RIS
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www.ris.org.in/abdr.html

Asian Biotechnology and Development Review
Vol. 9 No. 3, pp 19-40

Printed in India

Biosafety and Emerging Socio Economic Issues

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Abstract: India, as a party to the Convention on Biodiversity and having ratified the Cartagena Protocol (CP) is committed to the safe handling of living or genetically modified organisms (LMOs or GMOs). CP provides a broad framework on biosafety especially focusing on transboundary movements of GMOs and also covers seeds that are meant for intentional release in the environment, as well as those GMOs that are intended for food, feed or used in food processing. A number of countries have drafted their biosafety regulatory framework taking into consideration the socio-economic aspects of release of GMOs, the common feature emphasised being the health and economic loss due to the release of such GMOs. Besides many countries have also emphasised the labeling requirements to enable consumers to make a choice. In the case of India, the regulatory framework, does not adequately emphasise the socio economic aspects, the need for which has been realised after the release of GMO; in the environment. To examine the implications more research is going on in both public and private sector in India. The major lacuna in the Indian system of adoption of GMO was, the failure of the monitoring of the GM crop after the commercial release to ensure proper implementation of biosafety measures. Failure to adopt bio safety measures, irrational use of pesticides and an indiscriminate crossing of the unapproved variety could lead to wide spread pest resistance and resurgence and leading to a potential technology not utilised optimally.

Keywords: Biosafety, Labeling, GMOs.

Introduction

Biosafety can be broadly defined as the safety concern regarding damages to human, environment and other living beings due to intentional or unintentional, authorised or unauthorised experiment

This paper was prepared for the 'National Consultation on Cartagena Protocol on Biosafety: Issues before MoP-2', organised by the Research and Information System for Developing Countries and held in New Delhi, May, 2005. I thank Dr. Sachin Chaturvedi and other participants of the workshop for their comments and Ms. Diana Joseph for her able research assistance.

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or use of technology. These concerns surface in view of the opening up of agriculture for international trade through which trading of Living Modified Organisms (LMOs) or Genetically Modified Organisms (GMO) could take place. India is party to the Convention on Biodiversity and has signed and ratified the Cartagena Protocol on Biosafety (CPB) in January 2001 and is therefore committed to the safe handling of GMOs. The CPB provides a broad framework on biosafety, exclusively focussing on the transboundary movements of LMOs. The Indian biosafety policy as of now focuses on zealously detailed scientific considerations about the various testing procedures of GMOs prior to the open environment release/in-house research and testing (Department of Biotechnology available at http://www.dbtindia.nic.in/thanks/biosafetymain.html). A meticulously set up regulatory framework is in charge of implementing the biosafety regulations in the country.

Considering the research on a number of genetically modified food and other commercial crops undertaken both in the public and private sector in India, it is essential that the biosafety policy of India be 'reshaped' focusing on the socio economic aspects along with scientific aspects. Since a sizeable population in India is dependent on agriculture, which is linked to the monsoon and availability of appropriate material inputs, including seeds, the farmers would try any new technology introduced to improve the yield and returns as it happened during the green revolution days. However, the adverse impact of the green revolution namely, mono-cropping, loss of local cultivars or land races, imbalances in soil nutrients and excessive use of fertilisers and pesticides, have affected the soil productivity and the returns to agriculture. The damage caused has gone beyond repair in certain regions. Crop failures due to poor quality seeds or ineffective pesticide sprays on the pest are common which have led to farmers committing suicide in certain places of the country. However, there are limited cases in which the person/company responsible for the failure was legally tried and was made to pay compensation. Therefore, when India opened up the agriculture sector for international trade, many genetically modified organisms could enter the country either in the form of food or materials that can be used as a source of production. In this brief write up, we draw a socio-economic framework that may be taken into consideration when the government is considering the open release of GMOs as a source material for cultivation.

