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Technological Change and New Actors: Debate on Returns and Regulations

Sachin Chaturvedi*

Abstract: New technology in the seed sector has brought in new actors and new requirements for regulation. It is important to discuss how far India is working on new opportunities and policy options for effective and rationale regulatory framework. Equally important is to analyze how socio-economic dimension is often overlooked while evolving regulatory frameworks both for biosafety as well as for price control of seeds. There is systemic lack of technological sensitivity in the agricultural R&D system. We fail to appreciate the kind of technological support farmers are looking for and how best a delivery system for new technologies should be put in place. In this regard, India would have to evolve a dynamic innovation and technology policy to address diverse agricultural challenges and growing environmental concerns. There is need to do is to overhaul the institutional set-up and its linkages with ground-level experiences. This includes gearing up of decision making process for newer crops; setting up of necessary infrastructure and trained manpower for any eventuality related to biohazard; and, on top of that, identifying correctly the technological expectations from agricultural R&D systems.

Keywords: Seed, regulation competition policy, biosafety, India.

With the advancement of technology and adoption of new technological tools, regulations related to the seed sector have become more intricate and complex. New technology in the seed sector has brought in new actors and new requirements for regulation. It is important to discuss how far India is working on new opportunities and policy options for effective and rationale regulatory framework. Equally important is to analyze how socio-economic dimension is often overlooked while evolving regulatory frameworks both for biosafety as well as for price control of seeds.

As is very clear, in the case of seeds, quality is the major issue and this is an area where despite the best possible efforts, legislative frameworks and institutional back-up have not been to the level required to deal with seeds

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of doubtful quality. Though time and again, need for registration of seeds sold to farmers is emphasised and even proposed to be made mandatory, the concerned legislation is still pending for Parliament's approval. As has happened in many cases before and recently in case of Bt cotton, it has emerged clearly that a parallel economy of spurious seeds has come up in a major way.¹ Sometime in 2001, a Genetic Engineering Approval Committee (GEAC) team visited Mehsana in Gujarat to assess the illegal sowing of nearly 6000 kilograms of genetically modified (GM) cotton seed in several hundred hectares of land, which was detected after almost four months, when crop was actually ready with pollens and possibility of cross fertilization with non-GM crops was very high. Despite all the best intentions nothing could be done and many more places like Mehsana came up in the subsequent years, which throw up some pertinent issues relevant for the debate on the very policy on biotechnology in India, including GM crops and the related operational mechanism to support this.²

The wide spread adoption of spurious seeds also raises some broader issues like how technological change is being dealt with and in what different ways mechanisms are to be evolved for effective governance of biotechnology in the agriculture sector. One of the immediate implications is that the regulatory agencies become extremely cautious of approving of GM crops. There can be no doubt about the fact that one has to be cautious with new technologies but if we do not decide on the nature and magnitude of technological trajectory that nation has to go on, then we are deceiving our own people. While the effects of prolonged consumption of GM food or production of GM crops have yet to be scientifically established, the necessary measures for containing any adverse implications should not hold back India's position in the global race for technology. This is particularly essential for agricultural sector from where more than 60 per cent of our work force is deriving its livelihood and the question of food security is also intricately linked to it. The current spate of suicide by cotton farmers in Andhra Pradesh is a grim reminder of this reality.³ However, after the initial long-drawn approval system, GEAC went into a phase, when the regulatory agency became more accommodative and liberal till the recent controversy on Bt brinjal broke out and the government announced moratorium for two years.⁴

This incidence has highlighted the systemic lack of technological sensitivity in the agricultural R&D system. We fail to appreciate the kind of technological support farmers are looking for and how best a delivery system for new technologies should be put in place. In this regard, India would have to evolve a dynamic innovation and technology policy to address diverse agricultural challenges and growing environmental concerns. What we need to do is to overhaul the institutional set-up and its linkages with ground-level experiences. This includes gearing up of decision making process for newer crops; setting up of necessary infrastructure and trained manpower for any eventuality related to biohazard; and, on top of that, identifying correctly the technological expectations from agricultural R&D systems.

Regulatory Framework

In a long-term perspective, seed industry deals with regulatory frameworks at different levels. They include management of biosafety regulations, etc. The management of biosafety regulations is a rather new addition which has come up in light of the forceful intervention by several state governments for setting up of the prices for cotton seeds, since the introduction of second generation Bt cotton seeds. In the following sections we would focus on biosafety and price related regulatory framework.

In a globalised world, domestic regulatory guidelines often draw their frameworks from international commitments at different fora. There is an international framework in place for biosafety in the form of Cartagena Protocol on Biosafety (CPB), which is a legally binding international agreement for the transboundary movement of living modified organisms (LMOs), though some of its provisions and proposed mechanisms are still contentious, as the negotiations are still going on while others are ambiguous, causing hindrance in its full implementation. For instance, there is still no clarity as to what exactly is to be covered under the Article 26 when it says that socio-economic issues would be considered.⁵

Regulatory Framework on Biosafety

India was one of the first few developing countries to have established exhaustive biosafety guidelines. India's Biosafety and Recombinant DNA

Guidelines (1990) fall under the Environment (Protection) Act of 1986. In 1994, after India signed the Convention on Biodiversity, the Department of Biotechnology (DBT) revised its earlier guidelines to accommodate the safe handling of LMOs in research, application and technology transfer. These include large scale production and deliberate release of LMOs plants, animals and products into the environment. Guidelines are also provided for the shipment and importation of LMOs for laboratory research.

