Bt COTTON IN INDIA

A STATUS REPORT

Asia-Pacific Consortium on Agricultural Biotechnology
(APCoAB)
C/o ICRISAT, NASC Complex, Dev Prakash Shastri Marg, Pusa Campus
New Delhi - 110 012, India

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FOREWORD

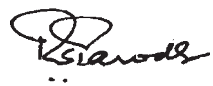
The Asia-Pacific Consortium on Agricultural Biotechnology (APCoAB) was established in 2003 under the umbrella of the Asia-Pacific Association of Agricultural Research Institutes (APAARI) – an initiative of the Food and Agriculture Organization that has been promoting appropriate use of emerging agri-technologies and tools in the region. APCoAB's mission is "To harness the benefits of agricultural biotechnology for human and animal welfare through the application of latest scientific technologies while safeguarding the environment for the advancement of society in the Asia-Pacific region".

The last decade has witnessed tremendous advances in the application of biotechnology for crop improvement. APCoAB has been documenting achievements in agricultural biotechnology that have led to improvements in crop productivity and farm incomes in the Asia-Pacific region. The first approval of Bt cotton cultivation in India was granted in the year 2002. Over the last four years, 20 Bt cotton hybrids, presently covering an area of approximately 1.3 million hectares, have been commercialized. Twenty additional Bt hybrids approved in April 2006 would be available to farmers during the next cotton-growing season. This Status Report on Bt Cotton in India gives details of the events that led to approval of the first Bt cotton hybrids, performance of the commercialized hybrids under experimental as well as farmer managed conditions, and the economic benefits realized from the adoption of Bt technology. Based on the experiences gained, strategies have been suggested for achieving improved pest resistance in cotton, revised protocol for large-scale field trials and better economic benefits especially to small and marginal farmers.

This report, an in-house effort of APCoAB, has been prepared by Dr. J. L. Karihaloo, Coordinator, Dr. R. K. Arora, ex-Consultant and Dr. Vibha Dhawan, ex-Coordinator, APCoAB. We acknowledge the help of several scientists, science managers and policy makers in preparing this report. Especially, we express our gratitude to Mr. Raju Barwale, Managing Director, Maharashtra Hybrid Seed Co., Mumbai, Dr. T. V. Ramniah, Director, Department of Biotechnology, Government of India, Dr. B. M. Khadi, Director, Central Institute for Cotton Research, Nagpur, Dr. P. Anand Kumar, Principal Scientist, National Research Centre on Biotechnology, New Delhi, and Mr. B. Choudhary, National Coordinator, ISAAA, South Asia Office, New Delhi for providing important information on research and development of

Bt cotton. We place on record our appreciation for Dr. James Clive, Chairman, ISAAA for permitting the use of information and photographs from their reports in this publication. Our thanks are also due to Dr. (Mrs.) Manju Sharma, ex-Secretary, Department of Biotechnology, Government of India and Dr. S. R. Bhat, Principal Scientist, National Research Centre on Biotechnology, New Delhi for their valuable comments on the manuscript.

It is hoped that this publication will be of use to the scientists, research managers, policy makers and the general public in the developing NARS of the Asia-Pacific region who are interested in the application of biotechnology. The experiences narrated in this report should help in evolving suitable systems of research, testing and commercialization of transgenic crops for sustainability, productivity, greater food security and poverty alleviation, while safeguarding the concerns of biosafety and environmental protection. We are pleased that this is the second Status Report being brought out by APCoAB, the first being on "Bt Corn in Philippines".



(R.S. Paroda)
Executive Secretary
APAARI

CONTENTS

1. INTRODUCTION

Cotton cultivation in India covers an area of approximately 9 million hectares representing about one quarter of the global area of 35 million hectares under cotton (Sen, 2005). Cotton is planted by 4 million small farmers and involves many more in processing, textile manufacture and trade. However, the average yield of cotton, 440 kg/ha, is far below the world average of 677 kg/ha and the production is only about 16% (4.13 million tonnes) of the world production of 26.19 million tonnes (Table 1). Main losses in cotton production are due to its susceptibility to about 162 species of insect pests and a number of diseases (Manjunath, 2004; Table 2). Among the insects, cotton bollworms are the most serious pests of cotton in India causing annual losses of at least US$300 million. The cotton bollworm complex comprises, American bollworm, also called 'false America bollworm' or 'old world bollworm', *Helicoverpa armigera*; pink bollworm, *Pectinophora gossypiella*; spiny bollworm *Earias insulana* and spotted bollworm, *Earias vittella. Spodoptera litura*, the leaf worm, is mainly a foliage feeder but it also damages cotton bolls. Insecticides valued at US$660 million are used annually on all crops in India, of which more than half are used on cotton (Manjunath, 2004). Cost of the 21,500 metric tonnes (active ingredient) of insecticides used on cotton in India in 2001 was US$340 million. Further, the most destructive pest, *Helicoverpa armigera,* is known to have developed resistance against most of the recommended insecticides (Kranthi *et al.,* 2001; Ramasubramanyam, 2004) forcing farmers to apply as many as 10-16 sprays. Incorporating insect resistance has, thus, been the most important objective of cotton improvement efforts in India. However, no sources of resistance to bollworm are available in cotton germplasm or its near relatives.

In India, the efforts to harness genetic engineering technology for bollworm resistance in cotton began in 1990s with the import of genetically modified (GM) cotton and initiation of research programmes in national laboratories. At present, 40 cotton hybrids having gene for bollworm resistance have been approved for commercial cultivation. The gene (*cry*) sourced from the soil bacterium *Bacillus thuringiensis* (Bt) subspecies *kurstaki* produces a protein toxic to bollworm, thus providing resistance to the plants and significantly reducing the need for chemical insecticides.

This report prepared by Asia-Pacific Consortium on Agricultural Biotechnology (APCoAB), a programme operating under the umbrella of Asia-Pacific Association for

Table 1. Estimated cotton production and consumption during 2004-05 in major cotton–producing countries of the world

Country	Production (million tonnes)	Consumption (million tonnes)
China	6.31	8.38
United States	5.06	1.41
India	4.13	3.26
Pakistan	2.46	2.34
Brazil	1.28	0.91
Uzbekistan	1.13	—
Turkey	0.90	1.52
Others	4.92	5.81
World Total	**26.19**	**23.63**

Source: Sen, 2005.

Table 2. Some major insect pests of cotton

Borers	Foliage feeders	Sap feeders
American bollworm	Leaf worm	Leaf hopper
Pink bollworm	Leaf roller	Aphid
Spiny bollworm	Semilooper	Whitefly
Spotted bollworm	Leaf perforator	Thrips
Stem weevil	Ash weevil	Red cotton bug
Shoot weevil	Surface weevil	Dusky cotton bug
Stem borer	Hairy caterpillar	Striped mealy bug
	Red hairy caterpillar	Black scale
	Cotton grasshopper	White scale
	Tobacco budworm	Yellow star scale
		Tea mosquito bug

Source: CICR, 2006.

Agricultural Research Institutes (APAARI), has attempted to provide the current status of research and commercialization of Bt cotton, the first commercialized GM crop in India. It is based on the reports emanating from both the public and private sectors. Opinions expressed by different Civil Society Organizations (CSOs) have also been included to present a broad spectrum of available information on the topic.

2. NATIONAL REGULATORY MECHANISM

Genetically modified crops are expected to play an important role in improving agricultural production and economic betterment of farmers. It is also recognized that the GM technology may entail rare unintended risks and hazards. Accordingly, Government of India has adopted a policy of careful assessment of the benefits and risks of GMOs at various stages of their development and field release to ensure biosafety. The rules governing the handling of GMOs and products thereof were notified in 1989 under Environment (Protection) Act 1986 (EPA) and guidelines issued subsequently (Ghosh, 2001; http://www.envfor.nic.in/divisions/csurv/geac/notification/html). Two nodal agencies, Ministry of Environment and Forests (MoEF) and Department of Biotechnology (DBT), Ministry of Science and Technology are responsible for implementation of the regulations. There are six Competent Authorities to handle various issues, viz. Recombinant DNA Advisory Committee, Institutional Biosafety Committee, Review Committee on Genetic Manipulation, Genetic Engineering Approval Committee, State Biotechnology Coordination Committee and District Level Committee. In general, these authorities are vested with non-overlapping responsibilities.

Recombinant DNA Advisory Committee (RDAC): This committee is constituted by DBT to monitor the developments in biotechnology at national and international levels. RDAC submits recommendations from time to time that are suitable for implementation for upholding the safety regulations in research and applications of GMOs and products thereof. This committee prepared the first Indian Recombinant DNA Biosafety Guidelines in 1990, which were adopted by Government of India for handling of GMOs and conducting research on them. The guidelines were revised in 1998 (http://dbtindia.nic.in/thanks/biosafetymain.html and http://www.envfor.nic.in/divisions/csurv/geac/biosafety.html).

Institutional Biosafety Committee (IBSC): This committee is constituted by organizations involved in recombinant DNA (r-DNA) research. It has the mandate to approve low-risk (Category I and II) experiments and to ensure adherence to r-DNA safety guidelines. IBSC recommends category III or above experiments to Review Committee on Genetic Manipulation (RCGM) for approval. It also acts as a nodal agency for interaction with various statutory bodies.

