight years or so dealing with *Bt* cotton has addressed a number of issues through a combination large and small-scale field trials and laboratory assessments. The field trials have focused largely on issues of agronomic performance, although there has also been monitoring of pollen escape and assessments of potential impacts on biodiversity. The laboratory assessments have focused on safety tests including those for allergenicity and toxicity. The procedures for these assessments are laid down in the regulations and associated guidelines, and have been confirmed by the RCGM, sometimes with marginal adaptations and extensions. The procedures follow those which have been pursued elsewhere, particularly in the US where transgenic assessments have proceeded further and earlier than anywhere else. In November 2002, DBT Director Dr S.R. Rao was quoted as saying that ‘transgenic crops were . . . absolutely safe for human consumption’.<sup>119</sup>

Despite the apparent scientific consensus on the approach, there have been a number of questions raised about the chosen approaches. Do they really highlight the full range of potential risks, or by their design do they actually ignore areas of uncertainty by choosing particular temporal or spatial scales, for instance? When probed regulators – both bureaucrats and scientists serving on the committees – are quick to agree with this proposition. Of course, they say, our assessments are only able to look at relatively short-term impacts, and, of course, they have to be concentrated in artificially small spatial scales (because otherwise the requirements for containment and pre-release testing would not be met). And, they point out, in any case longer term and broader scale impacts will be picked up through monitoring later on. The current procedures, they argue, have proved sufficient for the USDA/FDA, and the Indian regulations are even stricter, so what burden of proof do people require? They point (selectively it must be admitted) to the now voluminous published literature on *Bt* cotton in the US (and now increasingly China; see the much distributed paper by Huang *et al.* 2002 for example) as evidence for how this technology has been proven both safe and beneficial to farmers and the environment again and again.

Most critics would also recognise the practical limitations of any risk assessment, but perhaps object more to the sense that any debate about experimental design and analysis is not countenanced. Take the issue of field trial size and the degree to which one acre plots are sufficient. When this was raised in a discussion piece in a special issue of *Current Science* (Bharathan 2000), none of the respondents (from DBT, Mayhco etc.) reacted to this particular issue. This despite the fact that there is a much wider debate about ecological risk assessment for transgenics, where the conventional field trial approach adopted in India has been widely questioned (Scoones 2002a). A UAS scientist in Bangalore echoed many in sharing his scepticism of the trials: ‘These are not long term trials’,<sup>120</sup> he said, ‘You cannot tell much in one or two years . . . But you cannot recall a crop once it is released. We need to rethink soon’. DBT officials agree. One observed frankly: ‘We don’t know how to do long-term safety assessments. We cannot know what will happen in 20 or 30 years time’.<sup>121</sup> But the argument that it is impossible to deal with long term effects

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<sup>119</sup> See *Blonnet.com*, 27 November 2002.

<sup>120</sup> Interview UAS, 22 February 2001.

<sup>121</sup> Interview, DBT, 28 March 2001.

in this sort of assessment while true, is surely inadequate to assuage fears and doubts. A very real concern about the impact of *Bt* cotton technology on pest resistance dynamics is raised by many critics, again based on a wider and now substantial and well documented debate about the potential impacts on pest ecology of *Bt* technologies (Mayer 2002). Drawing parallels with elsewhere is clearly inadequate, given the particularities of the Indian pest complex, and the very different spatial patterning of the agroecological landscape in Indian cotton growing areas. And, as the UAS professor noted, there is no going back once transgenic material is released.

The way the regulations have been framed, essentially ignoring – or putting off – consideration of such wider ecological impacts, is perhaps a reflection of both their origins and the current emphasis of regulatory expertise. As already discussed the regulations were generated with limited input from agricultural scientists and perhaps no input from ecologists. They reflected an emerging consensus on what should be done which had emerged in the developing world in the 1980s, and had been heavily influenced by industry concerns and, in particular the US approach to product assessment, based on such principles as “substantial equivalence” (Newell 2002; Scoones 2002a).

