CROP BIOTECH & BIOSAFETY

Crop Biotech & Biosafety

Project Coordinating and Monitoring Unit (PCMU)
Ministry of Environment & Forest (MOEF)

In association with

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Ministry of Environment & Forest (MOEF) and,
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All correspondence may be addressed to

Project Coordinating and Monitoring Unit (PCMU)
GEF-World Bank Capacity Building Project on Biosafety
Ministry of Environment & Forest (MOEF)
Paryavaran Bhawan, CGO Complex
Lodhi Road, New Delhi-110003
Email: hota@nic.in
Website: www.envfor.nic.in

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1. INTRODUCTION

Biotechnology has emerged as the most important scientific tool of the 21st century. Exciting developments are taking place throughout the world in several areas such as drug discovery, manufacturing processes and agriculture. Biotechnology is going to contribute towards finding remedies for deadly diseases like cancer and genetic disorders to improve human health, enhancing agricultural productivity, developing more nutritious food, producing industrial products more economically, and improving the quality of environment on a sustainable basis.

As for agricultural biotechnology, the current global scenario is quite encouraging. The year 2006 marked the 10th anniversary of large-scale commercial cultivation of biotech crops, including food, feed & fiber crops, in multiple countries. It has been a tough, but interesting journey interspersed with speculated risks, calculated opposition and deliberate controversies, as with some of the new technologies in the past, gradually leading to greater acceptance, support and success of the products following their proven merits, safety and benefits. This is reflected by the fact that in 2006, biotech crops were cultivated on 102.0 million hectares (or 252 million acres) in 22 countries (11 developing, 11 industrial), including India, on six continents, by 10.3 million farmers, marking a 60-fold increase in the area since their first commercialization on 1.7 m ha in 6 countries in 1996. India made its long awaited entry into agricultural biotechnology in March 2002 with the regulatory approval of Bt-cotton by the Genetic Engineering Approval Committee (GEAC) of the Government of India for commercial cultivation. The area of Bt-cotton has increased from 44,500 hectares in 2002, the first year, to an exponential 3.8 million hectares in 2006 with about 2.3 million farmers opting for this technology. Such a fast rate of adoption of a new technology is unprecedented in agriculture and this trend is expected to continue in the coming years.

As we move forward, it is time to retrospect and analyze the progress made so far and examine the future prospects. An attempt is made to provide an overview, broadly covering the following aspects: why we need biotechnology; what is genetic engineering; regulatory framework for biotech crops; global status of biotech crops; Bt-cotton and the Indian scenario; what is Bt and how are Bt-crops useful; safety aspects related to Bt-cotton; benefits of Bt-cotton; and prospects.

2. WHY WE NEED CROP BIOTECHNOLOGY?

Agriculture has become increasingly tough and unpredictable in recent years. We are confronted with several serious challenges that are threatening to shake and destabilize our future if we do not take appropriate steps to find solutions. Some of these include:

- Global food demand is estimated to double by the year 2050 when the world population is expected to reach from the current 6.3 to 9.3 billion of which about 90% will reside in Asia, Africa and Latin America. In India, the population has already exceeded 1.1 billion and it is projected to be the most populous country in the world with about 1.5 billion by 2050.

- The arable land is diminishing every year as it is diverted for industrial, residential, recreational and other human needs. Other resources like water, fertilizer and labor are also becoming scarce and costly. According to a UN report, mankind's most serious challenge in the 21st century might not be war or hunger or disease or even the collapse of civic order, but it may be the lack of fresh water.

- About 1.2 billion people in the world are afflicted by severe poverty of which 852 million in the developing countries suffer from malnutrition.

- 1.4 billion women (22% of world population of which 55% in the developing countries) suffer from iron deficiency anemia, which impairs immunity and causes mental as well as physical weakness.

- About 140 million children suffer from vitamin A deficiency. An estimated 250,000 to 500,000 vitamin A deficient children become blind every year, half of them dying within 12 months of losing their sight. The number of such unfortunate children in India alone is about 50,000.