Review Committee on Genetic Manipulation (RCGM): This committee is constituted by DBT to review all ongoing projects involving high-risk (Category III and above) and controlled field experiments. RCGM approves applications for generating research information on transgenic plants. Such information may be authorized to be generated in contained green house as well as in small plots. The small experimental field trials are limited to a total area of 20 acres in multi-locations in one crop season. In one location where the experiment is conducted with transgenic plants, the land used should not be more than 1 acre. RCGM approval is granted for one season and applicant must provide entire details of the experimentation to the committee. Monitoring of field trials is carried out by Monitoring-cum-Evaluation Committee of RCGM. The latter also directs the generation of toxicity, allergenicity and any other relevant data on transgenic materials in appropriate systems. RCGM can lay down procedures restricting or prohibiting production, sale, importation and use of GMOs. It also issues clearances for import/export of etiologic agents and vectors, transgenic germplasm including transformed calli, seed and plant parts for research use only.

Genetic Engineering Approval Committee (GEAC): This committee functions as a body in MoEF and is responsible for environmental approval of activities involving large-scale use of GMOs in research, industrial production and applications. Large-scale experiments beyond the limits specified within the authority of RCGM are authorized by GEAC. GEAC can authorize approval and prohibitions of any GMOs for import, export, transport, manufacture, processing use or sale.

State Biotechnology Coordination Committee (SBCC): This committee, constituted in each state where research and application of GMOs are contemplated, has the authority to inspect, investigate and take punitive actions in case of violations of the statutory provisions. The committee also nominates state government representatives in the committee constituted for field inspection of GM crops.

District Level Committee (DLC): This committee is constituted at the district level to monitor the safety regulations in installations engaged in the use of GMOs in research and applications. The District Collector heads the committee who can induct representative from state agencies to enable the smooth functioning and inspection.

The overall mechanism and functional linkages among various committees and departments concerned with the approval of GM crops for commercial release are illustrated in a flowchart (Fig. 1).

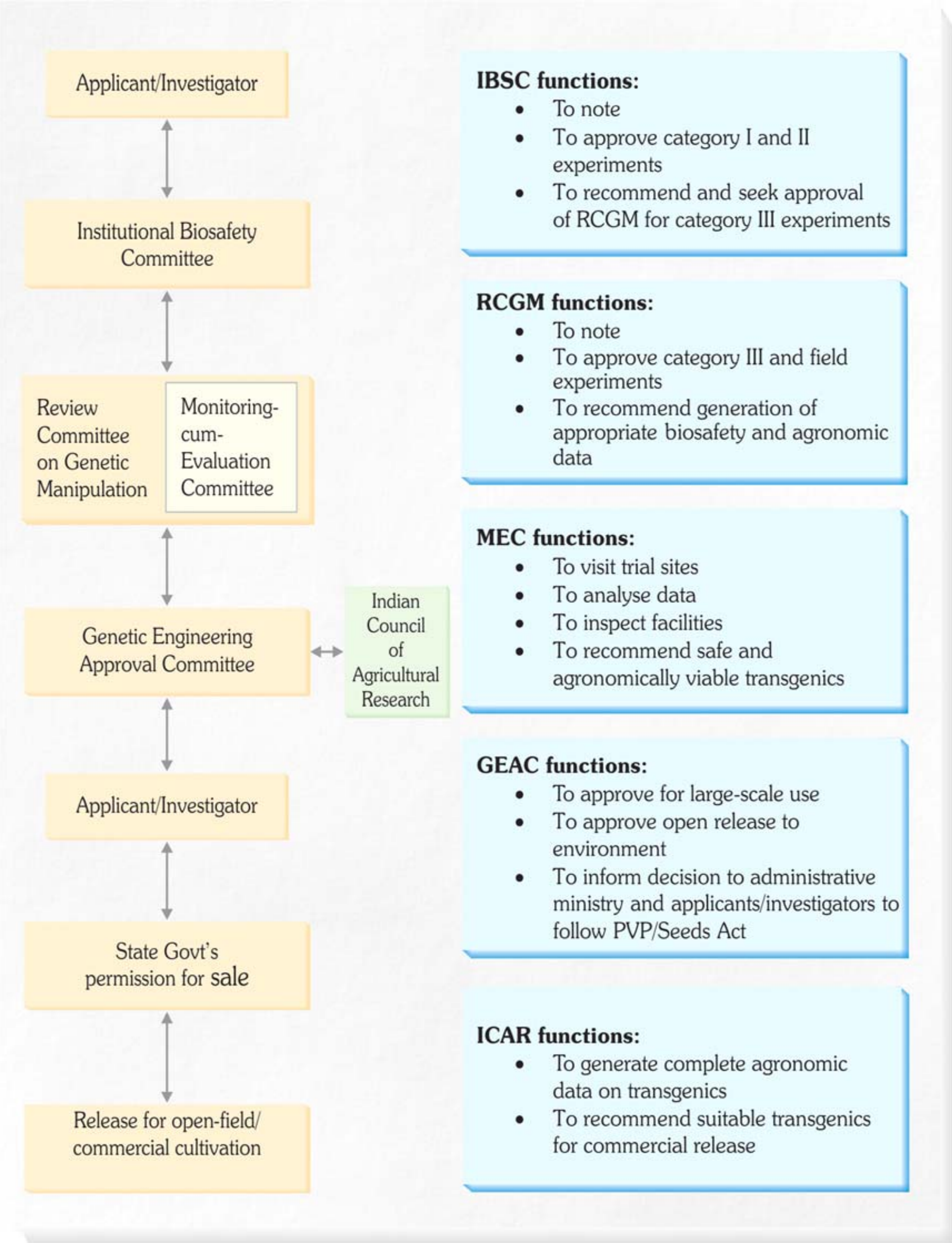


Fig. 1. Procedure of approval of GM crops for commercial release. (Modified from Sharma et al., *2003).*

3. DEVELOPMENT AND COMMERCIALIZATION OF Bt COTTON

The first approval for commercial cultivation of Bt cotton in India was granted to three cotton hybrids, MECH-12 Bt, MECH-162 Bt and MECH-184 Bt developed by Mahyco (Maharashtra Hybrid Seed Co.), a leading seed company (Barwale, 2002; Jayaraman, 2002). The insect resistance in these hybrids was introgressed from Bt containing Cocker-312 (event MON531) developed by Monsanto, USA, into parental lines of Mahyco's propriety hybrids.

Technology Involved

The core genetic engineering experiments which culminated in development of insect-pest resistant cotton (Bt cotton) were conducted by Monsanto, USA and comprised isolation of gene from *Bacillus thuringiensis* and its further development to ensure its expression in the fully grown plant. The plasmid construct comprised:

- The *cry1Ac* gene, which encodes for an insecticidal protein, Cry1Ac.
- The 35S promoter from *Cauliflower mosaic virus* that drives expression of the *cry1Ac* gene in all parts of the plant leading to the production of Bt protein.
- The *nptII* gene, the selectable marker, which encodes the enzyme neomycin phosphotransferase II (NPTII). It is used to select transformed cells/plants on media containing the antibiotic kanamycin.
- The *aad* gene which encodes the bacterial selectable marker enzyme 3"(9)-O-aminoglycoside adenyltransferase (AAD) and allows selection of bacteria containing the Cry1Ac plasmid on a medium containing spectinomycin or streptomycin.

Cotton tissue cultures (variety Cocker-312) were infected with the soil bacterium, *Agrobacterium tumefaciens* containing the plasmid with the above sequences. The transformed cotton lines were screened to identify those with desirable insect control and agronomic performance.

Chronology of Events

Following several years of field trials with Bt cotton, based on the recommendations of RCGM, GEAC in its 32nd meeting on 26 March, 2002 approved the commercial cultivation of three Bt cotton hybrids: MECH-12 Bt, MECH-162 Bt and MECH-184

Bt (Barwale *et al.*, 2004; http://www.envfor.nic.in/divisions/csurv/geac/bgnote.html). The sequence of events that led to the development and approval of these is listed below:

1996: After obtaining permission from DBT, Mahyco imported 100 g of Cocker-312 seed containing the *cry1Ac* gene from Monsanto, USA. Crossing with Indian cotton breeding lines to introgress *cry1Ac* gene was carried out and 40 elite Indian parental lines were converted for Bt trait.

1996-1998: Greenhouse, risk-assessment studies and limited field trials (1 location) were conducted using Bt cotton seeds from converted Indian lines for pollen escape studies, aggressiveness and persistence studies, biochemical analysis, toxicological studies and allergenicity studies

1998-1999: Multi-location field trials were conducted at 40 locations in nine states to assess agronomic benefits and biosafety.

1999-2000: Field trials repeated at 10 locations in six states.

July 2000: GEAC gave approval for conducting large-scale field trials on 85 ha and also to undertake seed production on 150 ha.

2001: Large-scale field trials were conducted covering 100 ha. Field trials were also conducted by All India Coordinated Cotton Improvement Project of the ICAR.

2002: GEAC approved three Bt cotton hybrids for commercial cultivation after taking into account the data on their performances.

Trial Results

Mahyco conducted the following biosafety, risk management and field performance trials on the Bt hybrids submitted for approval of GEAC. These studies were carried out in the laboratories and experimental fields designated by RCGM/GEAC. Besides, the socio-economic impact of Bt cotton cultivation was also assessed.

Biosafety Assessment

(i) Studies on Environmental Safety

Mahyco got the following studies conducted at a number of scientific institutes as per the protocol approved by RCGM.

- *Pollen escape/out-crossing:* Multi-location experiments conducted in 1996, 1997 and 2000 revealed that out-crossing occurred only up to two meters, and only 2% of the pollen reached a distance of 15 m. As the pollen is heavy and sticky, the range of pollen transfer is limited. The studies concluded that there is essentially no chance that the *Bt* gene will transfer from cultivated tetraploid species such as the present Bt hybrids to traditionally cultivated diploid species.