Socio-Economic Framework of Biosafety

The labeling requirement designed and adopted by different countries can be considered as a first step taken by the countries in the social framework of biosafety. Such labeling requirement gives the ethical right to the consumers to know and decide whether they should consume materials containing GMOs. The labeling requirement arises from the fact that there is a possibility of harm from GMOs, which could be categorised as serious irreversible harm, avoidable harm and likely harm (*to humans and environment)*. Hence countries resort to monitoring, labeling, bans, phase-outs, pre-marketing testing, setting goals *and standards for* degree of protection, reduction of hazard, prevention of and contamination of GM with non GM material, etc. The degree of protection adopted by different countries is presented in Table 1. Basically, this table outlines the global initiatives of different countries regarding labeling of GM crops and food. The EU requires mandatory labeling and has a threshold tolerance level of 1 per cent (majority of EU members comply with the EU standards) **(** EU Directive on Food Safety available at http://europa.eu.int/comm/food/fs/ifsi/eupositions/tffbt/tfbt_ec-comments_cl0127_en.pdf and European Legislation on GMO's, available athttp://gmotraining.jrc.it/docs/Session01.pdf). In the United States labeling is voluntary. Most Asian countries have signed and ratified the Biosafety Protocol, but do not have any specific regime on labeling. A majority of African countries on the other hand are still developing their biosafety regulatory framework and have banned GM food until the passing of the biosafety legislation. In this context it may be worth mentioning that Swaziland, Lesotho and Mozambique accepted GM food but Zambia, Malawi and Zimbabwe were reluctant to receive GM food aid from USA. These governments refused the food aid on the grounds of possible health and environmental effects. Another issue of concern is that of contamination of crops. Eventually under international pressure, USA sent 30,000 tons of non-GM food aid to that region (Clapp,2006).

Australia and New Zealand have identical labeling requirements for food with greater than 1 per cent GM ingredients (Baumeller, 2004, *Report of the Royal Commission on Genetic Modification*, 2002). One implication that emerges from this Table is that the labeling condition is perhaps related with the level of development of the country.

As far as India is concerned, though, the Indian regulatory framework is process based whereby the process of arriving at the GMO

Table 1: Comparison of Worldwide Regulations Concerning GMOs:

Country	Labeling Requirements	Ban or Moratorium on Commercialization	Ban on Imports
AFRICA			
Algeria		Dec 2000: Ministerial Order prohibits the import, distribution, commercialization and utilization of GM plant material	Dec 2000: Ministerial order prohibits the import, distribution and utilization of GM plant material
Benin		April 2002: 5 year moratorium on import, commercialization and use of GMOs and their products	April 2002: 5 year moratorium on import, commercialization and use of GMOs and their products
Sudan			May 2003: The govt issued a memorandum that food aid be GM-free; under pressure from USAID,the memorandum waiver has been extended until June 2005
Zimbabwe			May 2002: Govt rejected GM food aid.No GMOs are currently allowed into the country except milled maize
ASIA			
China	Jan 2002: Decree No 10 of the ministry of Agriculture. www.agri.gov.cn(Chinese)		
Indonesia	1996 Food Law contains regulations regarding Labelings, however yet to be implemented. www.deptan.go.id/english		

Table 1 continued

Table 1 continued

Country	Labeling Requirements	Ban or Moratorium on Commercialisation	Ban on Imports
Japan	March 2003: Food Sanitation Law and Japan Agricultural Standards Law www.maff.go.jp		
Korea (South)	March 2002: Regulated by the Ministry of Agriculture & Forestry and the Korea Food and Drug Administration. www.maf.go.kr		
Saudi Arabia	Dec 2001 Saude Ministry of Commerce Decree no 1666. www.commerce.gov.sa/english (under construction)		
Taiwan	Feb 2001 : Dept of Health No 0900011746		
Thailand	2002: Public Health Ministry Announcement		
EUROPE:			
European Union	April 2004: EU requires all foods and ingredients produced from GMOs to be labeled, except adventurous levels upto 0.9% of those GMOs currently approved in the EU	Sept 8: European Commission approves the first GE seeds for purchase and planting, marking the end of a nearly 6 year de facto moratorium.	May 19 2004:EC vote to allow imports of Bt 11 maize ending the moratorium in place since 1998.

