Biosafety in India
Rethinking GMO Regulation

Despite conflicting claims about the performance of Bt cotton, in 2002 the Genetic Engineering Approval Committee approved its commercial cultivation in several states of north India. Judging from the lackadaisical manner in which the genetically modified cotton was handled in the southern and western states, serious doubts about the efficiency of the regulatory agencies persist. More democratic forms of decision-making that involve greater public participation and debate could be one of the more critical factors that contribute to an effective biosafety regime. For satisfactory implementation of the regulation it is also vital to strengthen institutional infrastructure.

LIANCHAWII

It is now a widely acknowledged fact that the rapid adoption of biotechnology in India, especially in agriculture, has been accompanied by grave scientific risks and uncertainty.[1] These ambiguities and doubts raise several challenges for policy and governance. While a large portion of investment in biotechnology is made in "developed" countries, most of the derived products, or genetically modified organisms (GMOs), are exported and marketed to the "developing" world.[2] This transboundary trade has been occurring despite the fact that there are several scientifically unverified claims about GMOs and their impact. These apprehensions are usually sought to be dealt with within the realm of biosafety.

Biosafety or the prevention of potential risks from products derived from genetic engineering, has emerged as an important scientific and political concern worldwide. The Cartagena Protocol on Biosafety, 2000,[3] negotiated under the United Nations Convention on Biological Diversity (CBD),[4] is the first legally binding international agreement that purports to safeguard biodiversity concerns by regulating GMOs intended for use in agriculture. Widespread differences were rife during the biosafety negotiations that eventually gave way to a final text riddled with inadequacies, particularly from the perspective of developing countries, as there were gaps that allowed for the illegal entry of GMOs into a country. The protocol, nevertheless, came into force in September 2003.[5]

As a party to the Cartagena Protocol on Biosafety, it has become incumbent upon India to commit itself to meet the criterion specified in the provision, which encompasses the safe transfer, handling and use of GMOs, with a specific focus on transboundary movement. In India, apprehensions and controversies are linked mainly with socio-economic concerns vis-à-vis agricultural biotechnology as a novel technology and biodiversity conservation. Transnational companies involved in the commercial plantation of GMOs are often subject to public scrutiny as there is fear that reliance on transgenic seeds could increase dependence on the former. Chaia Heller (2001) has argued that agricultural biotechnology dilutes the skills of farmers who become more dependent upon agrichemical companies for seeds and other "accessory kits" (like herbicides) that they were earlier able to provide for themselves. This gives rise to a capitalist system which is inclined towards centralisation, hierarchy, and, consequently, "non-democracy". Instead, Heller has argued that citizens should have the power to discuss and determine public policies. The risks are particularly high for millions of Indian farmers who are subsistence based. Yet, depriving them of the opportunities and possible benefits of biotechnology may not necessarily be a practical proposition either.

Till date, India has not engaged in trade in GMOs with other countries, but the steady increase in the global acreage of GMOs is perhaps an indication of things to come. However, lessons drawn from India's experience with its first commercially grown GM crop – Bt cotton – reveal several loopholes in the existing implementation of the national biosafety regulation. The long-term economic impact of dependence on this technology may also require greater legal and scientific scrutiny. These various weaknesses question India's level of commitment towards a comprehensive policy on agricultural biotechnology. This article discusses some aspects of India's preparedness and capacity to handle GMOs on a large scale.

The Bt Cotton Experience

In India, the only GM crop that is commercially cultivated is the Bacillus thurengiensis (Bt) cotton, approved in March 2002 by the Genetic Engineering Approval Committee (GEAC) constituted under the ministry of environment and forests. Bt cotton was developed by the Maharashtra Hybrid Seeds Company (MAHYCO), a subsidiary of the transnational seed company Monsanto. This was a significant moment in the history of Indian agriculture since it was the first time that a GMO was officially approved for commercial cultivation.

Prior to its approval in 2002, MAHYCO's application for commercial cultivation was rejected by the GEAC which ordered further research under the supervision of the Indian Council of Agricultural Research (ICAR). This decision caused widespread disappointment among a large section of cotton farmers and some even warned of a civil movement, if application was rejected for the second time. Approval was given for three types of Bt cotton – Mech 9, Mech 12 and Mech 162 – in Andhra Pradesh, Gujarat, Karnataka, Maharashtra, Madhya Pradesh and Tamil Nadu. The period of approval was limited to three years after which the situation had to be reviewed further.