- *Aggressiveness and weediness:* To assess the weediness of Bt cotton, the rate of germination and vigour were compared with non-transformed parental lines by laboratory test and in soil. The results demonstrated that there were no substantial differences between Bt and non-Bt cotton for germination and vigour. Hence, there is no difference between Bt and non-Bt cotton with regard to their weediness potential.
- *Effect of Bt on non-target organisms:* Studies conducted during the multi-location field trials revealed that the Bt cotton hybrids did not have any toxic effects on the non-target species, namely sucking pests (aphids, jassids, whitefly and mites). The population of secondary lepidopteran pests, namely tobacco caterpillar remained negligible during the study period in both Bt and non-Bt hybrids. The beneficial insects (lady bird beetle and spiders) remained active in both Bt and non-Bt varieties.
- *Presence of Bt protein in soil:* Studies were conducted to assess the possible risk of accumulation of Bt protein in the soil, by insect bioassays. Bt protein was not detected in soil samples indicating that the Cry1Ac protein was rapidly degraded in the soil in both the purified form of the protein and as part of the cotton plant tissue. The half-life for the purified protein was less than 20 days. The half-life of the Cry1Ac protein in plant tissue was calculated to be 41 days which is comparable to the degradation rates reported for microbial formulations of Bt.
- *Effect of Bt protein on soil microflora:* Studies were conducted to evaluate any impact of Bt protein leached by roots of Bt cotton on the soil microflora. There was no significant difference in population of microbes and soil invertebrates like earthworms between Bt and non-Bt soil samples.

(ii) Studies on Food Safety

For evaluating food safety, the studies conducted included: compositional analysis, allergenicity studies, toxicological studies, presence of Bt protein in Bt cotton seed oil, and feeding studies on cows, buffaloes, poultry and fish. Salient results of these studies are as follows:

- *Compositional analysis:* Studies revealed that there was no change in the composition of Bt and non-Bt cotton seeds, with respect to proteins, carbohydrates, oil, calories and ash content.
- *Allergenicity studies:* Allergenicity studies were conducted on Brown Norway rats. No significant differences in feed consumption, weight gain and general health were found between animals fed with Bt and non-Bt cotton seed. At the end of the

feeding period, the relative allergenicity of traditional cotton hybrids and Bt cotton were compared to Bt and non-Bt protein extract in active cutaneous anaphylaxis assays. Results of the study concluded that there was no significant change in endogenous allergens of Bt cotton seed compared to non-Bt cotton seed.

- *Toxicological study:* A goat feeding study was conducted for understanding the toxicological effects of Bt cotton seed. The animals were assessed for gross pathology and histopathology. No significant differences were found between animals fed with Bt and non-Bt cotton seed.
- *Presence of* Cry1Ac *protein in Bt cotton seed oil:* Studies have indicated that Cry1Ac protein was not found in refined oil obtained from Bt cotton seeds.
- *Feeding studies on cows, buffaloes, poultry and fish:* The feeding experiments using Bt cotton seed meal were conducted at National Dairy Research Institute, Karnal, on lactating cows; Department of Animal Nutrition, College of Veterinary Sciences, G.B. Pant University of Agriculture & Technology, Pantnagar, on lactating buffaloes; Central Avian Research Institute, Izatnagar, on poultry and Central Institute of Fisheries Education, Mumbai, on fish. These experiments indicated that Bt cotton seed meal was nutritionally as wholesome and safe as the non-Bt cotton seed meal.

Risk Management

Pest populations exposed to Bt crops continuously for several years may develop resistance to the Bt toxin through natural mutation and selection. To prevent resistance build-up, it is recommended to plant sufficient non-Bt crops to serve as a refuge for Bt-susceptible insects. Growing 20% non-Bt cotton in the periphery of Bt cotton as refuge and taking necessary control measures against bollworm in the refuge crop as and when required has been found to be adequate (Ghosh, 2001). The refuge strategy is designed to ensure that Bt-susceptible insects will be available to mate with Bt-resistant insects, should they arise. Available genetic data indicates that susceptibility is dominant over resistance (Tuli *et al*., 2000). The offsprings of these matings would most likely be Bt-susceptible, thus mitigating the spread of resistance in the population.

Other Safeguards

Baseline Susceptibility Study

Project Directorate of Biological Control, Bangalore, carried out baseline-susceptibility study of *Helicoverpa armigera* to Cry1Ac protein in 1999 and 2001. Geographical populations of *H. armigera* collected from nine major cotton-growing states of India, viz. Punjab, Haryana, Rajasthan, Madhya Pradesh, Gujarat, Maharashtra, Andhra Pradesh, Karnataka and Tamil Nadu were exposed to insecticidal protein Cry1Ac through bioassays. LC_{50} (mean lethal concentration) ranged from 0.14 to 0.71 and LC_{90} from 1.02 to 6.94 μg of Cry1Ac/ml of diet (Jalali *et al.,* 2004). The median molt inhibitor concentration MIC_{50} ranged from 0.05 to 0.27, and MIC_{90} from 0.25 to 1.58 μg of Cry1Ac/ml of diet. The effective concentration (weight stunting related) EC_{50} ranged from 0.0003 to 0.008 and EC_{90} from 0.009 to 0.076 μg Cry1Ac/ml of diet.

Confirmation of the absence of "Terminator Technology"

As per requirements, molecular detection test in the Bt cotton hybrids was performed for *cre* recombinase gene which is an integral component of the so called "terminator technology". The study was carried out by the Department of Genetics, University of Delhi (South Campus), Delhi. The PCR analysis of DNA samples isolated from individual seedlings derived from Bt cotton hybrids showed that these lines were positive for *Cry1Ac* genes but did not contain *cre* sequence. This conclusively demonstrated the absence of "terminator gene" in Bt cotton hybrids.

Field Performance and Socio-economic Impact

On the recommendation of RCGM, two sets of replicated field trials were conducted in 1998-99 to test the performance of the three Bt hybrids, MECH-12 Bt, MECH-162 Bt and MECH-184 Bt. In addition, ICAR conducted multi-location field trials in 2001 on these hybrids especially to make a cost benefit analysis of Bt cotton. Detailed results of these studies are given in Chapter 4. In brief, the results proved the effectiveness of Bt technology in reducing bollworm infestation and the number of insecticide sprays, and increasing cotton yields and net incomes.

Conditions Stipulated by GEAC

The approval given to three Mahyco Bt hybrids for commercial release was accompanied by 15 conditions as listed in Annexure I. MoEF also reserved the right to stipulate additional conditions and the right to revoke the approval, if the implementation of the conditions was not satisfactory.

Hybrids Approved

Till date, 40 Bt cotton hybrids developed by 13 seed companies have been approved for commercial cultivation (Table 3) after going through a similar process of GEAC approval as prescribed for the three Mahyco hybrids. All the hybrids, except four, have the Monsanto-Mahyco Bt technology (event MON531) that has been sublicensed to the respective seed companies (Rao, 2005; http://www.envfor.nic.in/divisions/csurv/geac/geac-65.pdf). JKCH-1947 Bt and JK Varun Bt contain *cry1Ac* event 1 developed by Indian Institute of Technology, Kharagpur while NCEH-2R Bt and NCEH-6R Bt contain fusion genes *cry1Ab*/*cry1Ac* from China. The hybrids released up to 2004 were approved for cultivation in Central and South Zones while in 2005, six Bt hybrids were for the first time approved for cultivation in North Zone. Zone-wise, 14, 24 and 9 hybrids are presently approved for growing in North, Central and South Zones, respectively.

Table 3. Bt cotton hybrids approved by GEAC for commercial cultivation

Hybrid	Year	Zone	Company
ACH-33-1Bt, ACH-155-1 Bt	2006	Central	Ajeet Seeds
Ankur-09 Bt	2005	Central	Ankur Seeds
Ankur-651 Bt	2005	North and Central	Ankur Seeds
Ankur-2534 Bt	2005	North	Ankur Seeds
Brahma BG	2006	Central	Emergent Genetics
GK 205 Bt	2006	Central	Ganga Kaveri Seeds
JK Varun Bt	2006	Central	JK Seeds
JKCH-1947 Bt	2006	North	JK Seeds
MECH-12 Bt*, MECH-162 Bt**, MECH-184 Bt**	2002	Central and South	Mahyco
MRC-6025 Bt, MRC-6029 Bt	2006	North	Mahyco
MRC-6301 Bt	2005	North and Central	Mahyco
MRC-6304 Bt	2005	North	Mahyco
MRC-6322 Bt, MRC-6918 Bt	2005	South	Mahyco
NCEH-2R Bt	2006	central	Nath Seeds
NCS-138 Bt, NCS-913 Bt	2006	North	Nuziveedu Seeds
NCS-145 Bunny Bt, NCS-207 Mallika Bt	2005	Central and South	Nuziveedu Seeds
NECH-6R Bt	2006	North	Nath Seeds
PRCH-102 Bt	2006	Central	Pravardhan Seeds
RCH-2 Bt	2004	Central and South	Rasi Seeds
RCH-20 Bt, RCH-368 Bt	2005	South	Rasi Seeds
RCH-118 Bt, RCH-138 Bt, RCH-144 Bt	2005	Central	Rasi Seeds
RCH-134 Bt, RCH-317 Bt	2005	North	Rasi Seeds
RCH-308 Bt, RCH-314 Bt	2006	North	Rasi Seeds
RCH-377 Bt	2006	Central	Rasi Seeds
Tulasi 4 Bt	2006	Central	Tulasi Seeds
VICH-111 Bt	2006	Central	Vikki Agrotech
VICH-5 Bt, VICH-9 Bt	2006	Central	Vikram Seeds

*Discontinued from South Zone. **Not approved for Andhra Pradesh.
North Zone: Haryana, Punjab and Rajasthan. Central Zone: Gujarat, Madhya Pradesh and Maharashtra. South Zone: Andhra Pradesh, Karnataka and Tamil Nadu.
Source: Choudhary, 2005; DBT, 2006; http://www.envfor.nic.in/divisions/csurv/geac/geac-65.pdf

Commercial Cultivation

Following the approval of GEAC, commercial cultivation of Bt cotton was undertaken during 2002 in six states in India: Andhra Pradesh, Gujarat, Madhya Pradesh, Karnataka, Maharashtra and Tamil Nadu (Barwale *et al*., 2004). The three Bt hybrids approved for cultivation covered a total area of 0.038 million hectares in this year (Table 4).