Table 1 continued

Table 1 continued

Country	Labeling Requirements	Ban or Moratorium on Commercialisation	Ban on Imports
Austria	EU Compliant	Between 1997-2000: Banned 3 varieties of GM maize using the safeguard clause in EU legislation.	Between 1997-2000: Banned 3 varieties of GM maize
France	EU Compliant	Nov 1998: France banned 2 varieties of GM rapeseed	Nov 1998: France banned 2 varieties of GM rapeseed
Georgia		April 1996: Ban on GM import and cultivation until legislation created.	April 1996: Ban on GM import and cultivation until legislation created.
Greece	EU compliant	Sept 1998: A variety of GM rapeseed banned	Sept 1998: A variety of GM rapeseed banned
Germany	EU Compliant	March 2000: Banned a variety of GM maize Jan 2005: Genetic Engineering Act came into force; does not ban cultivation outright however, makes GM farmers liable for contamination and dissuades use of GM crops.	March 2000: Banned a variety of GM maize
Hungary	EU Compliant	Jan 2005: Temporary measure banning import, production, use and distribution of MON 810 maize seeds (EU approved crop)	Jan 2005: Temporary measure banning import, production, use and distribution of MON 810 maize seeds (EU approved crop)
Italy	EU Compliant	Feb 2005: Italian Parliament replaced the 2000 ban on GM food, feed and cultivation with a co-existence law that allows each region to set its own rules. Not a ban. However, most regions have said they want to remain GE free	

Table 1 continued

Table 1 continued

Country	Labeling Requirements	Ban or Moratorium on Commercialisation	Ban on Imports
Luxembourg	EU Compliant	Feb 1997: Banned a variety of GM maize	Feb 1997: Banned a variety of GM maize
Norway	Oct 1997: Products containing GM material are labeled if the modified component contains more than 2% of the ingredient	No ban, however Norway is a member of the European Economic Agreement and is obligated to follow EU food safety standards. Despite this, Norway has the authority to reject any EU approved GMO and has done so 8 times. Currently only non-food crops (tobacco and carnations) are approved for marketing	
United Kingdom	EU Compliant	2001: EU banned the cultivation of GM sugar beet	
SOUTH AMERICA			
El Salvador	1999: National Strategy for BiologicalDiversity allows experimentalPlanting of biotech cotton but does notPermit the planting of other biotechCrops		
Mexico	April 2003: Law of Bio safety for Genetically Modified Organisms	1999:Ban on experimentation with corn Oct 2003: De Facto Moratorium on growing GE crops lifted to allow planting for experimental purposes. Feb 2004: Banned commercialisation of GE maize	Feb 2004: Ban on import of GE maize

Table 1 continued

Table 1 continued

Country	Labeling Requirements	Ban or Moratorium on Commercialisation	Ban on Imports
Brazil	2002 Labeling required for products with more than 4% GMOMarch 2004: Food products with greater than 1%GMO must be labeled, except GM Soya. It is unclear if the law apples to imported products www.mj.gov.br/sde/	2000: Ban on cultivation of GE soy 12/1/2005: Provisional measure 223 allows the planting & marketing of GE soy till 31 Jan 2006	Prohibits the entry of Gmo without prior approval
OCEANIA			
Australia	Standard 1.5.2 of the Food Standards Code states that foods greater than 1% GM ingredients must be labeled www.foodstandards.gov.au.		
New Zealand	Standard 1.5.2 of the Food Standards Code states that foods greater than 1% GM ingredients must be labeled www.foodstandards.gov.au.	No ban, however there have been no approved release applications due to strict regulations	No ban, but strict regulations have resulted in any live GMO crops or seeds approved for importation

Source: Centre for Food Safety, Washington D C., February, 2005.

level is scrutinized, the Indian biosafety law on the other hand stops with saying that we need to tread cautiously in matters concerning hazardous materials like GMOs (Department of Biotechnology). In our opinion this should be the guiding force of any GMO research or/ entry of GMOs. For transboundary shipment of goods perhaps these may be sent back if identified appropriately at the entry point itself. But once the GMO is released as in the case of India, what are the options left?