The advisory committees that have overseen their implementation have been dominated, as we have seen, by biologists largely working at the molecular level, whose interest in and knowledge of complex ecological processes is, as they readily admit, negligible. So when issues of pest resistance are brought up, in addition to talking vaguely about principles of “integrated pest management” – an emerging catch-all mantra that allows transgenic solutions to be packaged with all other pest control solutions, chemical and non-chemical – the focus is on further genetic engineering solutions: seeking out and cloning new *Bt* toxins, stacking genes together, working on mid-gut receptor pathways and so on. It is not that these are inappropriate or invalid solutions, but the point is simply that the framing of the debate is such that other issues are cut out, or at least downplayed. This means that the scientific debate around *Bt* is conducted in a particular, and highly fragmented way. Those with access to the regulatory system frame the issue in one way (largely around genetic, molecular and chemical issues), and in so doing blackbox a whole range of uncertainties.

By contrast, those critics who engage in the scientific discussions around regulations open up these black boxes and raise questions about uncertainties not considered – or at least dismissed and put off – by the regulators. By failing to engage the critics – and this is partly due to a simple lack of expertise in the core science-policy network dealing with regulation at the centre which can address these issues in anything like a substantial and convincing manner – a sense of disengagement, distance and distrust with the regulatory process emerges. In interviews this was very tangibly expressed among agricultural and ecological scientists who, to their mind, had been excluded from the regulatory discussions, and whose very genuine concerns were not being heard.

## **8.2 Contests over values and politics**

The current regulatory process then certainly finds it difficult to deal with dissenting science, or science that does not fit within the regulatory frame, but it finds it even more difficult to deal with broader issues of values and politics as an explicit part of the regulatory process. Such issues are deemed to be firmly outside the remit of the regulatory process. As one senior scientist put it: ‘We deal with science, facts. We cannot mix this up with religion and politics. Those issues are important but they need to be dealt with elsewhere’.<sup>122</sup> By demarcating a very narrow area for the deliberation of regulatory issues – around, as discussed above, a very specific set of scientific issues, the scope of which is even disputed by other scientists with different disciplinary traditions – the regulators hope to keep the decision process on track, and by claiming it to be exclusively “science-based”, allowing a certain type of expertise to be granted the authority to decide.

But, as we have seen, maintaining this dividing line between the technical and the political has been a hard task over the last years, and, despite the attempts made by the DBT, members of the scientific community involved as regulators and industry representatives with an interest in the regulatory system, this has been very difficult to uphold in practice. It is clear to everyone – including, at least off the record, those members of the core network at the heart of regulatory decision making – that this is a highly political, value-laden question, and that the scientific questions are just one, unquestionably important, part of the debate.

At every turn those opposing *Bt* cotton have raised these wider questions, and through effective campaign work and a media eager for stories, they have managed to raise the wider debate – about multinational domination, about globalisation, about farmers’ rights and so on. Yet, without a forum to deliberate on such issues in the context of regulatory decisions about biotechnology, there is an evident impasse. The regulators admit that such issues are important (even if they violently disagree with the statements being made by the opponents), yet are not able to admit that they are part of the overall equation, and, inevitably influence the outcome of regulatory decisions, even if only indirectly. As the debate continues, the insistence that all the decisions are simply “science-based” is becoming more and more hollow. The broader political context within which any decision about approval of *Bt* cotton or any other transgenic product must be important, whether in relation to national media coverage, electoral support in certain areas, opposition political pressures, trade considerations with Europe, the US or China, or whatever. Yet, such issues remain implicit and are not seen as germane to the regulatory decision.

## **8.3 Contests over procedure and process**

Many of the disputes over the regulation of agricultural biotechnology come down in the end to contests over the regulatory procedure and process. There will inevitably be disputes about facts, measurements, values, politics and so on. These occur among scientists as much as they do between proponents and opponents of genetic engineering technologies. The issue at hand is whether the current regulatory system

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<sup>122</sup> Interview, IISc, February 2001.

can deal with such disputes and develop decisions that command broad approval and respect: not necessarily, or ever, consensus.