Optimistic predictions of the GEAC, the ICAR and the department of biotechnology (DBT) quoted an additional income

of Rs 10,000 per acre for the farmer.[6] The DBT also claimed that crop yields would increase by 80 per cent.[7] For the chairperson of GEAC, the fact that Bt cotton would drastically reduce pesticide use by 80 per cent among other benefits was reason enough to grant approval.[8] It is interesting to note that more than 50 per cent of the insecticides consumed in Indian agriculture is used on the cotton crop alone. Pesticides cause huge losses to the farmer as the fields are sprayed 12-14 times in many parts of north India [Yamaguchi et al 2003]. The American bollworm is the biggest threat and was responsible for the destruction of about 13 per cent of India's cotton crop production in 2000-2001.

However, results from the field were varied and inconclusive as inferences drawn from surveys by various organisations lacked a clear verdict. The agriculture ministers from Andhra Pradesh and Karnataka announced the failure of Bt cotton in both states. These statements were supported by independent surveys conducted in 2002-03, in the cotton growing belts of south India, by New Delhi-based organisations such as Research Foundation for Science, Technology and Ecology and Gene Campaign. Similarly, studies conducted by Greenpeace India, in three districts of Karnataka, also showed that the average yield of Bt cotton was lower than non-Bt cotton.[9] On the other hand, Monsanto proclaimed the three varieties a success, based on a survey conducted by the company with government officials in five states. The survey reported an increase in yield by 30 per cent and reduction in pesticide use by 65-70 per cent, giving an additional income of Rs 7,000 per acre. These different interpretations were cause for much confusion amongst farmers across the country.

In late 2001, cotton farmers in Gujarat were anticipating a bumper harvest when they received a strange instruction from the government. They were ordered to destroy all their cotton crops by burning them. The order was issued by the GEAC, which had claimed that it possessed startling evidence that "illicit" Bt cotton, unapproved by the committee, was being sown in many parts of Gujarat. Allegedly, these transgenic seeds, also called Navbharat seeds, were sold to farmers by Navbharat Seeds, an Ahmedabad-based company.[10] In the same year, most cotton crops were so heavily infested by the bollworm that even 15-16 pesticide sprays proved futile. In the midst of all this, some farmers observed that some cotton crops had also withstood the infestation and remained unaffected by the bollworms. This incident was reported to the GEAC, who along with the MAHYCO conducted a test which revealed the presence of Cry1Ac genes that had been patented and "owned" by Monsanto.

The central authorities requested the Gujarat government to retrieve the illicit Bt cotton that had entered the market and further directed that the crops be uprooted and burnt, the fields sanitised and the seeds destroyed. A compensation package was to be initiated for the growers whose crops would be destroyed. It has been argued that the decision to destroy the crops punished the farmers only and not the corporation that developed the technology.[11] By the time the GEAC took stock of the situation the "illegal" Bt cotton had already been grown in 11,000 acres of land and the seeds were sold to farmers in Andhra Pradesh, Haryana, Maharashtra, and Punjab for commercial cultivation.[12]

Ostensibly, the Bt cotton has an artificially introduced bacterial gene, which produces a toxin that helps the plant to ward off the American bollworm. The seeds of Navbharat and MAHYCO contain the same Bt bacterium but they were purportedly crossed with different hybrid plants. Unlike MAHYCO, Navbharat Seeds did not conduct the trials mandatory for obtaining approval from the government. Technically, the growers of the illicit Bt cotton were said to be liable under Rule 89 of the Environment Protection Act, 1986. But the state authorities were reluctant to initiate action that could affect the livelihood of the farmers.[13] The seemingly incompetent handling of the situation by the state and the GEAC left the markets awash with Navbharat Seeds.