Basically to help those countries which are on the threshold of GM research and use, the Cartagena Protocol (CP) stresses the need to set up a Biosafety Clearing House. The role of BCH is to:

(a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and

(b) Assist parties to implement CP, taking into account the special needs of developing country parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

The BCH is essential for the successful implementation of the CPB. For example, it provides a "one-stop shop" where users can readily access or contribute relevant biosafety-related information. This would assist governments to make informed decisions regarding the importation or release of LMOs. Information in the BCH is owned and updated by the users themselves, thus ensuring its timeliness and accuracy. By allowing easy and open access to key information, the BCH also fosters greater transparency in the implementation of the Protocol and this facilitates effective participation of the public and civil society in the decision-making process. Thus, for countries, which are still evolving an appropriate biosafety framework based on socio-economic considerations, setting up a BCH or being part of the BCH is essential. Presently, the Asia BioNet functions as the BCH of the Asian countries though it is yet to gain its official status. Asia BioNet initially started out as the official website of the Food and Agriculture Organisation-Regional Office for Asia and the Pacific (FAO-RAP) collaboration with the Government of Japan to fund Capacity Building Initiatives in the participating countries. Though the four-year project which started in May 2002 ended in April 2005, the website continues to be the depositary for GM information of all the participating countries. Participating

countries in the Asia BioNet effort are: Bangladesh, China, India, Indonesia, Malaysia, Pakistan, Philippines, Sri Lanka, Thailand, Viet Nam and other selected countries in Asia and the Pacific. Such a BCH would help in providing information on export and import policies and procedures regarding GMOs.

Risk Assessments and Management

Risk assessment and management principles should be the fundamental guiding force of an appropriate socio-economic framework. In the case of GMOs that are used as source material the risks need to be spelt in detail as they will have to take care of the risks that could arise during the handling of GMOs, open release of the same and the after effect of the open release. In this context, Article 26 of CPB directs attention towards, risk assessments that would basically look at the socio-economic impacts on indigenous and local communities (Cartagena Protocol on Biosafety**,** available at http://www.biodiv.org/biosafety/default2.aspx). The Indian biosafety laws also echo the same. Such impacts however need to be defined. In the following paragraphs we detail some of the risk assessment frameworks that are available.

When we talk about the risk assessment and management, it is worth taking a look at the Australian regulatory framework. Though this framework, (described as the Office of the Gene Technology Regulator–OGTR), does not explicitly mention the socio-economic framework, it allows for the assessment and management of two aspects of concern: (a) risk to public health and safety of the people and environment, and (b) non-compliance with the legislation. The frequency and severity of risk to the health and safety of the public and the environmental impacts determine the type of compliance response. A non-compliant activity may by itself represent negligible risk. However, the frequency of non-compliant behavior warrants a different type of compliance strategy. As part of the compliance strategy, the promoter educates his staff and provides information to the government on the GMO activities undertaken in his organisation. Based on this the OGTR conducts spot checks. In case of non-compliance, warning letters, minor penalties, etc. are issued. If the level of non-compliance is still persistent then the intervention of the court is sought. Even after this, if non-compliance is continued then extreme measures like cancellation of license, bans, imprisonments, etc. are resorted to. The OGTR also includes corporate commitment to

documentation on effective risk management and compliance practices together with corporate culture thus enabling organisations and personnel to comply (Risk Analysis Protocol and Monitoring and Compliance Protocol, OGTR, available at http://www.ogtr.gov.au/pdf/moncomp/riskanapro.pdf**).**

The brief outline of the system provided above points to the structure that has been created for the anticipation of risks as well as non-compliance by the promoters of GM technology. A system like the Australia system would be too ambitious for India at this juncture. However, considering the research that is currently being carried out in India both in the private and public sector and the products that could enter the country through the free trade regime, India should take initiatives to set up a similar strong risk assessment and compliance framework. India for instance, has already built in the corporate culture where by Mahyco (the company which has released a GMO in the form of Bt cotton) has been asked to monitor the bollworm infestation in the crop and to undertake studies on the possible impacts on non-target species and report the same to the government.

Presently, there is no established international liability regime for genetically modified crops and hence there exists the major challenge of linking GMOs to liability and redress issues. However, a few countries have considered the impact of GMOs on health and environment and have designed the liability regime based on that (Migues. 2004, Liability and Redress for Damage Resulting from the Transboundary movement of LMO's, 2001 available at http://www.biodiv.org/doc/meetings/bs/iccp-02/official/iccp-02-03-en.pdf). Hence to that extent this can be considered as the importance given to the socio economic aspects of biosafety.