- More than 30% of our crop yields are lost to biotic factors like pests, diseases and weeds despite spending heavily on chemical pesticides. Similarly, crop losses due to abiotic stresses like drought, cold, heat and salinity are high and unpredictable. Huge losses of fruits, vegetables and flowers also occur during storage and transport.

Therefore, the challenge before the agricultural scientists today is to 'produce more from less' i.e., more nutritious food from less land, water and other resources. Another challenge is to protect and preserve what we produce. We certainly need new technologies to accomplish these as the prevailing technologies alone do not seem to be adequate. Recent advances made in crop biotechnology offer exciting opportunities to address some of these challenges and have already provided certain breakthroughs.

3. WHAT IS GENETIC ENGINEERING?

The major objective of crop biotechnology is to enhance the value of a desired plant by adding one or more beneficial traits not already present in it. This is accomplished by selecting new DNA genes coding for specific traits from another organism and introducing it into the required plant. This process is known as 'genetic engineering' and such plants carrying the alien genes are called 'transgenic plants,' or 'genetically engineered plants' or 'genetically modified plants.'

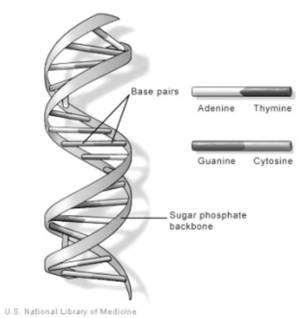
To understand how genetic engineering works, a few basic facts about biology must be understood.

What is DNA?

All living organisms - plants or animals, big or small - are made of cells. Every cell contains in its nucleus a unique molecule called DNA (deoxyribonucleic acid) in the chromosomes. DNA carries the genetic blueprint for life as it stores the genetic information and provides the key chemical information responsible for the inheritance of traits such as size, shape, colour, build and other physical attributes of microorganisms, plants, animals and humans.

The information in DNA is stored as a code made up of four chemical bases: adenine (A), guanine (G), cytosine (C), and thymine (T). Human DNA consists of about 3 billion bases, and more than 99 percent of those bases are the same in all people. The order, or sequence, of these bases determines the information available for building and maintaining an organism, similar to the way in which letters of the alphabet appear in a certain order to form words and sentences. The number of possible sequences is almost endless because an individual strand of DNA may contain millions of bases.

DNA bases pair up with each other, A with T and C with G, to form units called base pairs. Each base is also attached to a sugar molecule and a phosphate molecule. Together, a base, sugar, and phosphate are called a nucleotide. Nucleotides are arranged in two long strands that form a spiral called a double helix. The structure of the double helix is somewhat like a ladder, with the base pairs forming the ladder's rungs and the sugar and phosphate molecules forming the vertical sidepieces of the ladder.



DNA is a double helix formed by base pairs attached to a sugar-phosphate backbone.

An important property of DNA is that it can replicate, or make copies of itself. Each strand of DNA in the double helix can serve as a pattern for duplicating the sequence of bases. This is critical when cells divide because each new cell needs to have an exact copy of the DNA present in the old cell.

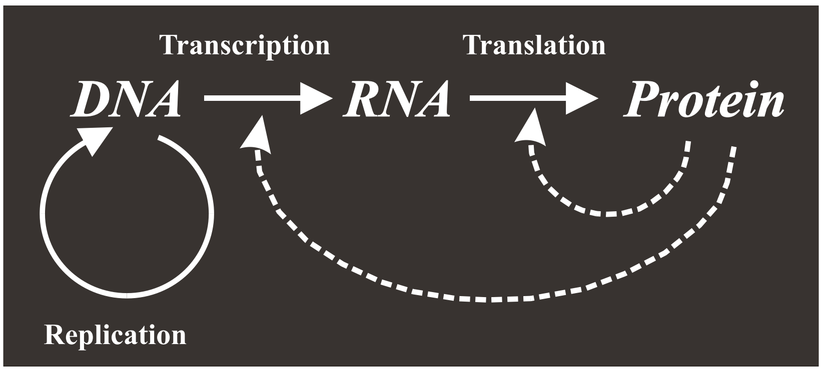
What is a gene and genome?