In India, there is no permanent secretariat to monitor the trials of the LMOs. Instead the regulations are implemented by various ad hoc committees.⁶ The most important committees are: Recombinant DNA Advisory Committee (RDAC), responsible for advising the DBT on national and international developments in the realm of biotechnology; the Institutional Biosafety Committee (IBSC), responsible for the local implementation of guidelines; the Review Committee on Genetic Manipulations (RCGM) responsible for issuing permits; and the Genetic Engineering Approval Committee (GEAC), responsible for monitoring the large scale and commercial use of transgenic materials.

These committees have statutory authority. Most of the committee members are from the scientific community and staff of DBT and the Ministry of Environment and Forestry. DBT appoints the members to the committees. The GEAC is supposed to be assisted by the State Biotechnology Coordination Committees (SBCC) and District Level Committees (DLC). However, none of the 28 states have established SBCC and DLC committees, not even in areas where field trials are already taking place.⁷ Moreover, while committee members are drawn from the scientific community, many are not well versed in the biosafety issues and risk assessment. The committees function under different departments and lack coordination. Consequently, decision making is inefficient. This subject is, at present, being dealt in three different Ministries, viz. the Ministry of Agriculture, Ministry of Environment and Forests, and Ministry of Science and Technology (Department of Biotechnology).⁸ Subsequently, government appointed a 'Task Force on Application of Biotechnology in Agriculture,' headed by Dr M. S. Swaminathan in 2003, to overcome these shortcomings.

The Task Force suggested certain institutional modifications, re-orientation of policy thrusts apart from several other measures to make the system more responsive and faster for diffusion of biotechnology products. The Task Force has recommended that the existing role of the Genetic Engineering Approval Committee (GEAC) be replaced by an autonomous statutory National Biotechnology Regulatory Authority (NBRA) on lines of the Atomic Energy Regulatory Board. Accordingly, the Government has moved the NBRA Bill, which is still in the formative stage of approval by Parliament.

This is not the first time India has opted to build a new institution. In the past, India has gone through major institutional changes when it comes to biotechnology. In the realm of science and technology policy formulation in the Indian planning process, the Sixth Five Year Plan (1980-85) stands as a watershed in terms of the development of institutional infrastructure. In this plan, there was significant expansion and consolidation of scientific infrastructure resulting in a sound base for major technological applications in the following years. Among the new initiatives launched in this plan period were the establishment of agencies such as the Department of Environment (1980), the Department of Ocean Development (1981) and the Department of Non-Conventional Energy Sources (1982). A Cabinet Committee on Science and Technology (CCST) was also constituted under the chairmanship of the Prime Minister (1981). Following this a Science Advisory Committee to the Cabinet (SACC) was formed within a few weeks of the CCST formation. The Member (Science) of the Planning Commission was made the Chairman of SACC. Subsequently, a Technology Policy Statement was also announced in 1983, covering all necessary elements of technology development, assessment, forecasting, import, absorption and ultimately the adaptation.

On the recommendation of SACC under the chairmanship of M. S. Swaminathan, the National Biotechnology Board (NBTB) was established in 1982 as an apex inter-ministerial coordinating agency to identify, coordinate and oversee priority areas of development and large scale use of high technology products and processes in the multidisciplinary areas of biotechnology.⁹ The Board was headed by Prof. M. G. K. Menon, the then

Member (Science) of Planning Commission. The rest of the members were drawn from the Department of Science and Technology, Ministry of Finance, ICMR, CSIR, ICAR, VARC, Department of Environment and included a joint secretary from PMO. However, somehow the momentum was soon lost and the NBTB came under criticism. Among the listed unaccomplished tasks of the NBTB were the failure to establish large scale manufacturing units based on technologies, processes and products developed through recent advances in the area of molecular genetics, genetic engineering, immunology, endocrinology, plant and animal tissue culture and bio-engineering within the country. These high technology based manufacturing units could have had a large R&D component which would have facilitated the development of totally new technologies. These failures along with other criticisms led to the proposal for a full-fledged department, which eventually was established in 1986 as the Department of Biotechnology. However, the regulation of biotechnology was kept out of the purview DBT and was placed under EPA 1986 to be governed by the MoEF.