International laws such as the European Union's Environmental Liability Directive EC, Council Directive 2004/35/CE of 21 April 2004 is not limited to trans-boundary damage alone. The EU Liability Directive covers the environmental damage caused by GMOs and is based on the *polluter pays* principle. The directive's narrow definition of environmental damage however includes damage to protected species and natural habitats, and land contamination that creates the significant risk of adversely affecting human health and the land productivity. The possible harmful effects that could occur outside the protected habitats are not covered. The directive does not confer protection for all potential damages; it is significant that it recognises

the release of GMOs as a possible activity leading to environmental harm (European Union, Regulations and Directives on GMO's, 2005 available at http://binas.unido.org/binas/regulations/EUdirectives.pdf).

The Nigerian Guidelines impose strict liability for any harm, injury or loss caused directly or indirectly by GMOs and it is specified that the harm encompasses personal injury, damage to property and financial loss (Nigeria Biosafety Guidelines, 2001). The German Act, 1993 (amended in June 19 2004) covers broad areas of private damage and liability (German Act, 1993). It includes damage to health and property and the recent amendment includes detailed heads of financial damage (*New Zealand Law Commission Report*, 2002). Three scenarios were outlined for possible compensation with a clear socio economic focus: one, contamination leading to a crop being prevented from entering the market (and thus could affect the economic returns earned by the farmer); two, contamination inducing a genetically modified labeling requirement (which could affect the trade prospects) and three, contamination destroying an *organic* distinction and thus may prevent organic cultivation in future.

The Chinese regulations are distinct from others and include economic loss as one of the items for claiming compensation. The Chinese regulation is unique because it contains a damage threshold and provides redress only for those damages that cause *great economic loss*. Unfortunately the threshold quantifier of *great* is not defined (Chinese Genetic Regulation, 1996).

The above discussion highlights that there are some elements of socio economic consideration in the biosafety framework of different countries. The bottom line is the damage to health and economic loss. With this background, a few observations are made in this section on the experience of open release of GMO, namely the Bt cotton, for commercial cultivation in India since 2002. These are known as the Mech 12, Mech 162 and Mech 184 cotton variety. The original Bt gene invented by Monsanto is patented in the US. This technology was licensed to MAHYCO, an Indian seed company which commercialised the above mentioned three varieties after conducting field trials for a period of three years which ended in 2005. In 2005 two more companies namely, Rasi seeds and Ankur seeds were given permission to release their varieties. The MAHYCO varieties were reviewed based on their performance and were given approval for sale for two more years. However, due to an unsatisfactory performance of the varieties in Andhra

Pradesh, the Mech 12, 162 and 184 have been withdrawn and new varieties of Mahyco have been introduced. Both the Mahyco and the Rasi seeds have been priced at around Rs.1600 for a packet of 450 grams.

The following are some of the observations based on the performance of the Bt cotton in different parts of India.

Observations from the Field

Yield Differences

Performance of the GMO released so far has not been consistent in terms of yield and economic returns, though the same varieties were released in other states. Generally the performance of Bt seeds had been better in the irrigated than in unirrigated areas. In Gujarat for instance, Mech 12 did not perform well, whereas in Andhra Pradesh Mech 162 was a failure. The farmers in any case did not get any compensation from the company though they had bought the seeds from authorized sources.

Further there are wide differences between the results obtained by studies sponsored by the company, independent researchers and NGOs as indicated in Table 2. In the absence of a uniform methodology adopted by these studies it is difficult to comment on the results. Yet from some of the independent research that has been done, it emerges that the new technology has not reduced the cost of cultivation and the yield increase reported in a few places seems to have been offset by the increase in the seed cost incurred by the consumers.

Price Impact

The price of the approved seed is relatively higher than the conventional and the hybrid seeds at Rs.1600,[1] whereas the unapproved variety is sold at half the price of the approved seeds. Both Gujarat and Andhra Pradesh states witnessed a widespread cultivation of the unofficial variety. Thus, in a way the higher price of the officially released seeds has also led to the spread of the unofficial seeds.