Table 4. Area in hectares under commercial cultivation of Bt cotton hybrids during 2002

State	Area under Bt hybrids (ha)			Total (ha)
	MECH-12	MECH-162	MECH-184	
Andhra Pradesh	44	5,564	-	5,608
Gujarat	76	4,136	4,642	8,854
Madhya Pradesh	60	404	1,756	2,220
Karnataka	-	3,828	80	3,908
Maharashtra	112	9,300	5,334	14,746
Tamil Nadu	-	2,042	660	2,702
Total	**292**	**25,274**	**12,472**	**38,038**

Source: Barwale *et al.*, 2004.

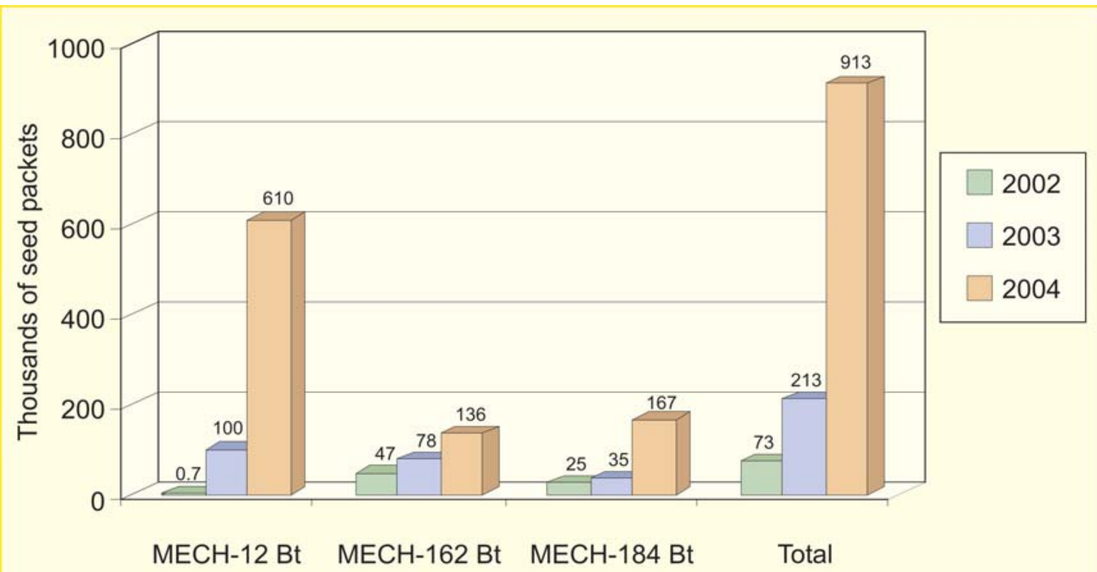


Fig. 2. Year-wise sale of 450 g seed packets of Bt cotton hybrids MECH-12 Bt, MECH-162 Bt and MECH-184 Bt

Source : DBT, 2006.

The seed companies are required to submit to GEAC the yearly sales figures of Bt cotton seed in different states. The seeds are sold in packets containing 450 g Bt seed and 120 g of non-Bt seed, sufficient to plant one acre of Bt cotton and required refuge. According to the figures available with DBT, the year-wise sale of 450 g seed packets of the three MECH Bt hybrids released in 2002 increased from 73,000 to 913,000 in 2004 (Fig. 2). The release of 17 other Bt hybrids during 2004 and 2005 and the first approval for cultivation of Bt hybrids in North India vastly increased the opportunity for farmers to adopt Bt technology. The number of Bt cotton seed packets sold in 2005 was 3.1 million accounting for an area of 1.26 million hectares (Table 5). The latter comprises 14% of the 9 million hectares under cotton cultivation in India.

Table 5. Year-wise cultivation of Bt cotton hybrids

Year	Seed packets sold*	Area covered (million ha)
2002	72,682	0.29
2003	213,098	0.86
2004	1,326,134	0.55
2005	3,102,067	1.26

**Source:* DBT, 2006.

Among the nine states in which Bt cotton was cultivated, Maharashtra, Andhra Pradesh, Gujarat and Madhya Pradesh were leading with 49.7%, 18.1%, 11.8% and 11.4% of the national Bt cotton acerage, respectively (Fig. 3). Central Zone showed the highest adoption of Bt cotton followed by South and North Zones (Fig. 4).

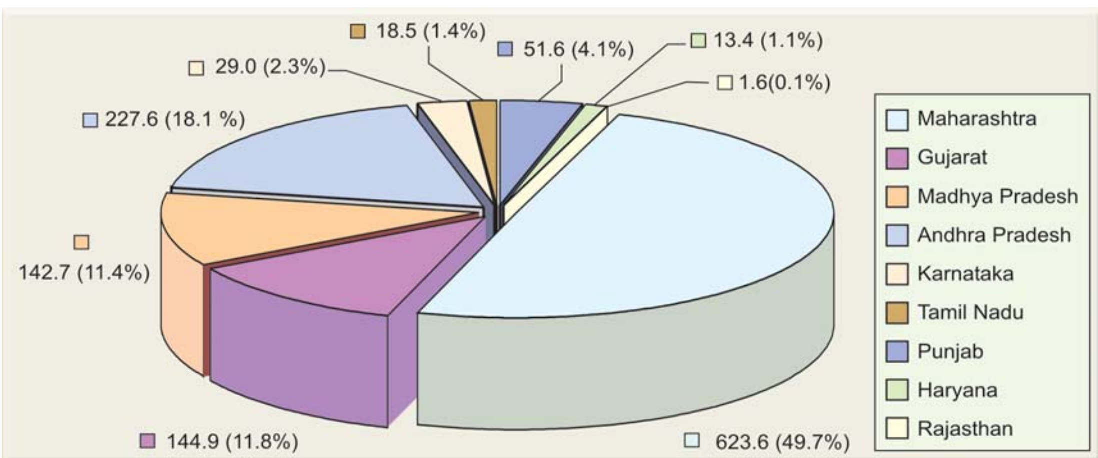


Fig. 3. State-wise area covered (thousand hectares) under Bt cotton during 2005.
Source of basic data: DBT, 2006.

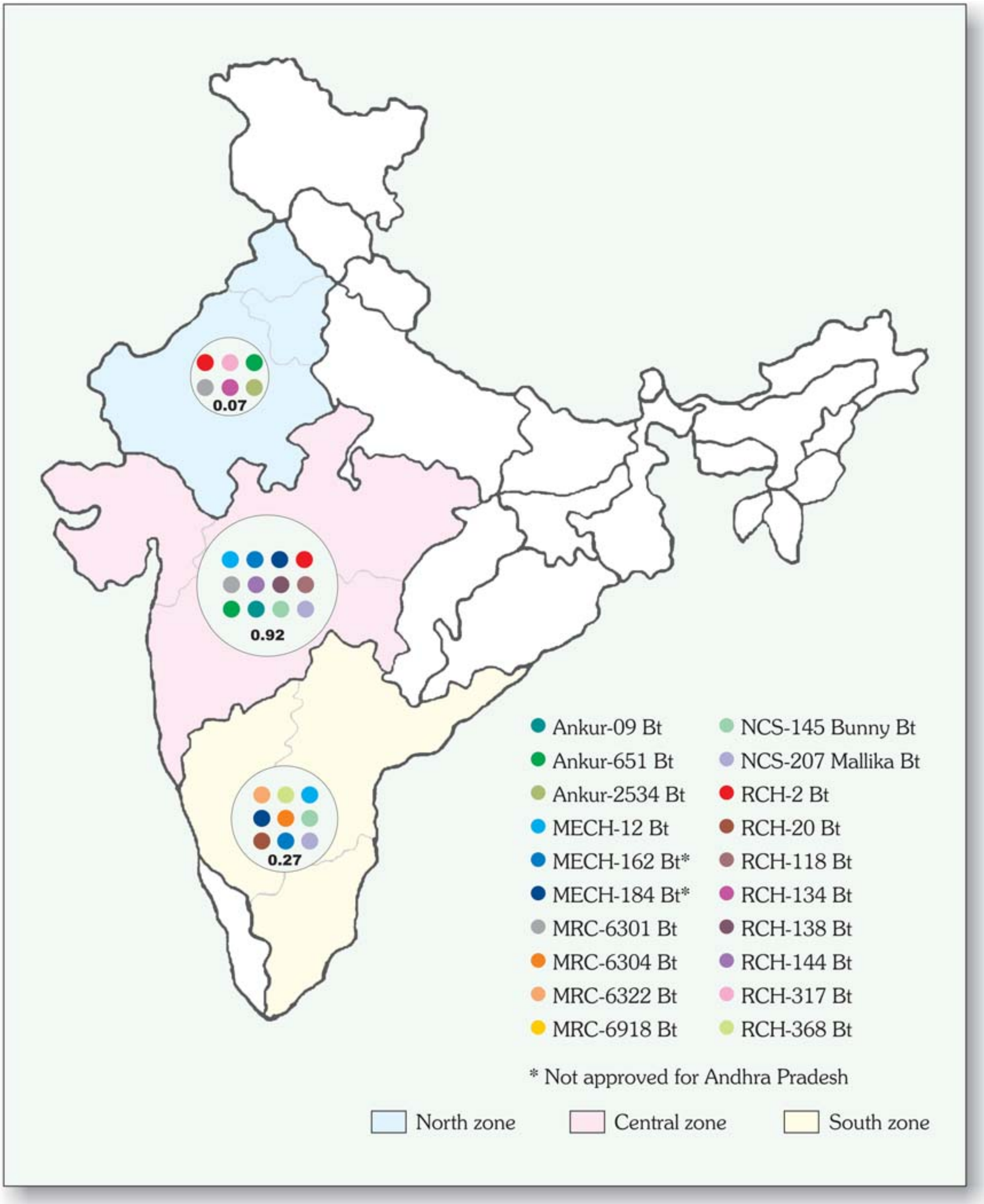


Fig. 4. Bt cotton hybrids under commercial cultivation during 2005 in three cotton-growing zones of India. Figures in circles represent area in million hectares under Bt cotton in each zone.