The NBRA would be a new experiment, which probably would reduce ambiguity and inordinate delays and may bring in professionalism to Indian regulatory approval mechanism. The Task Force has placed the biosafety debate again at the centre-stage. We need to take a broader view of regulatory issues. The regulation is to be seen beyond the industry boundaries. Though there is no unanimity across the globe about the breadth of a regulatory authority, it is being observed largely that more and more countries are going for a regulatory authority with broadest possible mandate, but in India we are doing just the opposite. The growing convergence of various technologies and production processes makes it a fit case for adoption of such an approach. The biotechnology sector has been discussed earlier but even in other areas one finds a similar trend. For instance, in the US the state regulator usually oversees more than one industry such as electricity, gas, telecommunication, transport and water.¹⁰ Similarly, in the UK combined electricity and gas regulatory authority has been proposed. Thus, it is a high time that we stop creating more institutions and focus on improving the existing ones. One also needs to overcome the euphoria about single window system. The environmental clearance of GMOs is a complicated process and should not be left on any individual agency alone. A review of different regulatory

procedures across different countries shows how revisions and modifications of the guidelines and procedures from time to time, based on feedback from different agencies, can make the system dynamic and responsive. Therefore, regulatory mechanisms need to be continuously evolved and updated. The need is to ensure that different agencies work towards similar guidelines as far as transgenics are concerned.

Regulation, Price Control and Competition Policy

Given the growing pitch of the GM debate, it is important to ensure that regulatory responses are not a knee-jerked reaction. There is need to assess the impact of a certain guideline from the regulatory agency for the technology providers (or seed firms), particularly from the stand point of the cost of regulation. There are efforts in other sectors like telecom, electricity, etc. where regulatory agencies have developed guidelines. As these sectors stabilise under the new regimes, guidelines would bring in elements of predictability for the technology providers and reliability for end users. In the case of the seed sector it would be for farmers on the yield-gain claims from the private sector companies.

Setting up of the regulatory agencies under a competition policy framework is an established norm at the global level. The number of new agencies that were set up grew up from fewer than five new agencies per year until the 1980s to more than 20 new agencies per year from the 1990s to 2002 (reaching peaks of more than 30 new agencies per year between 1996 and 2001). There are academic studies where detailed data is analysed for the agencies in 48 countries across 16 sectors since the middle of the last century.¹¹ This shows how state boundaries are being redefined, with the emergence of complex political-economy of regulation of industries. At the international level, there is a growing discussion on the role of the competition law and its position *vis-a-vis* sectoral law. This debate represents a new role for the governments, where industries are regulated through a new set of regulatory agencies, committed for a large consensus between the regulators and those to be regulated, and there is also commitment for equal distribution of gains from regulations. With this objective one may avoid extreme situations of a large number of litigations or a large number of informal dissolution of regulatory disputes.

The interplay of institutions such as the Sectoral Regulatory Agencies (SRAs) for telecom, electricity, etc. and the Competition Authorities (CAs) has attracted lot of attention. In several economies steps are being taken to achieve this sort of balance. In the UK, Office of Fair Trading (OFT), the key agency responsible for ensuring competition, has a number of SRAs for different sectors. For instance, some of them are: The Office of Gas and Energy Market (Ofgem), the Water Services Regulation Authority (Ofwat), and the Office of Communications (Ofcom). The idea is that the CAs would focus on the various aspects of competition while SRAs would focus on the details of the regulatory process. This refers to the conventional *ex ante* and *ex post* control and supervision of the markets,¹² which in a way extends the evolutionary life-cycle of regulatory agencies.¹³

In this context, pricing of the high technology goods within agriculture became an important issue, particularly when cotton seed was removed from the Essential Commodities Act (from where the Seeds Control Order of 1983 derives its strength) in 2007, and state governments lost control on their capacity to regulate seed business.¹⁴ The recent efforts by the various state governments to forcefully press for pricing of particular kind of seeds have generated lot of legal complications. The recent initiatives by the various state governments, led by the Andhra Pradesh (AP) government on controlling of Bt cotton seed process has brought out how socio-economic issues are inexplicably linked with new technological options in a setting like India. The socio-economic relevance of GM crops has been one of the major issues of discussion at most of the public fora. In this context, it would be useful to take stock of the sequence of development in this area. The Table 1 provides a detailed account of how various state governments have addressed this issue. The Andhra Pradesh government in January 2006 had objected to the pricing policy of Mahyco-Monsanto Biotech (India) Limited (MMB) and had approached the Monopolies and Restrictive Trade Practices Commission (MRTPC) for necessary guidelines. As soon as the objection was raised by the AP government, the MMB reduced the trait value charges. In 2006, Indian farmers were paying about Rs. 1600 to 1700 for 450 gram of Bt cotton seed. Of this, Rs. 1250 was going to MMB as trait value.¹⁵

In March 2006, MMB reduced the trait value by Rs. 300. As a result, the royalty charges came down to Rs. 900. The AP government had quoted trait value charges in China around Rs. 450 to 500.¹⁶ In the complaint to MRTPC, the AP government termed the trait value prices as nothing but monopoly and a restrictive trade practice. Prior to the filing of the case, the AP government had asked the MMB to compensate the cotton growers on account of failure of Mech 162 Bt and Mech 184 Bt in 2004 Kharif season. Since the company did not compensate, the AP government moved to AP High Court.