Many people have raised both publicly and informally in interviews their concerns with the current composition of the regulatory committees convened by the DBT. As one sceptic pointed out: 'Biotechnologists don't speak against biotechnology'.<sup>123</sup> The committees are seen to be composed largely of a relatively narrow clique of scientists, who themselves are perhaps excessively reliant on the largesse of the DBT – and in some cases commercial biotechnology companies. While this type of bias is unproven, the claim that the disciplinary bias – and the consequent ignoring of certain issues – is easier to uphold. But how wide a grouping should a committee of this sort include? DBT officials argue that the RCGM and Monitoring and Evaluation committee has a purely scientific function. While they may concede to expanding the scientific coverage to include agronomists, breeders or ecologists for instance, the idea of extending the regulatory deliberations to a wider remit is not contemplated.

Another complaint about the current process focuses less on the composition of the committees, but more on their functioning and style. This comes from both outsiders and insiders to the process. The pro-*Bt* cotton Indian Farmers Federation complained that:

The permission raj starts with the District Level Committee . . . It is very difficult to comprehend what has the Collector, Chief Secretary or a Minister to do with Biotechnology! . . . MNCs are expected to go round the committees, the Babus and the politicians to get approval . . . Let's face it. India can never be an industrial superpower and has missed the genetic revolution.<sup>124</sup>

Even with relatively few applications being presented to the DBT there is already a lot of paperwork, and the opportunities for detailed examination of particular cases is very limited. Short, rushed meetings where decisions must be made are not ideal for chewing over the complexities of risk assessment. In practice, as discussed earlier, much is decided in advance, through informal interactions and intensive preparation by the DBT member secretary. This may be an inevitable consequence of lack of time and funds, and the limits of bureaucratic and administrative procedure, but it does suggest that the deployment of expertise (of whatever form) might be improved. As one senior scientist with long involvement with DBT pointed out: 'DBT has plenty of regulations. And they are very good. But there is no way they can be enforced'.<sup>125</sup> If the committee members themselves have doubts about the process, what about the broader public who have to trust the outcomes?

The same applies to the monitoring and evaluation procedures for field trials, where particularly incisive criticism came from some scientists who had been coopted onto M and E field visits (see above). Others have criticised the field trial process as untransparent and secretive, with the lack of data disclosure

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<sup>123</sup> Interview, UAS, 22 February 2001.

<sup>124</sup> Indian Farmers Federation (P. Chengal Reddy and Dr J.R. Murthy): 'Betrayal of Indian Farmers!', 29 July 2001, posted on MonsantoIndia site, [www.monsantoindia.com/news](http://www.monsantoindia.com/news)

<sup>125</sup> Interview, IISc, 12 January 2001.

undermining trust in the findings.<sup>126</sup> Echoing the sentiments of others, one senior ICAR official commented: ‘what can you tell about agronomic performance from a one day visit to a site. It’s not appropriate at all’.<sup>127</sup> If, as everyone agrees, not all uncertainties can be ironed out in any risk assessment procedure, based on field trials and lab assessments, then careful monitoring will continue to be an important part of regulatory oversight. Yet the current system appears to be inadequate, even on the limited scale (a few hundred trials in selected locations for a few products) that it is being conducted at the moment.

The early resistance of DBT and MMB to allow agricultural universities to be formally involved in the trial process certainly irked many, and simply added to the distrust already building, among a group of essentially supportive scientific colleagues. This has to some extent been rectified with the involvement of ICAR from 2001. However, many interpret this move cynically, and protestors demand more involvement and transparency.