There are confirmed reports from almost all cotton growing parts of the country about the spread of the unofficial hybrid variety, which evidently contains the GMO. The first and foremost issue here is that, this variety cannot be recalled. This strikes a serious note in the context of unofficial and indiscriminate crossing of Bt cotton with other cotton varieties, which could develop resistance sooner than what, is expected. This needs to be looked at in the context of the declining popularity of

Table 2: Performance of Bt Cotton in Selected States

State	Reduction in Bollworm pesticide		Yield Increase		Increase in net profit	
	%	Rs.	%	Quintal per acre	%	Rs. Per acre
Andhra Pradesh	58	1856	24	1.98	92	5138
Karnataka	51	1184	31	1.36	120	2514
Maharashtra	71	1047	26	1.48	66	2388
Gujarat	70	1392	18	1.20	164	3460
MP	52	889	40	2.2	68	3876
All India Weighted average	60	1294	29	1.72	78	3126

Source: AC Neilson survey 2004.

the local varieties. It emerges from the State of Gujarat that since the release of both the official and unofficial Bt varieties, the sales of the state seed corporation, which sells conventional, and hybrid varieties, have reduced considerably which indirectly indicates the decline in popularity of the local varieties. It is not clear whether the farmers if and when they decide to cultivate the old varieties, can do so. Or would there be difference in the performance?

Refuge Compliance

One of the biosafety measures supposed to be adopted by the farmers was the cultivation of refuge, whereby 20 per cent or five rows of non-Bt cotton is supposed to be cultivated around the Bt plot which will serve as the host for the bollworms that could affect the Bt cotton. Evidence from the GIDR survey[2] and the Andhra Pradesh experience shows that not every body had complied with the refuge criterion (perhaps studies could be done on the extent of damage and resistance with and without refuge). The potential impact of all the refuge violations are not immediately visible. This is perhaps one of the reasons why the policy makers turn a blind eye or take mild action if at all.

Impact of the spread of the unofficial variety

The illegal crossing of the varieties also forewarns what kind of plant protection can be offered for any new variety that is developed in India or brought from elsewhere. It is also not clear what impact the GM cotton has had on the neighbouring field or the soil nutrients. Evidence from the field shows that soil testing is not done very frequently. A few farmers reported that they undertake soil testing on their own as they realised that their soil has turned hard after they started using GM cotton (GIDR survey). The Centre for Sustainable Agriculture's study (2005) done in Andhra Pradesh shows that (which however needs further investigation) farmers who cultivated chilli in the land that was used for Bt cotton cultivation in the earlier year got poor yields compared to others who did not cultivate Bt.

Other Issues in Bt cultivation

It is a matter of debate that had the Bt gene been introduced in the variety that is found suitable for the region then would there be difference in the results? But now for this lapse in the research, can the company be held responsible and liable to pay compensation to the

farmers, or should the government be held responsible for allowing these seeds uniformly in all the regions?

Further, the question of using farm-saved seeds is an important aspect of Indian agriculture. In the case of hybrid cotton varieties, the seeds loose their vigour after one or two cultivations. In the case of GM cotton also, it is not effective after the second use, which makes the farmers depend on the market which could affect their livelihood. In the absence of appropriately defined formal credit sources, farmers fall prey to informal credit sources.

Importantly, GM cotton has also entered the food chain in the form of cottonseed oil and cattle feed. Since the labeling requirement is not followed in India, many consumers may not even be aware of this aspect. This is an ethical issue as consumers are not aware of it.

These broad observations on different aspects of Bt cultivation suggest that in the absence of appropriate data on the socio economic framework/consideration, the government can not take appropriate decision on whether a new technology of the nature of GMO can be used as a source material. Hence, in the future before any further release of GMO is undertaken the government should ascertain some of the facts based on the following indicators to educate the farmers and diffuse the technology appropriately among the main stakeholders, namely, the farmers.