4. PERFORMANCE OF Bt COTTON

Several studies have been made on field performance of Bt cotton in India, initially by the seed companies as a part of the approval procedure of RCGM and GEAC and later by research scientists/organizations as independent studies or by CSOs. The first section presents results of studies either monitored by RCGM and GEAC or carried out by research scientists/organizations.

Two sets of field experiments were conducted by Mahyco in 1998-99 under the monitoring of RCGM. In one set, MECH-12 Bt, MECH-162 Bt and MECH-184 Bt along with their non-Bt counterparts were tested in replicated field trials at 15 sites in nine states while in the other set, one Bt and one non-Bt hybrid along with check were tested on large plots at 25 sites under typical farm conditions. Results of the first set of experiments indicated a 40% higher yield of Bt hybrids (14.64 q/ha*) over their non-Bt counterparts (10.45 q/ha) (James, 2000). Further, there was a significantly lower incidence of bollworm damage to fruiting bodies in Bt hybrids (2.5% at 61-90 days from planting) than in non-Bt hybrids (11.4% at 61-90 days from planting).

The large-plot field trials at 21 sites (4 trials were damaged) yielded similar results with Bt hybrids showing 37% (range 14% to 59%) higher yield over their non-Bt counterparts (Table 6). The overall pesticide requirement for controlling bollworm was reduced considerably.

Table 6. Results of Bt cotton field trials conducted by Mahyco at 21 sites during 1998-99

State	Number of locations	Yield q/ha			Number of sprays		
		Non-Bt	Bt	Check	Non-Bt	Bt	Check
Andhra Pradesh	6	9.63	11.98	8.68	3	0	3
Gujarat	2	24.91	38.89	28.45	7	1.5	7
Haryana	1	12.42	15.83	9.06	4	0	4
Karnataka	3	10.01	13.62	9.20	3	0	3
Madhya Pradesh	2	14.20	20.30	14.04	2	1	2
Maharashtra	6	17.22	22.30	18.44	4	1	4
Tamil Nadu	1	3.70	10.12	4.40	4	0	4
Average		**13.59**	**18.61**	**13.75**	**4**	**0.5**	**4**

Source of basic data: Naik, 2001.

*Quintals (100 kg) per hectare

The data generated from the above detailed multi-location tests were analysed by Naik (2001) to assess the potential economic advantage of Bt cotton in India. The results showed that there was 78.8% increase in the value due to yield and 14.7% reduction in pesticide cost with the growing of Bt cotton as compared to non-Bt cotton (Table 7). When compared with the prevalent farmers practices, the benefit from Bt cultivation increased to 110%. Taking into account the additional cost of Bt seeds, the farmer would still get more than 70% greater benefits. The author further opined that the reduction in expenditure on pesticides would adequately compensate for the seed/technology cost increase. Hence, the total cost of cultivation of Bt cotton would not increase making it possible for even small farmers to adopt the technology.

Table 7. Economic benefits of Bt cotton as estimated from 1998-99 field trials conducted by Mahyco

Item	Value of the yield increase over non-Bt (per ha)	Value of reduced pesticide over non-Bt (per ha)	Total benefit over non-Bt (per ha)	Benefit over farmer practices (per ha)
Average of six states	Rs 11,554.7 (US$262.6)*	Rs 2,148.9 (US$48.8)	Rs 13,703.6 (US$311.4)	Rs 16,126.6 (US$366.5)
% over average net return	78.8	14.7	93.5	110.0

Source of basic data: Naik, 2001; *Rs 44 = 1 US$.

ICAR conducted multi-location field trials in 2001 on the three Mahyco Bt hybrids specifically to make a cost benefit analysis of Bt cotton. Yield increases over local check and national check were recorded to the magnitude of 60% to 92% (ISAAA, 2002) and gross income showed a 67% advantage from average Rs 14,112 (US$320.7)/ha in local and national check to average Rs 23,604 (US$536.5)/ha in the Bt hybrids. After adjusting the additional cost of Bt hybrid seed the net economic advantage of Bt cotton ranged between Rs 4,633 (US$105.2)/ha and Rs 10,205 (US$231.9)/ha (ISAAA, 2002, Table 8).

In a widely quoted article, Qaim and Zilberman (2003) reported the results of data collected from 157 farms in 25 districts of Maharashtra, Madhya Pradesh and Tamil Nadu growing three Mahyco Bt hybrids along with their counterparts and a local check as a part of RCGM recommended trial. On average, Bt hybrids received three times less sprays against bollworm than non-Bt hybrids and local checks (Bt, 0.62; non-Bt, 3.68; local check, 3.63). The number of sprays against the sucking pests was, however, same among the three. Insecticide amounts on Bt cotton were reduced by about 70% both in terms of commercial products and active ingredients. More interestingly, the article reported higher average yield of Bt hybrids exceeding those

Table 8. Performance of Bt cotton hybrids in ICAR field trials

Variety/hybrid	Yield q/ha	Gross income/ha		Insecticide cost/ha		Additional cost of Bt seed/ha		Net income/ha	
		Rs	US$	Rs	US$	Rs	US$	Rs	US$
MECH-12 Bt	11.67	21,006	477.4	1,727	39.3	2,425	55.1	16,854	383.0
MECH-162 Bt	13.67	24,606	559.2	1,413	32.1	2,425	55.1	20,768	472.0
MECH-184 Bt	14.00	25,200	572.7	1,413	32.1	2,425	55.1	21,362	485.5
Local check	8.37	15,066	342.4	2,845	64.7	—	—	12,221	277.8
National check	7.31	13,158	299.1	2,001	45.5	—	—	11,157	253.6

Source of basic data: ISAAA, 2002.

of non-Bt counterparts and popular checks by 80% and 87%, respectively. Analysis of the results showed that the general germplasm effect was negligible and the yield gain was largely due to Bt gene itself. The authors further argued that the expected yield effects of pest-resistant GM crops would be high in South and Southeast Asia and Africa and medium to low in developed countries, China and Latin America. In India, the pest damage in 2001 was about 60% in conventional trial plots whereas in USA and China, estimated losses in conventional cotton due to insect pests amounted to only 12% and 15%, respectively.

The above study was criticized in two subsequent articles (Arunachalam and Bala Ravi, 2003; Sahai, 2003) on the argument that the study sites chosen did not cover the entire spectrum of cotton-growing areas in India, the data collection and analysis were faulty and that the reported yield effect of Bt gene was scientifically untenable.

Bennett *et al.* (2004) presented an assessment of the performance of Bt cotton under typical farmer-managed conditions. Unlike previous studies, it analysed commercial field data rather than trial plot data collected in Maharashtra from 9,000 farmers' plots in 2002 and 2003. The study met the recommendations of FAO (2004) for market-based studies that would accurately reflect the agronomic and economic environments faced by growers. Over both the seasons, the number of sprays required to control sucking pests (aphids and jassids) was similar for Bt and non-Bt plots. However, the number of sprays required for bollworm was much lower for Bt plots (1.44 for Bt versus 3.84 for non-Bt during 2002 and 0.71 for Bt versus 3.11 for non-Bt during 2003). There was a corresponding reduction of 72% and 83% in 2002 and 2003, respectively, in expenditure. However, when balanced with higher cost of Bt cotton seed, the results showed higher average costs for Bt cultivation compared to non-Bt cultivation (15% and 2% in 2002 and 2003, respectively). The real benefit came from the higher yield of cotton in Bt plots; in 2002, the average increase in yield for Bt over non-Bt was about 45% while in 2003 this was 63%. Taking into account the seed cost and variable cotton prices, the results showed a much higher gross margin for Bt growers [(Rs 50,904/ha) (US$1,156.9)] than for non-Bt growers [(Rs 29,279/ha) (US$665.4)] during 2003.

Bambawale *et al*. (2004) reported performance of MECH-162 Bt along with non-Bt MECH-162 and a conventional variety/hybrid under integrated pest management (IPM) in farmers' participatory field trials conducted in Maharashtra. Under IPM, 11.5% of the fruiting bodies were damaged in MECH-162 Bt compared to 29.4% in conventional cotton and 32.88% in non-Bt MECH-162. Population of sucking pests was also lower in MECH-162 Bt. Seed cotton yield in MECH-162 Bt (12.4 q/ha) was much higher than that of non-Bt MECH-162 (9.8 q/ha) and conventional cotton (7.1 q/ha). Net returns after taking into account cost of production and protection were Rs 16,231/ha (US$368.9) in MECH-162 Bt, Rs 12,433/ha (US$282.6) in non-Bt MECH-162 and Rs 10,507/ha (US$238.8) in conventional cotton.