A gene is a discrete segment of DNA encoding for a set of instructions in the cell and contains all the information relating to the form and functions of all living cells that give characteristics to an organism. Each gene holds the instructions for how to produce a particular protein.

An organism may have thousands of genes. The set of all genes in an organism is called a genome. Every living organism has its own genome and every cell in that particular organism has a copy of the same genome. The size of the genome varies from one organism to the other. For example, the human genome has an estimated 60,000 to 100,000 genes, most plants have about 20,000 and a single celled bacterium, Escherichia coli, about 4,000.

Why are proteins important?

Proteins are the building blocks of all living things. They regulate all reactions that take place in the cells or serve as enzymes to accelerate reactions. Everything in an organism is either made of proteins or is the result of a protein's action.



Genes contain the information required for the assembly of a specific protein. The protein then function as enzymes to catalyze biochemical reactions or as structural or storage units of a cell, to contribute to expression of a particular trait. The sequence of events by which the information encoded in DNA is expressed in form of proteins is via messenger Ribonucleic acid (rRNA) intermediate.

Basis for Genetic Engineering

Except for the sequence and number of letters in each recipe, DNA from any organism is chemically and physically the same. In other words, the genetic code is universal. One of the great scientific discoveries of modern biotechnology is that DNA genes from any organism be it plant or animal, will function if it is transferred into any other organism! This has been exploited in genetic engineering, thanks to advances made in molecular biology, plant transformation, tissue culture, plant genetics and other related areas. Today, the required genes from any source - be it bacteria, virus, fungi, plants or animals - can be isolated and introduced into a desired plant species irrespective of its relatedness. The introduced gene becomes a part of the host plant genome and an inheritable trait. This is the unique feature of genetic engineering. Transgenic plants are created by man, it is a remarkable scientific breakthrough and a tribute to his brilliance.