- Accessibility of the technology across different land holdings. Can farmers with different size holdings access this technology? Does the technology necessitate any prior knowledge or awareness for effective use?
- Will the specific characteristics of the technology like the price of seeds or the safe adoption measures prescribed lead to exclusion of certain classes of farmers from adopting GM technology?
- Have the farmers observed any impact on health such as poisoning, nausea, skin irritation, headache, temperature etc?. What kind of pesticides do the farmers use and what are the implications of using such pesticides? Also, did they lose income or man days due to their illness?
- Whether there is any difference in the health of cattle on farms where GM is used and those that were fed the by products of cotton.
- Has adoption of GM technology resulted in increased income realisation across different size holdings or increased income disparity?

- Does the new technology lead to displacement of labour? Are there any differences in the wages given to the farm workers between the GM and non GM farms.
- Has there been any difference in the employment created in the GM farm by gender?
- Are the consumers aware of the fact that since the farmers do not segregate the GM and non-GM cotton varieties in the yard, the GM residues, if any, could have entered the food directly and through the food chain? If so, what are the likely impacts?
- Have the farmers observed any difference in the material inputs requirement in the GM and non-GM farm? In other words does the use of new technology lead to increase in yield or reduction in use of the material inputs such as pesticides, fertilisers or water requirements?
- Can the technology be used in the rain fed region also? Or does it require irrigated conditions. Alternatively will there be yield differences between the irrigated and rain fed regions?
- Since the farmers routinely use the farm saved seeds for cultivation, is it possible to use the farm saved seeds for further production? Or will it lead to increased reliance on markets?
- Can the refuge criterion be complied with? If so, what are the mechanisms of monitoring? If not what is the alternative?
- Could there be differences in the yield due to adhering or non-adhering to the refuge criterion?
- If the farmers have experienced crop failure after they adopted GM, were they compensated by the company? Were there any form of security available to them?
- Will or/has there been any difference in the market price of these two varieties? At alternate price levels what could be the adoption rate and benefits?
- Could introduction of a few uniform varieties in different regions affect the bio-diversity in that place?
- If there is a need to separate the GM and non-GM crop, what are the cost implications for the farmers and is it feasible?
- Has there been a decline in the use of other varieties that were traditionally used by the farmers after the introduction of GM cotton?
- Have the farmers observed or undertaken any soil testing measures after they adapted GM cotton?

- What would be the cost of creating awareness among the farmers and the cost of monitoring of the same for safe and sustainable use of technology?
- Will the agency diffusing technology provide all credit and material input support? How expensive is the technology to adopt. Does it require, the setting up of a specialised credit system, etc?

Some of these issues clearly drive home the message that there has to be continuous follow up of the GMO once it is released and that information flow from the field level to the higher authorities in charge of regulation should also be continuous.[3] Both these are very essential to take a rational decision on whether India needs to continue research on the entry of GMO as a source material. It is now known widely that many of the states where GM cotton was released did not have a State Biotechnology Coordination Committee and where it was set up the officials hardly knew what they were supposed to do. This highlights the urgent need for capacity building at different levels of regulatory framework and among the different stakeholders/or users of the technology.

Whenever a new seed is released by the public sector, it goes through a routine process of seed certification after the research stations of the state agricultural universities report on the said seed. After this, the extension workers under the Training and Visit programme, who have adequate information about the new seeds visit and train the village-level workers. The village-level workers contact the farmers and explain the salient features of the new variety and motivate them to adapt the new variety. However, the scope of public extension workers is limited to the public sector seeds only.

The private sector has its own method in spreading information about their seeds — at the district level they have area managers and dealer networks up to the taluka level. At the village level, they have agriculture graduates or diploma holders who provide information about the seeds and the other features and the public sector is not in the picture at all. However, in the case of GM cotton in India, the technology has been introduced by the private sector, but since the technology is different the government had to intervene in terms of providing clearance and approval for diffusion of the same. The GM seeds are developed by the private sector. Therefore, the question is whether the government should leave the entire responsibility of performance evaluation from the fields to the company itself or should

it intervene and collect information periodically about the performance of the variety to get correct information/remedial measures. This is because, the public extension system mainly works for the public sector seeds/programmes, it appears there is very little information about the new seed technology. On the other hand, the private company's extension service had also served a very limited purpose.