Table 1: Snap Shot of Price Control Initiatives by Various State Governments

Price Control Initiatives	Concerned State	Current Status
Executive Order fixing the price at Rs. 650 and Rs. 750	Madhya Pradesh	High Court (HC) quashed the order (2008)
Ordinance issued notifying fixed price for Bt cotton (BG- Rs. 650 and BG II Rs. 750)	Maharashtra	The Ordinance lapsed and was re-issued on May 9, 2009. Challenged in HC, decision awaited.
Ordinance issued notifying fixed price for Bt cotton (BG- Rs. 650 and BG II Rs. 750)	Gujarat	The Ordinance was replaced with an Act. Challenged in HC, decision awaited.
Ordinance issued notifying fixed price for Bt cotton (BG- Rs. 650 and BG II Rs. 750)	Andhra Pradesh	The Ordinance was replaced with an Act. Challenged in HC, decision awaited.

Source: Compiled by the Author.

Later, the MRTPC directed the Mahyco-Monsanto Biotech (India) Limited not to charge the trait value of Rs. 900 for a packet of 450 grams of Bt cotton seeds.¹⁷ The MMB moved to the Supreme Court, against the MRTPC ruling, with the plea that there was not agreement to sell seeds by the company. The agreement between the Indian company and the sub-licensees was more of transfer of technology and there was no trade in goods.¹⁸ The company charged a trait fee which is in the nature of royalty payments required to

be paid by the sub-licensees for incorporation of the Bt technology into the seeds, which was different from ‘the trait fee’ as charged by the company in China. The MMB approached the Supreme Court against the MRTPC directive, on the basis of which the court sought response from the AP government and some of the other Indian seed companies, supporting the state government’s stand before the MRTPC.¹⁹ Meanwhile, the AP government came up with an idea of invoking the Essential Services Maintenance Act (ESMA) for the companies not agreeing to sell seeds between Rs. 650 and Rs. 750 for a packet of 450 grams, a price declared by the AP government in an order on May 29, 2006.²⁰

The developments in AP had a spill-over effect on other states. The Maharashtra and Gujarat governments, on the lines of AP, issued ordinance for price control of Bt cotton seeds. Later on the states of AP and Maharashtra came up with drafts of MoUs to be signed by seed companies for selling Bt seeds on a reducing rates of return. The MoU mentioned the initial price at Rs 925 to Rs. 750 and then finally at Rs. 650. The Madhya Pradesh (MP) government issued administrative order to control the price, which was later on turned down by the MP High Court. Some other states like Karnataka, Tamil Nadu and Rajasthan also issued similar orders.

What happened with the intervention of AP and other State governments in the case of Bt cotton seed prices and subsequent MRTPC interventions could have been avoided had there been a clear role for the Competition Commission and a roadmap for implementation of competition policy. Though the passage of Competition Act by Parliament in December 2002 replacing the Monopolies and Restrictive Trade Practices (MRTP) Act 1969 with competition policy has set the stage for this, we still need to move for an effective implementation. As happened in Bt cotton case, in the short run one may squeeze prices of technology intensive products but in the long run this may harm the very drive for innovation and development of new products. The companies may not be enthused enough to promote R&D and get in newer products. In the Schumpeterian sense, the innovation process would have to reflect the demand side of the product development. Schumpeter describes a view of industry where creative entrepreneurs take

advantage of opportunities as they arise, whereas large incumbent, often monopolistic, firms are focused on extracting rents in the way which made them successful. The emergence of entrepreneurial firms at the expense of incumbents was called “creative destruction”.²¹

Emerging Options

The state governments and other authorities would have to consider how best other possible instruments for price control may be used without adversely affecting market conditions. In the restructuring of the MRTP Act, the sections dealing with unfair trade practices have already been transferred to consumer courts but price regulation is an important component where technological conditions narrow down the possibility of competition. The modalities for such interventions should be best left with specialised government agencies with the superior courts laying down broad public interest guidelines.²² The idea of pursuing ‘public interest’ with administrative orders would amount to taking agriculture back to ‘command and control system’ (license raj) and may adversely affect fair play of market forces.

Since the passage of the Competition (Amendment) Bill, 2007, the criticism about limitations of the Indian competition policy has come up in a major way. Bhattacharjea (2008) has raised issues regarding ambiguity in chapter IV of the MRTP Act and its continuation in the current framework as well. Section 2(i) presents no clarity on maintaining prices at an ‘unreasonable’ level and ‘unreasonably’ preventing or limiting competition, limiting technical development or capital investment. This has continued the confusion on the abuse of dominance provisions in the Indian Competition Act. Therefore, an early response to this, preferably adhering to the desired public policy objectives of competition policy, would be extremely important. Apart from improving the various facets of the competition policy, one may also look into the alternative institutional frameworks prevalent in other economies and other sectors. One of that comes from the United Kingdom, where government has established the National Institute of Clinical Excellence (NICE) for promoting cost effectiveness by producing clinical guidelines, audits and R&D support. The policy makers in India should look for such cross sectoral flow of experience and insights. NICE

was formally launched in 1999 with following objectives: (a) to develop guidelines on the best available evidence of what works and for whom (basically the various category of people); (b) to encourage fast diffusion and even uptake of high value new technologies and medical innovations; (c) to ensure that the tax-payers money invested in the national health services (NHS) by the government is spent properly so that health benefit is maximized through considering not only the comparative clinical but also cost-effectiveness of alternative technologies and services; and (d) to the extent NICE's cost-effectiveness threshold reflects NHS's productivity across all services, health benefit maximisation can be achieved (or at least not severely undermined) through NICE's decision.²³