The incident laid bare the Indian government's poor preparedness in dealing with transgenic crops in agriculture. A M Gokhale, the then chairperson of the GEAC admitted that the state regulatory mechanism was hoodwinked by the private company, but that the experience served as a warning to other states to have their regulatory mechanisms in place.[14]

Indian Regulatory System and Its Pitfalls

The inadequacies in the Indian regulatory structure were thus starkly revealed by the Gujarat incident, which also brought out the inherent complications in the biosafety policy and its implementation. Clearly, there are concerns about the efficiency and particularly the preparedness of the country in dealing with the large-scale cultivation of GMOs and the risks arising from them. Poor coordination, breakdown of communication between the centre and the state authorities and absence of monitoring agencies were some of the glaring weaknesses observed in the system. For instance, the GEAC approved Bt cotton in Andhra Pradesh, despite the absence of a State Biotechnology Coordination Committee (BCC) and the District Level Committee (DLC). Both the BCC and the DLC were constituted to oversee the implementation of the regulation as well as the performance of the GM crop. Even during the field trials of MAHYCO's Bt cotton, BCCs were not yet formed in most of the states where trials took place; some state authorities were not even aware of transgenics being tested on their ground.

The authorities also revealed a complete inability to deal with rampant and widespread use of illicit GM crops. The GEAC admitted to shortcomings in the regulatory bodies of the state as well as the centre. It also declared that the performance of the three Bt cotton varieties did not surpass that of the best non-transgenic varieties,[15] and yet categorically maintained that Bt cotton performed better in terms of lesser requirement of sprays and insecticides.[16] The GEAC tried to prohibit farmers from planting unapproved seeds by promulgating an order to burn them down. However, no action has been taken against these farmers and the Navbharat seeds are still grown not only in Gujarat, but also in many other states and the extent of acreage is still not credibly verifiable. At present, there is a shortage of trained manpower both at the union and state government levels. Gadgets to locate and detect GMOs are not available with the quarantine or any other agency. Consequently, it would be difficult for the concerned agencies in ports or other entry points to detect GMO in agricultural products that are imported [Chaturvedi 2002]. Regulations are implemented by ad hoc committees whose members are mainly from the scientific community with no representation from social scientists or members of the public. Clearly, there is an absence of a coherent policy for GM crops. A set of rules and guidelines is therefore much required to check imports of GM food into the country and help to prevent India from becoming a dumping ground for GM food [Sahai 2003]. On the other hand, the simple banning of GM crops could cause several unintended outcomes. A ban could instead encourage

poor farmers to adopt the technology in the hope of high potential gain. And as experienced in Gujarat, any attempts to stop these farmers could have serious political repercussions as well.[17]

Other GM crops are currently awaiting clearance and many farmers are willing to experiment with the new varieties – out of sheer desperation or expectation. Since some of these crops are edible, the implications for health are more complex and serious. However, delaying the approval process, particularly from the farmer's perspective, offers no consolation; on the contrary, it could lead to frustration in having to wait for long periods, and in some cases, unauthorised activities, as seen in the Navbharat incident. In many ways, this experience is an eye-opener for those who perceived GM cotton as a saviour. The experience might have also inculcated a more practical approach towards investment in an expensive technology.

An effective regulation on GMOs is perhaps an important key to preserving the rich biodiversity of countries like India, where more than 70 per cent of the population is still dependent on agriculture for livelihood. Ground realities, however, confirm India's poor preparedness in dealing with GM crops on a large scale. The Environment (Protection) Act, (EPA), 1986 provides guidelines on the handling, research, application and technology transfer of GMOs, but the transboundary movement or trade in GMOs is yet to be addressed. The limitation of the Indian biosafety framework is perhaps compounded by the lack of a domestic biotechnology policy, despite the fact that India is the first country to have an exclusive department of biotechnology.[18]

The Indian regulatory structure comprises of six committees to regulate GMOs:[19] (i) Recombinant DNA Advisory Committee (RDAC), (ii) Review Committee on Genetic Manipulation (RCGM), (iii) Institutional Biosafety Committee (IBSC), (iv) Genetic Engineering Approval Committee (GEAC), (v) State Biotechnology Coordination Committee (SBCC) and the (vi) DLC; the first three come under the DBT and the remaining three are associated with the ministry of environment and forests (MoEF). The RDAC monitors development in GMOs at the national and international levels and suggests appropriate regulations. The RDAC also drafted the first Indian Recombinant DNA Biosafety Guidelines in 1990 which were implemented by the government [Ghosh 2000]. Meanwhile, research trials on transgenic material are administered by the RCGM. A recently constituted monitoring-cum evaluation committee assists the RCGM, evaluates the transgenic crops and monitors biosafety data collection. All institutes that conduct research on transgenic material are supposed to constitute an IBSC, which then reports to the RCGM. Meanwhile, large-scale and commercial release of GMOs are to be cleared by the GEAC under the MoEF. The GEAC is assisted by the SBCC and the DLC that oversee the safe use of GMOs. The function of these regulatory agencies are summarised in the table.