Therefore, in the interest of the larger community, it is essential that the government steps in and sets up a public private partnership. This partnership should strengthen the (a) monitoring and extension mechanism, and (b) emphasise thecapacity building aspect of those field level functionaries. Capacity building of the field level functionaries and the link between the government/company and farmer, is important so that there should be an unhindered flow of information on the salient features of the technology and the appropriate method of cultivation. This public-private partnership would not only be useful for minimising the risks in the case of GMO that has already been released, but it would also be helpful in strengthening/laying down strong principles.

The setting up of an effective regulatory regime that incorporates all these aspects could be highly resource draining at least in the initial stages but would lead to lesser risks in the future. On the other hand, if the government does not have the regulation in place, it could lead to more risks.

Perhaps in the case of agricultural GMOs like the present GM cotton in India, greater weightage should be given to strengthening the field level functionaries who could present important information on the performance, health and environmental impact of the GMO. If this could function along with an effective public-private partnership in reaching the ultimate consumers of GMO, perhaps avoidable risks like compliance with the refuge mechanism, failure of an approved variety which is the reason for farmers options for unapproved seeds, and the indiscriminate crossing of the varieties could have been prevented/minimized. More importantly, the said benefits of the approved variety, namely the reduced use of pesticides could have been experienced. As the farmers have not been properly explained the technology, the refuge criterion is not complied with and the excess use of pesticides on the cotton continues. The Indian case presents a situation where this important link with the farmer

and the aspect of capacity building has been completely missed out. Capacity building of the ground level functionaries would prove to be helpful in identifying the risks if any and passing of this information to the higher authorities that can plan risk management mechanisms and also in identifying the faulted person/persons in fixing compensation.

Conclusion

The above discussion indicates that Indian biosafety measures should take the socio-economic issues into consideration. Since more yield enhancing and pest controlling GMOs could be introduced in the future, the social and economic impact that GMOs could leave on the ultimate consumers should be seriously thought of. For instance in case of failure of technology who will pay and how the compensation will be paid? In this context, a lesson or two can be learnt from the Andhra Pradesh model. Since the early 2000, companies selling seeds here have to enter into a memorandum of understanding with the state government. In the event of seed failure, such a company will be directed to pay compensation to the farmers. Mahyco was also held liable for the failure of the crop in the Warrangal region[4] where it was asked to pay a huge compensation. However, the company has gone to the court. The Indian Plant Variety Protection Act states that where any propagating material of a variety registered under this Act has been sold to a farmer or a group of farmers or any organization of farmers, the breeder of such variety shall disclose to the farmer or group of farmers or organization of farmers as the case may be the expected performance under 'given conditions'. If such propagating material fails to provide such performance under such given conditions, the farmer or group of farmers or organization of farmers may claim compensation in the prescribed manner before the authority. The authority after hearing both the parties may direct the breeder of the variety to pay compensation to the farmer or the group of farmers. However, both the Andhra Pradesh model and the plant protection route would be helpful only for those farmers who have taken seeds from authorised sources selling authorised or certified seeds. But the problem for India is that a lot of seeds are circulating. In the case of failure of these seeds who would be held responsible?

The underlying argument is that a technology such as the GMO has a high potential to benefit the developing countries if applied

carefully. But inadequate knowledge and improper diffusion could lead to the improper use of technology by which the potential of the technology is lost for short-term gains. As mentioned earlier, the adverse impacts of the green revolution are emerging now which are not rectified yet. Before that we have opened the doors for another technology. Now at least in order to realise the potential impact of the technology and sustainable use of the same, adequate safety measures based on the socio-economic considerations should be set up and complied with.

Endnotes

1 In May 2006, the Monopolies Trade Restrictive Practices Commission based on the point raised by the Government of Andhra Pradesh has imposed price control on Bt cotton seeds by which the price of a 450 gram packet has been reduced to Rs.750.

2 Survey conducted among the cotton cultivating farmers in selected districts in Gujarat, by Gujarat Institute of Development Research in 2002 and 2004.

3 The present regulatory framework prevailing in India indicates a top-down approach and stops at the District level Committee. Such an approach necessitates that the reverse order flow of information from the district to the central government has to be there to ensure that bio safety regulations are complied with and GMOs are monitored for their safety and performance considerations.

4 Private communication with seed sellers in Hyderabad.

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