We have growing experience with agencies like the Telecom Regulatory Agency (TRAI), which is following a policy of establishing licensing arrangements for dissemination of technology at cost-effective prices. TRAI Act (1997) says that it should facilitate competition. Its own mission statement refers to protecting consumer interests and ensuring growth in telecommunications among its priorities. Similarly, India also has the experience to draw from the National Pharmaceutical Pricing Authority (NPPA), which was established to fix or revise the prices of controlled bulk drugs and formulations and to enforce prices and availability of the medicines in the country. It works under the Drugs (Prices Control) Order of 1995. The ceiling prices are fixed or revised for commonly marketed standard pack sizes of price control formulations and are notified in the Gazette of India (Extraordinary). The ceiling prices are usually notified as exclusive of excise duty, local tax, etc. but maximum retail price (MRP) printed includes excise duty. The formula used by NPPA for retail price is as follows:²⁴

$$RP = [MC + CC + PM + PC] \times [1 + MAPE/100] + ED$$

Where, RP is retail price, MC is material cost, CC is conversion cost, PM is packaging material cost, PC is packing cost, MAPE Maximum allowable post manufacturing expenses (MAPE) and ED is excise duty.

The South African government has also established a Pricing Committee at the Ministry of Health with clearly defined functions to monitor and regulate the drug prices.

Cost of Regulation

There is detailed discussion on various facets of regulatory framework across various sectors of economic importance. In several cases impact of regulations and prospective areas of governance are time tested. The growing literature on this is benefited by detailed studies from various international organisations. The OECD report on regulatory reforms²⁵ laid out a framework for establishing mechanisms for improvement in the regulatory processes, covering various policy options like deregulatory efforts focusing on eliminating regulations that impede competition and reducing the number and cost of regulation along with a focus on nature of the institutions and their performance. In this context, following points may be kept in mind while defining the work profile for NBRA and its regulatory processes.

At this point various data collection parameters are in vogue. This has to be streamlined for conformity assessment procedures, particularly for socio-economic requirements. The OECD experience suggests that the regulators may opt for performance based assessments for simplifying administrative burden. One would have to continuously assess how a particular institution or a regulatory tool is contributing to good regulation and economic performance with a strong cost effectiveness component in it. This may require target review of regulations which may yield highest and most visible benefits.

Table 2: Indicative Regulatory Costs to Commercialise a Biotechnology Product, USD Thousands

Agriculture	
Plant	
GM crop	435-13 460
MAS Crop	5-11
Animal	
Vaccine	242-469
Therapeutic	176-329
Diagnostic	9-189
Health	
Therapeutic	1 300
<i>In vitro</i> diagnostics	150-600
Industry	
GM open release	1 200-3 000
GM in closed loop	Unknown

Source: OECD (2009).

Table 2 provides estimates of the regulatory costs of bringing a biotechnology product to the market. Most of the estimates are for the US. Almost all biotechnology firms are likely to apply for market approval for their products in this jurisdiction, since the US is the largest market in the world for most biotechnology products. These estimates reflect the administrative and legal costs, plus the costs of conducting research that has more than a purely regulatory function. They do not include lost potential income due to the time required to obtain regulatory approval.

The fact that India is soon going to have NBRA, it must have a specialised wing to access fair prices unless the pricing behaviour is such that it undermines competition and falls in the category of being called as predatory prices. In a country like India, institutional monitoring of prices is important to be attended to particularly when agriculture is largely practiced by the small and marginal farmers. One may agree to some extent with the private sector view that high prices of their products are due to rising cost of R&D, the rising cost of management talent, the rising threat of patent insecurity, and the rising challenge from other firms but how much high is high enough for the technology firms is also to be looked into. Primarily, in a sector like agriculture, the necessary guidelines should come from the seed firms themselves or at best may come from the specialised agencies like NBRA.

This should not be very difficult as the Indian regulatory authorities have exhibited necessary dynamism and flexibility for adopting pragmatism. Though the first case of Bt cotton approval took six years at various stages, this was duly attended to by the authorities as in 2008 the GEAC decided to switch over to ‘event-based’ approval system instead of case by case approval. This was much easier for private companies in terms of ensuring wider adoption of their technological accomplishments. As a result, undue delay in regulatory process could be avoided to a great extent.

Regulatory Frameworks and Socio-Economic Concerns

Apart from the safety considerations, the agriculture biotechnology debate also refers to concerns related to socio-economic implications of biotechnology products. Though developing countries at the international fora have

been quite vocal about this demand, in practice, even in their own national legislations, there is very little clarity in as to what all would be included under this caption. It is worth analysing after all to what extent socio-economic issues would also cover cultural and ethical considerations and issues like the impacts on small farmers, indigenous people, women, small and medium enterprises. These are important issues for developing countries, like India, where a sizeable population is dependent upon agriculture. Socio-economic impact assessment is as essential as scientific and technical assessment, if not more. However, there has to be a clearly defined content so that regulatory process is not used for blocking proposals from the private companies for commercialization of their products.²⁶

The Article 26 of the CPB (Socio-economic Considerations) is perhaps one of the most significant aspects of the Protocol, from the perspective of developing countries, since it takes into account the latter's concerns. The CPB maintains that an exporting country should notify the importing parties about the first living modified organisms (LMOs) meant for intentional introduction into the environment, such as fish or seeds. The importer reserves the right of approval for the LMO shipment in accordance with scientifically sound risk assessments before agreeing to its import through a process termed as the advance informed agreement (AIA).