Table: Institutional Structure of Biosafety in India

A Recombinant DNA Advisory Committee
- Monitors development in GMOs at the national and international levels.
- Gives recommendations on safety regulations of GMOs and its products.
- Prepared the first Indian Recombinant DNA Biosafety Guidelines in 1990.

B Institutional Biosafety Committee
- All institutes that conduct research in rDNA and different aspects of biosafety are to be set up Institutional Biosafety Committees (IBSCs). Institutions are awarded official recognition by the department of biotechnology.
- Representatives from department of biotechnology and a medical officer are to oversee the safety aspect.
- All research using GMOs is to be inspected by an investigator who reports the status and result of experiments to the IBSC. The progress of such experiments is to be reported to the Review Committee on Genetic Manipulation of the DBT at least once in every six months.

C Review Committee on Genetic Manipulation
- Constituted under the department of biotechnology with members from Indian Council of Medical Research, Indian Council of Agricultural Research, Council of Scientific and Industrial Research, etc.
- Monitors and regulates all safety aspects of research on genetic manipulation, including small experimental field trials.
- Clears import of genetic material meant for research purposes, including vectors used for producing or cloning genetically modified micro-organisms, animals and plants. Institutes guideline that restrict the production, sale and use of GMOs.
- Publishes manuals of guidelines for the regulatory process of genetically engineered organisms in research and applications. Approves applications for the generation of information on transgenic organisms and plants.
- A monitoring-cum-evaluation committee (MEC) comprising of scientists, agricultural experts, and other officials nominated by relevant ministries is formed under RCGM.
- The MEC conducts on the spot visits to field trial sites and advises the RCGM on the kind of initiatives to be taken, on the basis of their assessments. Assists the RCGM in conducting trials and collecting data. Collects information on comparative agronomic advantages of transgenic plants.

D Genetic Engineering Approval Committee
- Constituted under the ministry of environment and forests, with members from DBT, Indian Council of Agricultural Research, Indian Council of Medical Research, Council of Scientific and Industrial Research, Directorate of Plant Protection, Central Pollution Control Board, etc.
- Authorises clearance for large scale field trials, industrial application, and the commercial cultivation of GMOs, mainly from the viewpoint of environmental safety.
- Can approve or prohibit GMOs used for import, export, transfer, manufacture, processing, use or sale of GMOs. Approved commercial cultivation of Bt cotton in March 2002.

E State Biotechnology Coordination Committee
- Members include, chief secretary of the state government, secretaries, department of environment, health, agriculture, commerce, forests, public works, public health, chairman, state pollution control board, microbiologists and pathologists from the state.
- States that conduct research in GMO are to constitute a SBCCs for effective enforcement of biosafety regulations.
- Assists and coordinates with the GEAC. Can inspect sites, and take punitive actions when necessary. Coordinates with the central ministries and nominates state government officials as representatives to conduct field inspections on GMOs.

F District Level Committee
- Members include the district collector, factory inspector, representative of the pollution control board, chief medical officer, district agricultural officer, representative from the public health department, district microbiologists or pathologists, municipal corporation commissioner, etc.
- Nodal agency at the district level to assess damage from GMO release. Reports infringement of regulation to the SBCC or the GEAC.
- Monitors safety regulation and ensures smooth functioning and compliance with the rDNA guidelines and procedures.

Source: Ghosh (2000), Gupta (2003).

The RCGM mandates small field trials to a limited area of upto 20 acres in different locations during one crop season. It is mandatory that land used for research on transgenic plants should not exceed one acre and the design for such plots should be approved by the RCGM. Open field research is conducted to generate more information on risks posed by the technology to animal and human health. The economic advantages of transgenic crops as well as their toxicity and allergenicity are also explored through these trials. Critical issues related to GM traits, such as pollen dispersal, the possibility of crossing with non-transgenics and their intensity of invasion or competition are also studied under experimental trials. The RCGM also mandates that research on transgenic plants be conducted in contained green houses or in small plots [Ghosh 2000].