The claims and counter-claims made by various protagonists in 2002 and 2003 about the success or otherwise of *Bt* cotton in different parts of the country is simply witness to the fact that no-one believes anyone else’s data. It is open season to report big claims on the basis of short visits, video testimonies and limited surveys, in the hope that the media will pick up the story and report it. That some reports, even in apparently reputed international journals, are so obviously biased has annoyed even industry officials who see such efforts as undermining any possibility of making a pro-GM case (see above).

As many pointed out in interviews, issues of trust, legitimacy and authority are paramount in the regulatory process. And these do not seem to be rated highly at the moment, by a wide range of people, both those notionally for and against *Bt* cotton. This is potentially a major problem, and suggests the need to rethink in fairly fundamental ways the approach to regulation being taken. While DBT claims they are being ‘as transparent as they need to be’, while strictly correct in relation to the current regulations, this is clearly not enough, and many players from all camps are demanding more. In an editorial, the *Financial Express* argued that ‘the secrecy and bureaucratic infighting which plagued *Bt* cotton approval, and needlessly delayed commercialisation, left critics and proponents of GM technology, as well as the public, wondering about the efficiency of Indian regulators’. The piece went on to argue for putting data in the public domain, as ‘the success or failure of any technological application must be dictated by individual freedom and market economics not controversy and doubt’.<sup>128</sup>

The argument for openness and transparency can of course be argued in a number of ways, reflecting, inevitably, the positions and interests of the commentators. A number of industry players argue that the current centralised process overseen by DBT is just too slow, cumbersome, confusing and non-transparent, and that it should be handed over to the states to oversee regulatory approvals, under an umbrella legislative framework and national oversight. As one commentator put it: ‘We started with the best rules and regulations you can imagine. They did not miss a point. But now it is time to rationalise, and

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<sup>126</sup> See ‘Make field trial results of GM crops public’, *Financial Express* (18 November 2002).

<sup>127</sup> Interview, Delhi, 2 April 2001.

<sup>128</sup> *Financial Express* (7 November 2002).

choose from the longer checklist'.<sup>129</sup> This arrangement, they say, would cut red tape, speed up regulatory decisions, and allow local concerns to be more easily accommodated. Some, particularly from the NGO community, regard this route to be a recipe for the capture of the regulatory process by well-connected commercial interests, and for new forms of secrecy to creep in. Particular fears are expressed at handing over regulatory authority to the state level where patronage networks and interest based politics operate to much effect.

Others argue that the particular issues of agricultural biotechnology need special attention, and that the regulatory role should be taken over by the agricultural bureaucracy, who have long experience of approving the import of plant products, carrying out field trials and undertaking seed and other certification requirements. The large ICAR network, they point out, including the state agricultural universities allows for a decentralised approach which links the states and the centre in a more coordinated fashion. As one senior ICAR official commented: 'Transgenic plants should come under ICAR. The biotech people don't know field conditions and agronomy issues'.<sup>130</sup> But others point to the vested interests of the ICAR network in this. How can they take over regulation when they too are producing the technology often in competition with the private sector.

Others argue for a fundamental opening up of the national process, removing the regulatory function from DBT, who, they argue cannot both promote and regulate an industry at the same time. M.S. Swaminathan for example has long argued for a more strategic national policy, and an independent regulatory commission.<sup>131</sup> Such a solution would potentially allow deliberation on both scientific issues, but also broader economic, political, and if needed moral issues, with appropriate forms of expertise – including those of farmers and “the public” – represented. As the chair of the new Karnataka Biotechnology Council argued: 'Once you make things known to people, then regulation becomes secondary'.<sup>132</sup> Others similarly have argued for a more cautious approach (cf. Iyengar and Lalitha 2002)<sup>133</sup>. Such an arrangement would, advocates hope, command broader and deeper respect and trust, and, in the end, would serve the interests of society better, in a more democratic and open way.

## 9 Negotiating regulations: future perspectives

Regulating biotechnology is not a straightforward task. As the *Bt* cotton case shows, it is the politics of negotiations rather than the linear approach to science-based decision-making that dominates. Different sites and different styles of negotiation occur depending on the political context. Contests over science and facts, over values and political meaning, and over processes and procedures have dominated the

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<sup>129</sup> Interview, TERI, Delhi, 29 March 2001.