LMOs intended for food, feed and processing (FFPs), which constitute a bulk of traded goods worldwide, are exempted from the AIA. Instead, they are subjected to a milder and simpler form of stipulation where the exporter notifies the biosafety clearing-house (BCH), an information exchange mechanism on the Internet in which countries share information on LMOs. Countries that approve the use of LMOs have to submit their decision to the BCH and provide detailed information regarding their decision. However, exporting FFPs to a member country of the CPB will not be any less stringent if the national regulations of the importing country require the FFPs to be subjected to labelling and identification requirements as mandated by the Protocol.²⁷ Similarly, LMOs meant for contained use, pharmaceuticals, and those passing via a third party country have not been covered by the Protocol. In India, these mechanisms are still to be worked out, as the BCH programme is being developed and implemented by the MoEF.

Indian regulatory framework has in the recent past attracted severe criticism from the civil society organisations and some members of legal fraternity for its lack of focus on socio-economic concerns in the GM approval process. The Biosafety guidelines (Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/Genetically Engineered Organisms or Cells, 1989) as emanated from the Environment Protection Act, EPA, 1986, had no provision on socio-economic concerns. It was only in the revised guidelines (Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts, DBT, 1998) that the following provision was included,

“RCGM can authorize applicants (PIs) to conduct limited field trials in multi-locations in the country. The design of the trial experiments is either provided by the RCGM or it may approve the protocol designed by the PI. The Protocol will seek answers related to animal and human health. Data should also be generated on economic advantage of the transgenic over the existing varieties (3.b.viii).”

Though the Act has an environmental objective, most of its provisions have direct bearing on the agricultural production practices as also on the trade and commerce. The Act on lines of the CPB aims to ‘ensure an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, taking into account the risks to human health, and specifically focusing on transboundary movements’.²⁸ Unlike many other developing countries the Bt Cotton debate in India has evolved at a considerable pace in last few years.

We have already discussed the key expectations from Article 26 of CPB under socio-economic criteria of assessment. The Revised Biosafety Guidelines, 1998 set the stage for socio-economic expectations from biotechnological advances in agriculture without in-depth delineation of them. As a result private sector firms followed their own framework for

data presentation on those indicators, which they felt were more of concern to the regulators and were relevant according to their product profile. In this section we profile some of the concerns expressed in empirical studies focusing exclusively on India.²⁹ Table 3 shows there are 6 studies chosen for the purpose.

One of them (Naik 2001) was initially submitted by the Mahyco-Monsanto along with their Bt cotton approval application. Incidentally, this is the only study that focused on the global scenario and its impact on the domestic cotton prices. It also extrapolated changes in the cotton prices as a result of access supply with new technologies. All these issues were somehow missing in the later studies. The focus in most of the other studies remained around cost advantages with decline in pesticide consumption and profits to farmers as an outcome of this. There are particular issues covered in different studies which are very interesting and must be considered for a long term policy consideration like quality of produce and in this case quality of Bt Cotton (Gandhi *et al.* 2006). Qaim (2003) has raised an interesting issue of welfare and distributive effects of GM Cotton and observed: “The analysis shows that cotton growers would capture two-thirds of the overall benefits so that there is no evidence of private firms misusing their monopoly power.” Such studies are important as similar issues ended up with the MRTP commission for detailed investigations. The effect of Bt cotton across different social categories is presented by Dev and Rao (2007), which is another important policy indicator for impact analysis.

There is only one study from Narayanamoorthy *et al.* (2006) which has forcefully raised the issue of private seed companies in the extension services as they showed a direct linkage between the level of education and adoption of Bt cotton through their results. Though we could not get copies of all the submissions, what is very clear from this discussion (an available submission) is that the nature of studies presented to the RCGM and the GEAC on socio-economic studies is very different from the general expectations from the crops and their role in wider Indian settings. In light of this a general framework as a guideline should be issued to the firms so that they also are clear about the nature of the data required and the regulatory agencies would also be aware of the expected data contents.