The GEAC provides clearance for large-scale field trials, industrial application, and the commercial cultivation of GMOs. This clearance is mainly from the viewpoint of environmental safety. The GEAC can approve or prohibit GMOs used for import, export, transfer, manufacture, processing, use or sale of GMOs. So far, the only GM crop cleared by the GEAC for commercial cultivation is Bt cotton.[20] However, the performance of the GEAC has come under constant scrutiny and the agency is often mired in controversy. Proponents of GMOs are critical about the long period taken by the GEAC to approve GM crops and they maintain that farmers should make their own decisions when opting for a technology.[21] On the other hand, environmental organisations express the need for more concrete research on a technology prior to its release since the threats to animal and human health are real. They also demand greater transparency and accountability in the functioning of the GEAC by means of public participation and the inclusion of representatives from civil society in the regulatory committees.

The GEAC comprises mainly of scientists from the public sector and bureaucrats from various ministries, but no trained officials in risk assessment, and in environmental and ecological impact assessment.[22] The fact that the GEAC has changed its chairperson so often,[23] and is caught up in bureaucratic internal conflict also does little to allay public concerns.[24] A radical change in the composition and function of the agencies that regulate GM technology and their replacement by new and competent bodies is argued to be a practical alternative to these repeated criticisms [Sahai 2003:29]. A Task Force on Agricultural Biotechnology, constituted to study the potential and problems of GM crops, suggested the setting up of an autonomous body, National Biotechnology Regulatory Authority under a biosafety and technical expert to handle GMOs and that the powers of the GEAC be limited to only environmental clearance.

The guidelines on GMOs appear to delineate the responsibilities of different agencies, but there are several grey areas that have become the source of widespread controversy. As mentioned earlier, the role of the RCGM is to administer experimental research, while the GEAC oversees the deliberate release of transgenic crops. But whether field trials constitute an experimental research or a deliberate release is not clearly defined in the regulation [Gupta 2003]. This problem was reflected in a public interest litigation filed in the Supreme Court in 1999 by the Research Foundation for Science, Technology and Environment (RFTSE), a Delhi-based organisation. The case was filed against the DBT, MoEF, the Ministry of agriculture, MAHYCO, and MAHYCO-Monsanto Biotech India, a joint venture of Monsanto and MAHYCO. The RFSTE appealed that the field trials of transgenic crops imply its deliberate release and therefore the GEAC, not the RCGM, should oversee such testing. This was countered by the regulatory agencies, who asserted that the field tests were not a deliberate release but small-scale "experimental research".[25] However, the 1989 rules clearly state that the biosafety committee of the MoEF should administer the GMOs released into the environment.

Gupta (2003) points out that the late amendment to the 1998 Biosafety Guidelines, which was issued in September 1999, was perhaps in part, a result of this controversy. In the amendment the RCGM is authorised to approve small experimental field trials for research limited to a total area of 20 acres in multi-locations in one crop season, and any one location where the experiment is conducted should not exceed more than one acre [Ghosh 2000]. Field trials more than this specified area require approval from the GEAC.

The fact that 11,000 hectares of farm land were cultivated with the Navbharat seeds and remained undetected for so long reveals the weakness of the regulatory mechanism. The episode also exposed the GEAC's inability to wield its legal authority over those who cultivated the unapproved seeds, and also upon those who failed to maintain the mandatory refuge belt, i e, 20 per cent of the total land area. This was a clear indication of the lack of official capacity to implement the regulatory mechanism. Those who violated the regulations are unlikely to be prosecuted, since the GEAC has no judicial powers. Under the EPA, they can be held in the court of law, but the conditions of liability and redress are considered to be weak and time consuming. [Chauhan et al 2000].