Notwithstanding the doubts raised by some workers (Arunachalam and Bala Ravi, 2003; Sahai, 2003), the overall finding of above detailed studies establish that Bt cotton has significantly lower infestation of bollworms compared to non-Bt cotton leading to fewer number of sprays required for bollworm control. The reduced pest infestation is also associated with higher cotton yields, a major factor contributing to economic advantage of Bt cotton in India (Figs. 5-10).

Other Reports: In 2003, ACNielsen ORG-MARG, unit of a Dutch publishing and

Fig. 5. Bt cotton hybrid MRC-6304 Bt laden with bolls.
Source: Mahyco.

Fig. 6. Field view showing MRC-6304 Bt (left) and non-Bt cotton (right). Note the prominently higher boll retention in the Bt hybrid.
Source: Mahyco.

Fig. 7. Non-Bt cotton being sprayed for pest control.
Source: ISAAA.

Fig. 8. Spotted bollworm damaged cotton boll from the field shown on the left.
Source: ISAAA.

information group, conducted a survey of more than 3,063 farmers in Andhra Pradesh, Madhya Pradesh, Maharashtra, Gujarat and Karnataka growing Bt and non-Bt cotton (ACNielsen ORG-MARG, 2004). The survey revealed that due to control of bollworm, on an average Bt crop had an increase in yield by 29% and reduction in pesticide sprays by 60% as compared to non-Bt cotton. The net profits thus accrued averaged Rs 7,724(US$175.5)/ha). In this survey, 90% of the Bt cotton growers and 42% of the non-Bt growers expressed their intention to purchase Bt cotton seeds in 2004.

Gene Campaign conducted a survey of 100 farming families in Maharashtra and Andhra Pradesh growing both Bt and non-Bt cotton (Sahai and Rahman, 2003). The survey reported that: (i) Bt cotton yields were 15% lower than that of non-Bt cotton, (ii) Bt cotton was of lower quality in terms of length and strength of fibre, and (iii) the average net returns from Bt varieties were lower than those from non-Bt varieties.

Mahyco made a survey of the performance of their three Bt hybrids, MECH-12 Bt, MECH-162 Bt and MECH-184 Bt grown on over 1,000 farmers' fields in five states after their release in 2002 (Barwale *et al*., 2004). Yields of Bt hybrids (average 13.25 q/ha) were higher by an average of about 30% over non-Bt hybrids. Further, there was significant decrease in the number of insecticide sprays (from an average of 3.10 to 1.17) associated with the use of Bt cotton. These two factors added to the total economic benefit providing an average additional income of more than Rs 18,000(US$409.1)/ha for Bt compared to non-Bt cotton.

Deccan Development Society and AP Coalition in Defense of Diversity conducted a three year study (2002-03 to 2004-05) in four cotton-growing districts of Pradesh, viz. Adilabad, Kurnool, Nalagonda and Warangal covering 440 farmers growing Bt and non-Bt cotton under irrigated and rainfed conditions (Qayum and

Fig. 9. Bountiful yield from Bt cotton.
Source: ISAAA.

Fig. 10. Harvested Bt cotton being marketed.
Source: ISAAA.

Sakkhari, 2005). The study concluded that: (i) on small farms under rainfed conditions, Bt cotton yielded nearly 30% less than non-Bt, (ii) there was a 7% cost reduction on pesticides with the adoption of Bt, and (iii) the earnings with non-Bt cotton cultivation were 60% more than with Bt cotton cultivation.

Gokhle Institute of Politics and Economics, Pune, conducted comparative study of Bt and non-Bt cotton during Kharif 2003 in two prominent cotton-growing districts of Maharashtra, Yavatmal and Buldhana (Vaidya, 2005a, b). The study involving 150 cotton farmers reported that substantially higher profits (79.2%) were realized from Bt cotton cultivation [Rs 31,880/ha (US$724.5)] compared to non-Bt cotton cultivation [Rs 17,790/ha (US$404.3)]. However, similar returns were not observed under rainfed conditions and the report called for comprehensive study covering the crop under both irrigated and rainfed areas to find out whether Bt cotton can be cultivated without any risk under rainfed conditions. The study further noted complaints of bollworm and other pest disease attacks in Bt cotton.

5. EMERGING CONCERNS

Bt cotton has evoked unprecedented interest and emotion among a large section of Indian public comprising biotechnologists, plant breeders, social scientists, environmentalists and CSOs. The amount of ongoing debate can be gauged from the fact that a Google search for 'Bt cotton in India' generates more than six hundred thousand hits. The present publication is not intended to cover the entire spectrum of opinion expressed on Bt cotton in India. That some of it can be ignored without prejudicing the scientific facts is evident from widely reported incidents of 1998 and 1999 when activists of Karnataka Rajya Raitha Sangha uprooted and burnt experimental plots of Bt cotton on the pretext that they contained 'Terminator technology' and they would cause 'gene pollution' and sterility in surrounding plants (http://www.krrsbtcottonsetafire.8m.com/; Manjunath, 2004). Nevertheless, some genuine concerns have been reported from time to time in popular media and scientific publications. NGOs like Gene Campaign, Centre for Sustainable Agriculture, and Research Foundation for Science Technology and Ecology have been expressing opinions about the performance and desirability of GM crops in general and Bt cotton in particular for Indian agriculture and social environment. Some of the major concerns that have not been covered in earlier chapters are presented below.

Genetic Background

As detailed in Chapter 4, some Bt cotton hybrids have been reported to perform poorly under unirrigated conditions while others have yielded inferior quality cotton staple (Arunachalam and Bala Ravi, 2003; Vaidya, 2005a, b). These observations suggest that the genetic backgrounds in which the *cry* gene was introduced were not the most desirable ones. The need for appropriate genetic background was further highlighted in a recent article (Kranthi *et al.*, 2005) which reported variation in Bt toxin levels among eight commercial Bt cotton hybrids. Since all these hybrids have the same *cry* gene (event MON531 in Cocker-312), the variation in toxin expression has been attributed by the authors to the parental background of the hybrids. They have suggested that the seed companies should evaluate their hybrids critically for highest levels of toxin expression in fruiting bodies. This suggestion could be extended to include the need for critical pre-release evaluation for all economic traits under different agronomic situations so as to ensure high field performance and remunerative prices for the produce.

Concern has also been expressed about the non-availability of Bt technology in true breeding varieties (Sahai, 2005). In order to save seed cost, innocent farmers are using seeds harvested from the F_1 hybrids for planting next crop with disastrous consequences. It is also alleged that even some unscrupulous traders are resorting to this practice (see below). In India, the strategy for Bt incorporation in hybrid cotton has been to transfer the gene into one of the parent lines of F_1 commercial hybrids. Thus, the hybrids are hemizygous for *cry* gene. When seeds from such hybrids are used for planting (i.e. F_2 seeds), 25% of the progeny plants would not carry the gene at all and, hence, would be completely prone to bollworm attack. Thus, the use of farmer-saved seeds gives a mixed stand of resistant and susceptible plants. Other agronomically important traits show similar variation over generations. Comparative studies on "official" Bt hybrids, "unofficial" Bt hybrids (seeds saved by farmers or "illegal" Bt hybrids) and non-Bt hybrids grown in Gujarat state (Morse *et al*., 2005) revealed that the gross margin of "official" Bt hybrids was 132% that of the non-Bt varieties. The first generation "unofficial" seeds were the next best performers in terms of gross margin, followed by second generation "unofficial" seeds.

Low Bt Toxin Level

A recent publication (Kranthi *et al*., 2005) reported a critical minimum level of 1.9 μg/g of toxin in plant tissue to be essential for bollworm mortality. The leaves of Bt cotton were found to have the highest levels of toxin expression followed by squares, bolls and flowers. The toxin expression in the boll-rind, square and ovary of plants was found to be inadequate to confer full protection to the fruiting parts. Cry1Ac expression decreased consistently as the plant aged, the decline being more rapid in some hybrids than others. This report was interpreted by some (Sahai, 2005) as the failure of Bt cotton in India. However, the author of the earlier report published a rejoinder arguing that Bt cotton is the most potent and best available option for bollworm management in the country (Kranthi, 2005). Continuing the debate, Manjunath (2006) opined that since bollworm starts its life cycle in the leaves and the newly hatched larvae feed on chlorophyll in the tender leaves, the presence of high level of Cry1Ac toxin in the leaves ensures the death of a large number of larvae.

Refuge Crop

One of the conditions for environmental release of Bt cotton, which includes commercial cultivation, is that each field of Bt cotton is to be surrounded by a belt of non-Bt cotton of the same variety to serve as a 'refuge' for bollworms. The size of the refuge belt should be either five rows of non-Bt cotton or 20% of total sown area whichever is more. Due to small land holdings, these norms are not followed in practice which could lead to rapid build-up of Bt toxin resistance in bollworm. However, some workers have questioned the need for refuge in the Indian farming situations (Manjunath, 2004, 2005). The author argued that *Helicoverpa armigera*, the most predominant bollworm in India has a large number of alternative hosts like chickpea, pigeonpea, sorghum and tomato which serve as its natural refuge. Further, since at present only about 14% of the cotton area is under Bt hybrids, the rest of the non-Bt crop and other surrounding crops already serve as a refuge.