Table 3: Socio-Economic Focus of Select Empirical Studies on Bt Cotton in India

Study	Nature of Data	Criteria/Focus	Methodology
Narayanamoorthy A. and S. S. Kalamkar (2006)	<ul style="list-style-type: none"> - Field Survey based on 2 districts of Maharashtra. - Sample Size: 150 - 100 adopters and 50 non- adopters. - Sample included marginal (<1ha) small (1-2ha) medium (4-10ha) and large (>10ha) - Balance for rain-fed and irrigated - Balance for soil quality 	<ul style="list-style-type: none"> - Input use patterns - Cost of cultivation - Productivity - Inter-farm productivity variation. - Relative profit comparisons. - Extension support from seed companies. 	Linear Regression.
Naik Gopal (2001)	<ul style="list-style-type: none"> - Gains assumed with standard 60 per cent reduction in pesticide consumption - Global cotton price data. 	<ul style="list-style-type: none"> - Returns to farmers - Competitiveness 	Domestic Resource Cost Coefficient.
Dev Mahendra S. and N.Chandrashekhar Rao (2006)	<ul style="list-style-type: none"> - Field Survey in 4 districts of AP in 4 agro-climatic zones. - Sample Size: 623 (Adopters 437 and non adopters 186) - Sample included small (less than 4.99 acres) medium (5-9.99acres) and large (>10acres) - Balance for gender/ religion and social categories. - Type of land and size. - Nature of employment. 	<ul style="list-style-type: none"> - Cost of Production across social categories. - Impact on employment across social categories 	Multi-stage stratified random sampling.

Qaim Matin (2003)	<ul style="list-style-type: none"> - Field survey in 3 states of Maharashtra, MP and TN - Sample Size: 157 (all adopters of Bt) 	<ul style="list-style-type: none"> - Pesticide use and yields - Welfare and distributive effects 	Cobb- Douglas Production Function
Gandhi P. Vasantha and N V Namboodari (2006)	<ul style="list-style-type: none"> - Field Survey in 4 states of Maharashtra, AP, TN and Gujarat. - Sample Size: 694 (355 adopters and 339 non adopters) - Average farm size 3.73 ha for Bt cotton and 3.02 for non Bt growers. 	<ul style="list-style-type: none"> - Yield and pesticide use. - Costs and returns. - Cotton quality. 	Regression analysis

However, the key issue is how far the institutional arrangements are feared towards capturing the expected outcomes from the assessment process. Neither the Institutional Biosafety Committee (IBSC) nor the RCGM have any mandate on this theme. With fractured mandate the GEAC looks into whatever is supplied by the private companies. Apart from this the ICAR is also not engaged in extensive and exhaustive review of GM crops.

The IBSC has no mandate to look into the non-safety issues like socio-economic aspects of GM products. As part of this while interviewing different experts, we did not come to know of any instance when any IBSC had undertaken any *ex ante* analysis on any aspect of these issues. The RCGM has received application for eight crops so far. They are cotton, brinjal, cabbage, okra, cauliflower, mustard, maize and rice. Out of these cases, RCGM received detailed socio-economic analysis with the application of Bollgard-I (2001) renewal of Bollgard-I (2005) and Bollgard-II (2006) from Mahyco-Monsanto; JK Agri Genetics and Nath Seeds for Bt cotton. There was no deliberation on these aspects at the committee and the submissions were forwarded to GEAC along with RCGM's views on the safety aspects.

The primary responsibility of the RCGM is envisaged more from the safety perspective. As a result, the current format within which information is sought for the RCGM does not have specific elements to be mentioned by the applicants regarding *ex ante* socio-economic analysis. As the mandate suggests, at the RCGM the work focus has largely been confined to the safety aspects only. In most of the other cases, the RCGM simply forwarded the submissions on socio-economic analysis to the GEAC for detailed deliberations. However, in the RCGM application form there is a separate column asking applicants to enumerate cost benefit analysis of the products developed. In case of brinjal, the GEAC was pro-active and asked the concerned company to attempt socio-economic analysis particularly from the following point of view: a) cost of seed, b) cost saved on account of pesticide and man hours, and c) yield differentials. As discussed earlier, the GEAC has so far received only five applications along with socio-economic analysis. All of these cases are in respect of Bt cotton. Out of the five cases, three were from Mahyco-Monsanto (Bollgard 1, Bollgard 2 and Renewal application). The other two applications were from Nath Seeds and J K Agri-Genetics. In our analysis of these five applications following details have come out.

Over the last five decades, the Indian Council of Agricultural Research (ICAR) has created a model of multi-locational evaluation under the All India Coordinated Crop Improvement Research Projects (AICRPs) to identify promising crop varieties to be recommended for release under Seed Act by the Department of Agriculture and Cooperation (DAC). At this point as per the guidelines, the system is that the data from the company/applicant is compared against the data coming from Multilevel Trials (MLT), Large Scale Trials (LST) and ICAR led All India Coordinated Research Projects (AICRPs). The yield criteria is important while decision is being made by the committee but at the same time weightage is given to special features like fibre length, response in rain-fed conditions, tolerance to sucking pest, fibre quality, etc.

The AICRPs test the production and protection technologies of these improved high yielding varieties to provide packages that could be taken up by the State Agriculture Universities (SAUs) for being incorporated in packages

of practices. The ICAR has accumulated strategic insights in matters related to agronomic data generation. The ICAR through AICRPs follow designed steps:

1. Initial Evaluation Trials (IETs) where preliminary and promising breeding materials along with the Breeders' in house data on yield and fibre quality is taken on board AICRP workshops to include those in the IETs. This applies to private bred hybrids too.
2. Advanced Varietal Trial (AVT) where, based on performance, promising entries are promoted for national and zonal trials depending upon their suitability to different climatic conditions.
3. Promising entries from them would be qualified for Coordinated Varietal Trial (CVT).
4. The best performer under specified criteria would be then considered for recommendation to the Central Sub-Committee on Crop Standards Notification & Release of Varieties for Agricultural Crops of DAC.