As mentioned earlier, there was no infrastructure at the state level – the mandatory state BCC and DLC that were to conduct inspections or risk assessments were not even constituted. Moreover, some state authorities were not even aware of GMOs being grown in their territories. Though the GEAC has permitted the commercial cultivation of Bt cotton in selected states, there is no mechanism to check its entry or use in other states that are yet to receive an approval.[26]

Several other weaknesses in the existing system reflect the need for a stronger regulation on GMOs. As a member party to the Cartagena Protocol on Biosafety, India is committed to prepare domestic biosafety regulations, in conformity to the rules of the protocol. Such commitments require greater institutional and technical efforts. However, there is no credible mechanism as yet to monitor or detect the import of unauthorised GM agricultural or plant material since there are many entry points in the country [Chaturvedi 2002]. This lapse can prove to be particularly fatal. Likewise, it has also been argued that the segregation, identification, preservation and traceability of GM products are realistically impossible to implement in India due to the limitations in government machinery. These inadequacies, in fact, would render it difficult for the farmer to choose between GM, non-GM, or organic crops.[27] Consequently, consumers would also lose the privilege of making an informed choice.

GMOs pose various potential health and environmental risks, one of which is the gene flow involving the transfer of transgenes from GMO to their wild relatives. Many developing countries are rich storehouses of biodiversity that could thus be contaminated, and eventually wiped out by the more resilient and dominant GM crops. Moreover, it has been argued often that for India, which has one of the world's largest collections of rice germplasm, the threat of infecting its genetic material is real and therefore

deserves a cautious policy. Another threat is the potential for the emergence of new forms of resistance or secondary pests or weeds [Jules 2002] About 40 per cent of the world's people suffer from blindness and micronutrient deficiencies because of poor nutrition. Proponents of the technology claim that GM crops like "golden rice" or "vitamin A rice" could help in reducing such malnutrition.[28] On the other hand, those opposed to GMOs argue that GM crops with enhanced nutrition are being used as a "Trojan horse" to gain better public acceptance of the biotech industry as a whole and that the GM solutions to micronutrient deficiencies in developing countries should not be overplayed.[29] It is these uncertainties and risks that have in fact encouraged many scientists who were instrumental in discovering the technology in the 1970s to call for a moratorium until proper guidelines were in place, under the Asilomar Declaration [Appleyard 1999][30] Nevertheless, it is agreed by many that the technology does not necessarily solve the world food problem. Other issues such as the social, economic and political problems in food production and inequity in distribution are some of the reasons that have contributed to this malady.

Concluding Remarks

It appears that biotechnology is developing at a pace in which technological strides in the field can seldom be regulated through credible biosafety norms. These anxieties have, perhaps, contributed to the growing scientific and popular reaction against GMOs, whose potential risk continues to be a matter of intense debate worldwide. The central reason for stoking such dilemmas on genetic transfers, it has often been argued, stems from the largely anticipatory nature of biosafety governance as GM technologies tend to be shrouded in scientific uncertainties. Given such strong reservations amongst the popular and scientific community, the export and adoption of biotechnology, not unexpectedly, has also fuelled the demand for an internationally agreed regulatory mechanism in the form of a biosafety protocol. Presumably, an effective regulatory structure could, inter alia, prevent the possibility of disputes between countries, regarding international trade in GMOs, and the risks posed to biodiversity. Thus, it was hoped, the Cartagena Protocol on Biosafety could allay many of the above-mentioned fears. Many have, in fact, argued that the protocol has managed to initiate several precedents in governing biosafety. For example, the provisions of the protocol sought to lay minimal standards for the transboundary movement of GMOs and thereby tried to harmonise a framework for trade in genetic material. Notwithstanding these claims about the protocol possessing several salutary features, biosafety regulations still remain inadequate. It is perhaps possible to plug these weaknesses by having a strong national biosafety policy in place and as a member party to the protocol, India is obliged to do so. Some severe limitations, however, are fairly evident in the Indian biosafety policy, which is encompassed within the EPA, 1986. The handling of India's first GM crop – Bt cotton, as discussed earlier, reflects severe weaknesses in the national regulatory structure. These limitations are evident within both the policy structure and its implementation. Despite the ambiguities in the yield of Bt cotton in southern states, the GEAC, in March 2005, permitted three companies to grow Bt cotton in several north Indian states.