Genetic Uniformity of Cry Protein and Pest Resistance

All the 20 cotton hybrids under commercial cultivation in India have the same source of resistance to bollworm, *cry1Ac* gene transferred through transformation event MON531 in Cocker-312. The same technology is being utilized by several seed companies for developing new Bt cotton hybrids (PTI, http://www.envfor.nic.in/divisions/csurv/geac/geac-65.pdf). Resistance developed by the insect to protein toxin encoded by this *cry1Ac* gene will make all the hybrids equally susceptible to bollworm and pose a serious threat of widespread breakdown of resistance to the insect. The need for using diverse resistance genes and pyramiding more than one such gene in a hybrid/variety has been emphasised by a number of workers (Krattiger, 1997; Tuli *et al*., 2000).

Illegal Bt Cotton

The high demand for Bt cotton has spawned a parallel industry of unapproved Bt cotton seed which is of dubious origin and quality. In fact, illegal Bt cotton seed was in the market even before the first approval of Bt cotton for commercial cultivation was granted by GEAC (Jayaraman, 2001, 2004b). A recent news report (Sainath, 2005) states that against 90,000 seed packets of legal Bt cotton sold in Yavatmal district of Maharashtra the number of illegal packets sold was 250,000. According to field reports of Research Foundation for Science Technology and Ecology, illegal Bt cotton sold under 32 different names was sown in 2004 season (Sharma, 2005). Not having been approved by GEAC, production, sale and use of such seeds is a violation of rules and liable to punitive action under the EPA period.

Concerned by the reports of illegal Bt cotton being sold in Gujarat, GEAC got ten packets of such seeds tested at Central Institute for Cotton Research, Nagpur, for verification (http://www.envfor.nic.in/divisions/csurv/geac/vrguj.doc). PCR and ELISA tests revealed the presence of *cry1Ac* gene in all the samples. Eight of these were F_1 seeds while two were F_2 seeds, one of the latter also having mixtures.

Intellectual Property Rights Issues

The Plant Variety Protection and Farmers' Rights Act 2001 of India has a crucial provision according to which farmers are allowed to save, use, sell and exchange seeds of a protected variety, the restriction being that the seed cannot be sold under the breeders' registered name (Brahmi *et al*., 2004). The *cry1Ac* MON531 technology for incorporating bollworm resistance in cotton is patented in USA. While the non-Bt hybrid seed is sold at approximately Rs 450 (US$10.2) per 450 g packet, the Bt hybrid seed is sold at Rs 1,500 (US$35.2) to Rs 1,800 (US$40.9) per packet of which Rs 1,250 (US$28.4) is charged towards "trait value" or "technology fees" (Mitta, 2006). Andhra Pradesh government has filed a case under Monopolies and Restrictive Trade Practices Act claiming that the Indian farmers have to pay unusually high rates for the "trait value" of Bt seed. On the other hand, the seed companies claim that the Bt seed saves 4-5 insecticide sprays and gives a higher net profit to the farmer. Recent reports of an agreement on a 30% reduction in "technology fee" of Bt cotton seed is a welcome development (http://www.newkerala.com/news2.php?action=fullnews&id=21312).

Another intellectual property related issue of concern is the restriction imposed on commercialization of "gifted" or "borrowed" *cry* genes. Substantial research has been done in public sector laboratories using "gifted" *cry* genes, but the efforts have not culminated in release of commercial varieties since the genes were available for academic and experimental purposes only and the required authorisation for their commercialization could not be negotiated.

Recommendations of National Commission on Farmers

The National Commission on Farmers headed by Dr M.S. Swaminathan held consultations with farmers on September 22, 2005. Information dated November 19, 2005 posted online by the Indian Society for Sustainable Agriculture provided details of some concerns expressed on Bt cotton. Although none of the farmers reported cases of any health, food or environmentally negative effects of Bt cotton, some expressed concerns about the possible risks. Several farmers emphasized the need for a cautious approach while exploiting GM technology and asked for a science-based pre- and post-release testing and monitoring. The commission recorded that "Inadequate testing under the major cotton-growing agroclimatic conditions is a serious problem." The commission also observed that "Genetic literacy (amongst farmers) has been generally low as most of the Bt cotton farmers grew no refugia and did not provide recommended isolation distances needed for preventing cross-pollination between Bt and non-Bt strains so as to reduce the chances for breakdown of resistance to bollworm in Bt cotton varieties. A general misgiving prevails, may be partly due to aggressive advertisement by seed companies, that the Bt cotton needs no pesticide applications, forgetting that the Bt provides protection (often not 100%) only against bollworms. For controlling other pests, which at times assume serious proportions, such as aphids and whitefly, pesticides will need to be applied as per recommendations." The commission noted that some participants reported failure of Bt cotton due to drought and multiple pest epidemics, while reporting additional net profit of at least about Rs 12,000 (US$272.7) per hectare and about 40% to 50% savings in the pesticide use and in the number of sprays. The commission also expressed grave concern over proliferation of spurious Bt cotton seeds and suggested that in order to curb this trend, "The company must compensate the losses incurred by the farmer." It also suggested insurance cover to be provided along with the sale of GM seeds.

6. OPPORTUNITIES AND THE WAY AHEAD

Bt cotton has been under commercial cultivation in India since 2002. During these four years, the number of Bt cotton hybrids released for cultivation has risen from 3 to 40 and the cultivated area under these hybrids has expanded to approximately 1.3 million hectares. Initially, GEAC had approved Bt cotton cultivation in Central and South Zones. In 2005, approval was granted for cultivation of six hybrids in North Zone, thus providing opportunity to cotton growers from almost the entire country to benefit from Bt technology. During these years of technology demonstration, field verification and commercialization, the feedback received from farmers, members of the monitoring and evaluation teams, officials of the seed companies and state agricultural departments, and NGOs provided important insight into the issues involved in farmers' field level application of this technology. These issues are related to the technology *per se*, field evaluation, performance under different agroclimatic conditions and trade.

Diversifying the insect toxin sources is essential to overcome the possibility of bollworms developing resistance to Cry1Ac toxin as also to incorporate resistance to a wider spectrum of insect pests. This is all the more important since many farmers believes Bt cotton to be indestructible and do not take any protective measures against pests and diseases (Sridharan *et al*., 2006). Worldwide, several microbial genes for pest resistance have been identified and are at different stages of deployment in cotton (Agbios, 2006; Table 8). Event MON531 commercialized as Bollgard© has been followed by Monsanto with event 15985 (Bollgard© II). The latter, having the dual genes *cry1Ac* and *cry2Ab,* is expected to provide growers with broader control over a wide variety of insects like cotton bollworm, fall armyworm, tobacco budworm and pink bollworm (Marchosky *et al*., 2001; Perlak *et al*., 2001). Syngenta Seeds has commercialized COT102 containing *vip3A(a)* gene that imparts resistance, among others, to cotton bollworm, tobacco budworm, pink bollworm and fall armyworm (Agbios, 2006). Chinese Academy of Agricultural Sciences (CAAS) has developed a modified fusion gene, *cry1Ab/cry1Ac,* which has been incorporated in more than ten cotton varieties that are being grown over large areas in China (Dong *et al*., 2004). Further, cowpea trypsin inhibitor gene, *CPTi* with a different mechanism of insect resistance has been stacked with *cry* in cotton varieties by CAAS. In India, the fusion gene has been incorporated in cotton hybrids NCEH-2R Bt and NCEH-6R Bt. Within the Indian public sector, significant progress has been made to develop indigenous genes for deployment in local true breeding cotton varieties. Noteworthy among these is the development of modified *cry1Ac* and *cry1E/C* genes by National Botanical Research Institute, Lucknow, Indian Institute of Technology, Kharagpur, National Research Centre on Plant Biotechnology, New Delhi, Central Institute for Cotton Research, Nagpur, and University of Agricultural Sciences, Dharwar (Anand Kumar, 2004; Khadi, 2006). Transgenics with *cry1Ac* gene have been deployed in Indian cotton genotypes, Bikaneri Nerma, Sahana, Anjali, LRA-5166 and RG-8. Limited field trials have revealed that transgenic lines exhibit significant insect protection. Bikaneri Nerma carrying *cry1Ac* has been crossed with elite cotton genotypes DS-28, Surat Dwarf, Surabhi, Sahana and L761 to develop Bt version of elite varieties of the country. Further efforts are required, particularly in the public sector, to develop insect resistant locally adapted true breeding varieties that could be made available to the farmers at affordable prices.

Table 8. Genes for insect resistance in cotton

Gene	Event	Company/Institute
cry1Ac	MON531	Monsanto Company
cy1Ac and *cry2Ab*	15985	Monsanto Company
cryIF	2581-24-236	Dow AgroSciences
cry1Ac	3006-210-23	Dow AgroSciences
cry1Ac	31807/31808	Calgene
vip3A(a)	COT102	Syngenta Seeds
cry1Ac and *cryF*	DAS-21023-5 x DAS-24236-5	Dow AgroSciences
cry1Ab/cry1Ac		CAAS/Nath Seeds
cry1Ac		NRCPB/UAS Dharwar
cry1E/C, cry1Ac		NBRI/Swarna Bharat Biotechnics Pvt. Ltd.
cry1Ac	Event 1	IIT Kharagpur/JK Agri-Genetics
cry1c, CPTi		Mahyco
cry1c, CPTi		Nath Seeds, CICR

Source: PTI, 2003; Agbios, 2006; Khadi, 2006 and personal information.

As mentioned in Chapter 5, questions have been raised about the need for refuge crops under the Indian multi-cropping system. Farmers in general have not been very enthusiastic about growing refuge crops owing to their small land holdings. It would be desirable to generate local data on insect populations and resistance build-up under different cropping regimes to develop reliable and cost-effective strategies for insect resistance management.