<sup>130</sup> Interview, Delhi, 2 April 2001.

<sup>131</sup> See 'MSS calls for national policy on GM crops', *Business Line* (13 January 2003). Also *Business Standard* (26 November 2002). See also Chennai Declaration, released following the MSSRF dialogue on the legacy of Watson and Crick: 50 years later, *Hindu* (13 January 2003).

<sup>132</sup> Interview, V. Prakash, CFTRI, 16 April 2001.

<sup>133</sup> See *Financial Express* (9 December 2002).

Indian experience. Whether in the Delhi-based committees or in the machinations of the policy process at a state level, a variety of actors and interests are involved.

While the administrative narrative of regulation suggests there are distinct decision points made according to standardised and objective criteria, this is clearly not borne out in practice. There is not a single regulatory decision, but much more of an ongoing process. This is wholly compatible with a precautionary approach, now widely accepted in Europe for example, where iterative learning and reflection result in changing regulatory positions. This continues to the post-release stage, with “market stage precaution” (Levidow *et al.* 1999) being the guiding principle for continued monitoring and evaluation. In a precautionary approach issues of trust, legitimacy and an openness about what is within the regulatory remit is crucial. One reading of the Indian case would suggest that India, having faced a crisis of legitimacy and trust in its regulatory procedures, is likely to go down the European route of embracing a more precautionary approach, and with this a more inclusive and participatory approach to the framing and implementing of regulations. But this may be too simple a story-line. The conditions and contexts of India are very different to those of Europe in the 1990s, and a different set of complexities need to be envisaged.

Nevertheless, building confidence in and legitimacy for regulatory decisions is clearly essential.<sup>134</sup> This needs to be among a range of different groupings, and not necessarily the “usual suspects” directly involved in the debate and often repeating rather tired pro and anti-GM slogans. The biotechnology debate touches a much wider set of issues than often assumed, and, for the agricultural sector, suggests the need for a debate which goes to the heart of the agricultural and development policy. Unlike in Europe, this is an issue of basic livelihoods for 700 million people who to some degree are reliant on agriculture. Clearly as currently framed – around a rather narrow conception of biosafety derived from European and North American concerns – the regulatory debate remains very limited. With all the focus on the supposed health and environmental consequences of adopting *Bt* cotton taking much of the attention of activists and proponents alike the bigger picture may be being missed. While some have correctly highlighted the importance of looking at food and farming futures as central to the biotechnology debate,<sup>135</sup> this has not been at the centre of much of the discussion framed as it has been “back end” risk assessment issues of trial results, pre-set regulatory criteria and so on. Meanwhile decisions are made for example to recast public agricultural research priorities in a major way, with ICAR announcing that its targets now are aimed at export crops, rather than those of national food security.<sup>136</sup>

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<sup>134</sup> This is widely agreed. See for example comment piece by Jaraim Ramesh in *India Today* (23 July 2001) where he notes: ‘The only way to inspire confidence is to make all results of the trials under Indian conditions public and have them subjected to scientific peer review. Even though highly complex scientific issues are involved, the debate has to be conducted in easy-to-understand language without clouding public concerns in some technical mumbo-jumbo. A bit of humility on all sides – on the part of gung-ho scientists and self-righteous and scare-mongering NGOs will help’.

<sup>135</sup> See, for example, the report on the Prajateerpu citizens’ jury in AP (Pimbert and Wakeford 2002), and various commentaries by Devinder Sharma reported on the AgBioIndia site. Also see Shah and Bannerji on this theme in an op-ed piece for the *Hindu* (24 August 2002).

<sup>136</sup> ‘IARI shifts attention to export markets’, *Financial Express* (22 April 2002).