The Task Force on Application of Agricultural Biotechnology formed by the Indian government recommended the restructuring of the regulatory system, including that of the GEAC, and the formation of a new biotechnology regulatory authority – whether India requires another agency is still a matter of debate. Nonetheless, this initiative appears to give two clear indications: (i) that the Indian government recognises the potential of agricultural biotechnology, and ii) that it is taking steps to tighten the loopholes in the current regulatory system. The authorities came under severe criticism for their lack of transparency while giving clearance to the Bt cotton. More democratic forms of decision-making that involve greater public participation and debate could perhaps be one of the most critical factors that contribute to an effective biosafety regime. Furthermore, for effective implementation of the regulation it is critical to strengthen the institutional infrastructure.

No single technology, it is claimed, is the answer to an ecologically sustainable agriculture. However, different approaches to technological improvements or innovations in agriculture will continue to strengthen agricultural productivity. For countries like India, where the economic system is rapidly evolving and becoming more knowledge intensive, science and technology are bound to play an increasing role in the agriculture sector. In recent years, research has focused on agricultural biotechnology, which has enormous potential in agricultural productivity. Since this technology is at its formative phase, it is dynamic and constantly developing, and is therefore tentative. All said and done, establishing a regulatory mechanism is one thing, but it is in the effective process of implementation and a functional system of delivery that the real challenge lies. EPW

Email: lian_chawii@yahoo.com

Notes

[I would like to thank Rohan D'souza and Sachin Chaturvedi for their critical comments and suggestions.]

1 Modern biotechnology or genetic modification, which was made possible in the 1970s, involves the transfer or insertion of DNA – the genetic structure – from one organism to the genetic material of another in order to get desired traits. While this relatively new technology can be used to produce wonder drugs, or produce high agricultural yields, it can also be used to create new species of plants or animals whose impacts cannot be predicted as yet.

2 The description of the developed and the developing worlds has been derived from Lorraine Elliott's *The Global Politics of the Environment*, in which the former comprise countries from the Organisation of Economic Cooperation and Development and parts of the former Soviet Union, while the remaining countries of the world comprise the developing countries.

3 *The Cartagena Protocol on Biosafety to the Convention on Biological Diversity: Text and Annexes*, Secretariat of the Convention on Biological Diversity, Montreal, Canada, 2000. The text states that the protocol 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" (p 3).

4 Article 19 (3) of the Convention on Biological Diversity addresses the need for a protocol for the safe handling and use of living modified organisms that may have an adverse effect on the conservation and sustainable use of biodiversity.

5 For a detailed discussion on the Cartagena Protocol on Biosafety refer to my M Phil dissertation titled, "Biosafety in India: Issues and Challenges", Jawaharlal Nehru University, 2004.

6 Devinder Sharma 'Bt Cotton: The Flop Show', www.agbioindia.org, April 15, 2003.

7 Sonu Jain, 'First Bt Picking: High Yield with Strings Attached', *Indian Express*, November 12, 2002.

8 A M Gokhale, former chairperson, Genetic Engineering Approval Committee, personal communication, March 2003.

9 The Greenpeace study was conducted in Dharwad, Haveri, and Raichur districts of Karnataka. *Source*: 'Bt Cotton: Future Imperfect' in http://www.financialexpress.com/fe, April 13, 2003.

10 Indira Khurana, 'Genetic Crime' in *Down to Earth*, November 15, 2001, pp 6-7.

11 Vandana Shiva, 'Charter of Farmer's Right to Safe Seeds', Navdanya, New Delhi, November 1, 2001.

12 Mukund Padmanabhan, 'The Dilemmas over Illicit GM Cotton', *The Hindu*, October 24, 2001.

13 Ibid.

14 Personal communication with A M Gokhale, March 2003.

15 'No Bt Cotton, No GM Mustard: GEAC', *The Times of India*, April 18, 2003.

16 Sonu Jain, 'Govt Admits Bt Cotton Is Better cotton, Denies It to Farmers', *The Indian Express*, October 19, 2001.

17 Per Pinstrup-Andersen, 'Should GM Crops Be Allowed?', *Economic Times*, New Delhi, November 13, 2001.

18 'Biotech Revolution', *Frontline*, Chennai, August 29, 2003, pp 109-26.