From the seed industry perspective, it is important to see how the ICAR responds to this. Since ICAR undertakes these trials for cotton and all other crops, the GEAC adopted the ICAR system to conduct GM crop variety/hybrid evaluations. It seems that being an additional workload without any additional funding to AICRPs, they are unable to cope up (in terms of pressure on land and manpower) with the parallel system of testing and evaluation of GM genotypes and have accommodated them with reduced number of replications. In the case of cotton, since most of the Bt hybrids of all private seed R&D systems that have been released for cultivation by GEAC are products of backcross with COCKER 312 or its derivatives bearing the DESIRED Bt gene, they have been contaminated by many undesirable genes that make these hybrids susceptible to many new diseases and pests. Hence, the risk analysis of these hybrids due to these novel stresses that the genotypes are subjected to as well as enhanced cost of cultivation to mitigate them are never considered by the Indian regulatory system as well as by any follow-up studies by the socio-economic analysts.

The weighing of benefits in the light of such extraneous risk factors that got built into these cotton hybrids seems to be a price for the GM

technology offered to mitigate the bollworm damage. One of the basic differences in these GM crop variety evaluations from regular the AICRP evaluation is that there is no IET and CVT. All what is done is AVT from two years in case of approved GM event in new genetic background and in case of already released varieties/hybrids this AVT is for just for one year. Hence, due to the condensed evaluation scheme, the actual performance of the Bt cotton hybrids in different agro-ecologies in nine cotton growing states became subjective.

It seems that the agronomic inputs to the GEAC coming from the ICAR are not supplemented by the long-standing insights the MoEF has accumulated from the historical experience by virtue of being nodal point for the CPB. During the negotiations of the CPB, several points came up which place biotechnology products in a different category for socio-economic analysis than the usual agricultural varieties, which go through standard agronomic framework. The historical experience also shows how in bulk approval of the Bt hybrids may confuse farmers in a large way. The relevance of brand, efficacy, yield and quality should be retained as the top most priority. In the agronomic trials the relative performance of the Bt hybrid may itself be compared as a benchmark. Bringing these hybrids under the usual Seed Act Bill, after the due approval from safety purposes, may be one of the options in this regard.

It is in this context, the regulatory agencies would have to look into the nature and scope of the regulatory regime which may ensure crucial balance between adoption and diffusion of new innovations in the agriculture sector and their cost implications for the end users. As the National Biotechnology Regulatory Authority (NBRA) Bill is being prepared for switching over from current regulatory process, we need to consider the broader regulatory reforms in our approach. The goal of such regulatory reform should be to improve economic contribution of agriculture and enhance the ability of the farmers or end users to adapt to new changes in the technological regimes. This process should be robust, transparent and must involve expertise at multi-disciplinary levels. There seems to be right intentions for such interventions but they are probably not backed by the best policy instruments. The specific orders for pricing of high technology products or on trait values

or on royalties have raised several issues regarding the development and diffusion of agricultural products with the help of new technologies.

Endnotes

- ¹ Karihaloo J. L. and P.A.Kumar (2009); Jayaraman, K. S. (2001) and Murugkar, M., Bharat Ramaswami and Shelar, M. (2007).
- ² Murugkar, Milind, Bharat Ramaswami and Mahes Shelar (2006), Narayanamoorthy, A. and S. S. Kalamkar (2006), Peshin, Rajinder, A. K. Dhawan, Kamal VAtta and Kamaldeep Singh (2007) and Shah, Esha (2005).
- ³ Vasavi, A. R. (2009).
- ⁴ *Hindu Business Line* (2010), Padma, T. V. (2010).
- ⁵ Chaturvedi, Sachin, Wendy Craig, Vanga Siva Reddy and Decio Ripandelli (2007).
- ⁶ Dhar B. (2001)
- ⁷ Only few State governments have announced setting up of these committees but they have yet to assume their responsibilities.
- ⁸ GoI (2004)
- ⁹ Bhargava (1995)
- ¹⁰ Sundar and Sarkar (1999)
- ¹¹ Jacint Jordna (2011)
- ¹² Blumenthal, W. (2006)
- ¹³ Bernstein (1955)
- ¹⁴ Kuruganti (2008)
- ¹⁵ *Hindu Business Line* (2006b) and Sadashivappa, Prakash and Matin Qaim (2009).
- ¹⁶ *Business Standard* (2006).
- ¹⁷ *Hindu Business Line* (2006a)
- ¹⁸ *Business Standard* (2006).
- ¹⁹ *Financial Express* (2006).
- ²⁰ *Hindu Business Line* (2006a).
- ²¹ Schumpeter (1975).
- ²² Bhattacharjea (2007).
- ²³ Chaïlkidou, Kalipso (2009)
- ²⁴ <http://nppaindia.nic.in/index1.html>
- ²⁵ OECD (2008).
- ²⁶ Falck-Zepeda, J.B. (2009)
- ²⁷ Damodaran (2005).
- ²⁸ CBD (2000).
- ²⁹ These studies were short-listed for review after deliberations at the research committee for this project.

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