The need for improving the processes and protocols for large-scale field trials of transgenic cotton has been expressed by some authors (Scoones, 2003; Das, 2005; Rao, 2005; Sahai, 2005). A sub-committee constituted by GEAC has given a number of recommendations for field testing of new Bt cotton varieties/hybrids (MoEF, 2005). These include suggestions on; zone-wise number of locations for different types of hybrids, parameters to be monitored, number of years of testing for different genes and recipient varieties, and the stage at which the Bt lines should enter ICAR trials. Implementation of these recommendations should expedite the commercial release of Bt cotton varieties/hybrids without compromising biosafety considerations.

Curbing trade in spurious Bt cotton seed is essential for the survival of a good technology that has proved its worth on farmers' fields. Further, with no containment measures adopted during the cultivation of spurious varieties, there is a real possibility of Bt toxin gene contaminating contiguous non-Bt varieties and germplasm. Such uncontrolled spread of toxin gene would lead to faster build-up of resistance in bollworms. Measures like seed registration and strict field monitoring would be required to control the proliferation of spurious Bt cotton seed.

Translating the potential of Bt technology into tangible benefits for farmers has become possible through enormous and cooperative efforts of public and private sectors. Mahyco took a leading initiative in introducing the technology into India and following a long and rigorous testing procedure as directed by RCGM and GEAC. The role played by DBT, MoEF and ICAR in conducting/monitoring the trials, promoting technology dissemination and creating public awareness is well known. So also is the role of CSOs and NGOs, particularly that of the network of local NGOs engaged in monitoring Bt cotton performance in different zones. Further, stronger public-private partnerships are being forged to accelerate development of new and improved insect-resistant cotton varieties/hybrids. National Botanical Research Institute, Lucknow, has licensed its Bt technology to a consortium of seven companies, Swarna Bharat Biotechnics Pvt. Ltd. while Indian Institute of Technology, Kharagpur, has licensed its Bt technology to JK Agri-Genetics (Jayaraman, 2004a; Krishna, 2004). These and other models of public-private partnership need to be pursued vigorously to make available the promised benefits of agricultural biotechnology to the stakeholders and to achieve a competitive position in the globalized agricultural market.

7. EPILOGUE

In an article on the future of agricultural biotechnology, Giddings (2006) commented "…in ten years time, we will likely look back and wonder how we ever could have doubted".

In this status report, efforts have been made to synthesize information on the events leading to Bt technology adoption, results of trials/experiments conducted to meet the statutory requirements for their release, and research findings and observation of various CSOs on the on-farm performance of Bt cotton. The key role of organizations such as Department of Biotechnology, Ministry of Environment and Forests, Indian Council of Agricultural Research, and seed companies like Mahyco in initiating research and development of Bt cotton has been detailed.

The large-scale adoption of Bt cotton by Indian farmers is a testimony to the success of Bt technology under diverse and highly complex Indian farming conditions. Besides protecting the crop against bollworm attack that results in higher cotton yield and increased net income, the technology offers promise of other benefits associated with reduction in the use of broad-spectrum pesticides. These include, conservation of natural enemies of bollworm, reduced soil and water contamination, and health benefits to farm workers who would come in lesser contact with pesticides.

Any technological innovation takes time to stabilize and become widely acceptable. This is particularly so in agriculture, as many factors are involved in its success at the grassroots level. We still need to have Bt technology which could be afforded by small farmers, diverse sources of insect-pest resistance in agronomically superior genotypes, good public/farmer awareness programmes, well-regulated seed distribution system and conducive market for the produce. Strict adherence to the prescribed procedures and regulatory measures at all stages of development and cultivation of GM crops is an imperative. Equally important is the cooperation between Bt variety developers in both public and private sectors and CSOs in producing factual and reliable information about the performance of these varieties at farmers' field level.

It is hoped that the attempt made by APCoAB/APAARI in bringing out this publication will serve to generate more interaction among different stakeholders to benefit from the technology as also resolve various issues and concerns as expressed in this status report. Ultimately, it should lead to greater realisation of the potential of biotechnology for enhancing farm production, improving livelihoods and creating safer environment. Further, in the regional context, dissemination of this report should prove useful to other NARS of the Asia-Pacific where genetic modification technology is under various stages of development and adoption for increased productivity and resource conservation.

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Annexure I

Conditions stipulated by MoEF for release of MECH-12 Bt, MECH-162 Bt and MECH-184 Bt

(i) The period of validity of approval is three years from April 2002 – March 2005.

(ii) Every field where Bt cotton is planted shall be fully surrounded by a belt of land called 'refuge' in which the same non-Bt cotton variety shall be sown. The size of the refuge belt should be such as to take at least five rows of non-Bt cotton or shall be 20% of total sown area whichever is more.

(iii) To facilitate this, each packet of seeds of the approved varieties should also contain a separate packet of the seeds of the same non-Bt cotton variety which is sufficient for planting in the refuge defined above.

(iv) Each packet should be appropriately labelled indicating the contents and the description of the Bt hybrid including the name of the transgene, the GEAC approval reference, physical and genetic purity of the seeds. The packet should also contain detailed directions for use including sowing pattern, pest management, suitability of agro-climatic conditions etc., in vernacular language.

(v) MAHYCO will enter into agreements with their dealers/agents, that will specify the requirements from dealers/agents to provide details about the sale of seeds, acreage cultivated, and state/regions where Bt cotton is sown.

(vi) MAHYCO will prepare annual reports by 31st March each year on the use of Bt cotton hybrid varieties by dealers, acreage, locality (state and region) and submit the same in electronic form to GEAC, if asked for by the GEAC.

(vii) MAHYCO will develop plans for Bt based Integrated Pest Management and include this information in the seed packet.

(viii) MAHYCO will monitor annually the susceptibility of bollworms to Bt gene vis-à-vis baseline susceptibility data and submit data relating to resistance development, if any, to GEAC.

(ix) Monitoring of susceptibility of bollworms to the Bt gene will also be undertaken by an agency identified by the Ministry of Environment and Forests at applicant's cost. The Ministry has entrusted Central Institute for Cotton Research, Nagpur, to carry out the above monitoring.

(x) MAHYCO will undertake an awareness and education programme, interalia through development and distribution of educational material on Bt cotton, for farmers, dealers and others.

(xi) MAHYCO will also continue to undertake studies on possible impacts on non-target insects and crops, and report back to GEAC annually.

(xii) The label on each packet of seeds, and the instruction manual inside the packet should contain all relevant information.

(xiii) MAHYCO will deposit 100 g seed each of approved hybrids as well as their parental lines with the National Bureau of Plant Genetic Resources (NBPGR).

(xiv) MAHYCO will develop and deposit with the NBPGR, the DNA fingerprints of the approved varieties.

(xv) MAHYCO will also provide to the NBPGR, the testing procedures for identifying transgenic traits in the approved varieties by DNA and protein methods.

Source: http://www.envfor.nic.in/divisions/csurv/geac/bgnote.doc

Annexure II

Acronyms

APAARI	:	Asia-Pacific Association of Agricultural Research Institutions
APCoAB	:	Asia-Pacific Consortium on Agricultural Biotechnology
Bt	:	*Bacillus thuringiensis*
CAAS	:	Chinese Academy of Agricultural Sciences
CICR	:	Central Institute for Cotton Research
CSO	:	Civil Society Organization
DBT	:	Department of Biotechnology, Government of India
DLC	:	District Level Committee
EPA	:	Environment (Protection) Act
FAO	:	Food and Agriculture Organization of the United Nations
GEAC	:	Genetic Engineering Approval Committee
GMO	:	Genetically Modified Organism
GM	:	Genetically Modified
IBSC	:	Institutional Bio-safety Committee
ICAR	:	Indian Council of Agricultural Research
IIT	:	Indian Institute of Technology
IPM	:	Integrated Pest Management
ISAAA	:	International Service for the Acquisition of Agri-biotech Applications
Mahyco	:	Maharashtra Hybrid Seed Company
MEC	:	Monitoring-cum-Evaluation Committee
MIC	:	Molt Inhibitor Concentration
MoEF	:	Ministry of Environment and Forests, Government of India
NARS	:	National Agricultural Research System
NBPGR	:	National Bureau of Plant Genetic Resources
NBRI	:	National Botanical Research Institute
NGO	:	Non Government Organization
NRCPB	:	National Research Centre on Plant Biotechnology
RCGM	:	Review Committee on Genetic Manipulation
RDAC	:	Recombinant DNA Advisory Committee
r-DNA	:	Recombinant DNA
SBCC	:	State Biotechnology Coordination Committee
UAS	:	University of Agricultural Sciences

ASIA-PACIFIC CONSORTIUM ON AGRICULTURAL BIOTECHNOLOGY

The Asia-Pacific Consortium on Agricultural Biotechnology (APCoAB), was established in 2003 under the umbrella of the Asia-Pacific Association of Agricultural Research Institutions (APAARI) — an initiative of Food and Agriculture Organization that has been promoting appropriate use of emerging agri-technologies and tools in the region.

APCoAB's mission is "To harness the benefits of agricultural biotechnology for human and animal welfare through the application of latest scientific technologies while safeguarding the environment for the advancement of society in the Asia-Pacific Region".

APCoAB's main thrust is:

- To serve as a neutral forum for the key partners engaged in research, development, commercialization and education/ learning of agricultural biotechnology as well as environmental safety in the Asia-Pacific region.
- To facilitate and promote the process of greater public awareness and understanding relating to important issues of IPR's *sui generis* systems, biosafety, risk assessment, harmonization of regulatory procedures, and benefit sharing in order to address various concerns relating to adoption of agricultural biotechnology.
- To facilitate human resources development for meaningful application of agricultural biotechnologies to enhance sustainable agricultural productivity. as well as product quality, for the welfare of both farmers and consumers.