19 The framework covers activities in genetically modified organisms including research involving genetically modified organisms, genetic transformation of green plants, rDNA technology in vaccine development, and large-scale production and deliberate/accidental release into the environment of organisms, plants, animals and products derived from rDNA technology. *Source:* Department of Biotechnology, *Recombinant DNA Safety Guidelines*, ministry of science and technology, Government of India, New Delhi, 1990.

20 So far, the GEAC has approved four varieties of Bt cotton seeds.

21 Sharad Joshi, Shetkari Sangathana, in Bharuch, Gujarat, November 14, 2002, personal communication.

22 'National Symposium on Relevance of GM Technology in Indian Agriculture', Gene Campaign, November 26-27, 2003, mimeo.

23 The GEAC had six chairpersons in the last three years. *Source*: Ashok B Sharma, 'Not Yet Born, Biotech Monitor Draws First Blood', *Indian Express*, New Delhi, April 30, 2004. The official that holds the post of additional secretary in the ministry of environment and forest automatically becomes the chairperson of GEAC.

24 Pallava Bagla, "Report Says India Needs Stronger Independent Regulatory Body", *Science Magazine*, June 11, 2004. *Source*: http://www.sciencemag.org/cgi/content/full/304/5677/1579a.

25 Department of Biotechnology, 'Counter Affidavit on Behalf of the Union of India-Respondent No1 to the Writ Petition', Supreme Court of India, Extraordinary Original Jurisdiction, Civil Writ Petition No 71/1999.

26 Biswajit Dhar, 'Globalisation and the International Governance of Modern Biotechnology: Regulating Biotechnology in India', Research and Information Systems for the Non-Aligned and Developing Countries, New Delhi

27 Gene Campaign, National Symposium on Relevance of GM Technology in Indian Agriculture, November 26-27, 2003, mimeo.

28 S K Datta: 'The Need for Genetically Engineered Food When Enough Is Produced and Unused', *SCOPE* GM Food Controversy Forum, 2001, scope.educ.washington.edu/gmfood/commentary/show.php?author+Datta April 16.

29 *Biotech – The Next Generation: Good for Whose Health?* Food Commission, UK, April 2000.

30 In 1975, prominent scientists who discovered genetic engineering met at Asilomar in California and called for a moratorium on certain types of recombinant DNA research till a regulation was in place.

References

Appleyard, Brian (1999): *Brave New Worlds: Genetics and the Human Experience*, Harper Collins Publishers, London, p 33.

Chauhan, K P S, R K Tyagi (2000): 'Implications of the Protocol on Biosafety: An Indian Perspective' in *RIS Biotechnology and Development Review*, Vol 3 (2) Research and Information System for the Non-aligned and other Developing Countries, New Delhi, p 24, December.

Chaturvedi, Sachin (2002): 'Status and Development of Biotechnology in India: An Analytical Overview', RIS Discussion Paper # 28/2002, RIS, New Delhi, p 37.

Ghosh, P K (2000): 'Evaluation of the Transgenic Organisms: An Overview of Risks and Procedures in India' in *RIS Biotechnology and Development Review*, Vol 3 (2), Research and nformation System for the Non-aligned and other Developing Countries, New Delhi, pp 39-60.

Gupta, Aarti (2003): *The Role of Knowledge Flows in Bridging North-South Technological Divides: A Case Analysis of Biotechnology in Indian Agriculture*, Centre for Science, Policy, and Outcomes, Washington.

Heller, Chaia (2001): 'Mc Donalds, MTV, and Monsanto: Resisting Biotechnology in the Age of Information Capital' in Brian Tokar (ed), *Redesigning Life? The Worldwide Challenge to Genetic Engineering*, Zed Books, London.

Jules, Pretty (2002): 'The Genetics Controversy', Agriculture: Reconnecting People, Land and Nature, London, pp 126-45.

P K Ghosh (2000): 'Evaluation of the Transgenic Organisms: An Overview of Risks and Procedures in India', RIS Biotechnology and Development Review, Vol 3(2), RIS, New Delhi, December, pp 39-60.

Sahai, Suman (2003): *Social and Ethical Concerns about Agricultural Biotechnology*, Gene Campaign, New Delhi.

Yamaguchi, Tomiko et al (2003): 'Agrifood Biotechnology Discourses in India' mimeo, Department of Sociology, Institute for Food and Agriculture Standards, Michigan State University, Michigan, USA.