Bringing in multiple expertises in an active inclusionary process, where issues fully deliberated, could potentially allow the reframing of the crop biotechnology debate in India to begin to address some of these more “front end” issues of technology choice and rural livelihood futures in more concrete ways.

Yet such debates cannot be conducted in the abstract, out of context. One key lesson of the *Bt* cotton saga, is that states matter and localities are important. Local to global debates reverberate through regulatory decision-making. What happens in Haveri in Karnataka may make news through the internet services around the world and so impinge on political processes both in Delhi and Bangalore. Assuming that regulation – of whatever form whether precautionary or otherwise – emerges from a central, technocratically defined national authority is, as we have seen, inadequate. In a large, federal country with complex political and other connections between the centre and the states, there are often only very fragile threads based on limited networks between central authorities and state level practice. As the “transgenic chaos” in Gujarat – repeated elsewhere, although less dramatically – has shown informal markets, astute entrepreneurs and farmers demanding effective products combine to undermine any neat, regulatory system imposed from elsewhere. Thus regulatory authorities must be embedded locally and have local legitimacy, yet must tread the fine line between this and becoming prone to local capture by particular interest groups. The *Bt* cotton story thus highlights one of the key dilemmas of the federal arrangement, and a challenge for how to conceive of the state and its regulatory function in the contemporary setting.

In rethinking regulation, we must also be cognisant of the fact that this setting is not that found forty years ago at the height of the Green Revolution. The state does not have the resources or the reach to implement complex regulatory frameworks however wonderfully designed. Biotechnology is very much part and parcel of the post-reform era, where private investment is seen as key to the success of the economy, and science-based technologies, such as GM crops, very much part of the package. In the deregulated agricultural supply sector, it must be asked whether regulation is practical at all. Is this not just fanciful wishful thinking, harking back to the days when the state could actually do something? That the formal regulatory process for the commercial release of *Bt* cotton was taken over by events, with *Bt* cotton already illegally being farmed over several years by thousands of farmers across a number of states is perhaps witness to the impossibility of regulation. And this is with only one product: what about when there are many GM crops and traits on the market? This unregulated free-for-all is feared by many – by those who go through the official process only to find their proprietary product being sold illegally; by regulators who see their neat and tidy technocratic regulations unravelling before them; and by those opposed to GM-crops who see such a scenario as the worst of all worlds.

That there is some consensus that the unregulated option is undesirable from nearly all major protagonists perhaps offers some hope of rescuing the idea of regulation. But the form it will take, if it is to have any effect at all, will clearly have to differ from the narrow, technocratic focus employed to date. The last eight years have been a test of the state’s capacity, autonomy and commitment to regulation in the post-reform context and it has been found wanting on a number of counts. Clearly some opening up of the process is required, increased transparency of procedures and information is essential as is a recasting of the regulatory remit to a wider set of issues. Moving the regulatory function away from an

implementing department – whether DBT or ICAR – makes sense, as does a broadening of the composition of committees and oversight roles. Independence is the key word, and succumbing to the pressures of industry for fast-track, one-stop shop options will probably not be in anyone’s interests in the long-term. Ensuring that processes are coordinated between the centre and the states is also clearly an important factor, so that unnecessary bureaucratic delays are avoided and policy responsiveness at a more local level is possible.

But even this will not be enough. The state – whether central or more locally – does not have the capacity. Other tacks will have to be taken, which ensure multiple forms of accountability on the regulatory process. One of the important lessons of the past few years is that the contests to the regulations – in the media, in the courts, in the streets, or in the rural hinterlands of Karnataka, or indeed more discreetly in the informal lobbying of scientists, committee members and others – has ensured another set of accountabilities on the regulatory process. As we have seen – however ill-informed or misguided that some of these interventions have been – these have affected the way *Bt* cotton and its regulation has been thought about. Such forms of accountability, from outside the science-industry-policy networks that make up the core of the regulatory machinery, are essential if biosafety regulations are to have any meaning in the contemporary setting.

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