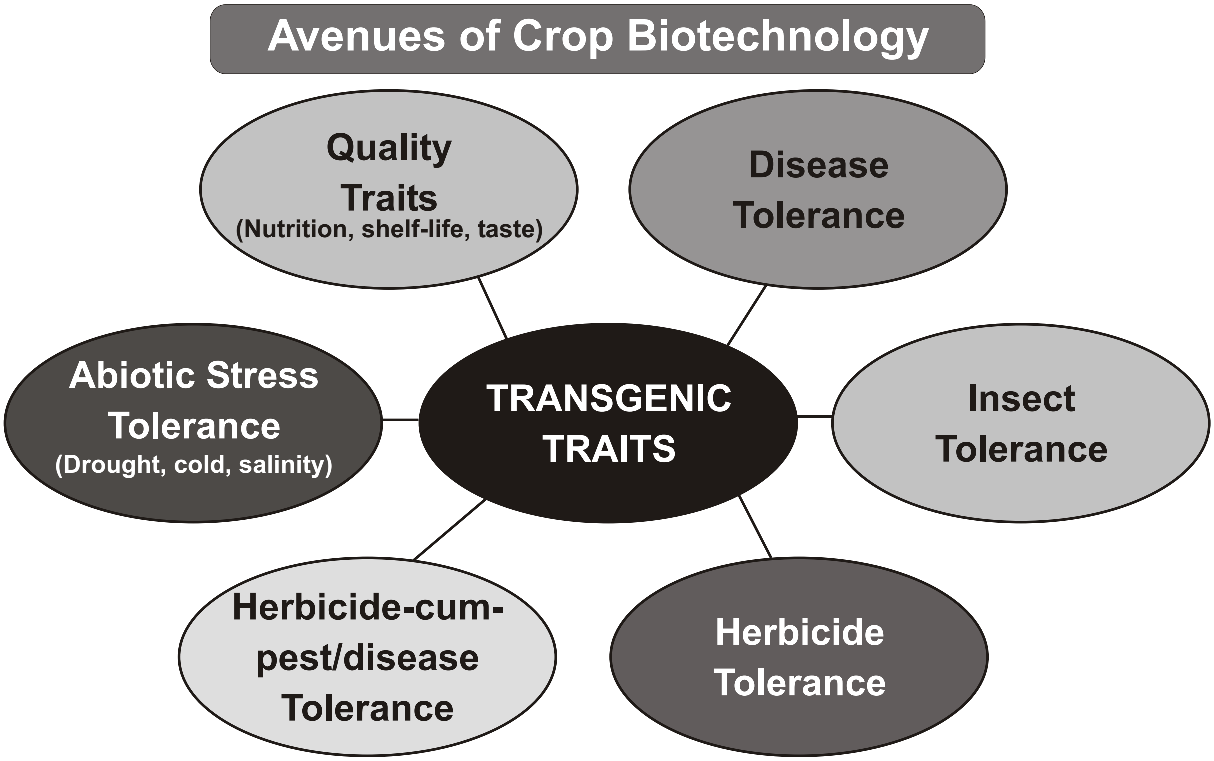
4. AVENUES OF CROP BIOTECHNOLOGY

Crop biotechnology can be utilized to develop plants with various beneficial traits such as;

A) crop protection traits which include resistance to pests, diseases and herbicides;

B) abiotic stresses in the form of tolerance to drought, heat, cold or salinity, thus enabling plants to be grown in inhospitable habitats, adding more land for cultivation; and

C) quality traits leading to enhanced nutrition; prolonged shelf-life or improved taste, color or fragrance of fruits, vegetables and flowers; and increased crop yield.



In fact, the crop biotechnology has opened up enormous opportunities and has the potential to revolutionize modern agriculture. Safety is accorded the highest priority in biotechnology. However, being a new technology, several doubts are raised with regard to its safety. These need to be clarified so as to remove any apprehension regarding biotech products.

5. HOW ARE TRANSGENIC PLANTS DEVELOPED?

The objective of genetic engineering, also known as transformation, is to obtain a gene of interest from the genome of one organism and insert it into the genome of another. This gives the recipient organism the ability to express the trait encoded by that gene. The process of genetic engineering involves the following broad steps:

1. Identification of an organism that naturally contains the desired trait.

2. Extraction of the DNA from that organism.

3. Out of thousands of genes that were extracted from the donor organism, the one desired gene must be located and copied. This is called gene cloning.

4. The selected gene may be suitably modified and designed to express in a specific way ('gene construct').

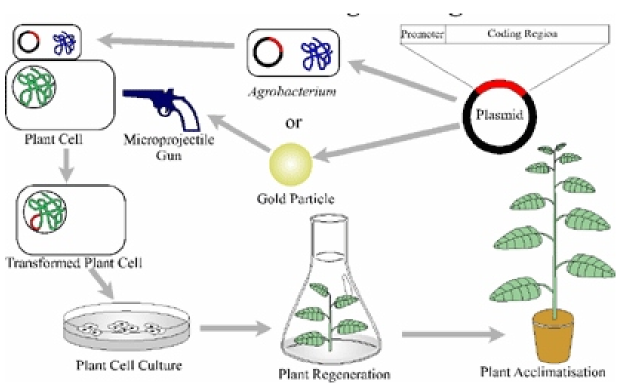
5. Transfer of this gene construct ('transgene') into plant cells/tissue in vitro (maintained as organized explants such as immature embryos, stem sections, cotyledons etc. using tissue culture techniques), along with 'marker genes', using appropriate transformation technique. The most common transformation technique in plants uses the bacterium called Agrobacterium tumifaciens. This bacterium has the natural ability of genetic engineering the host plants with its own DNA. The transgene is inserted into the bacterium, which then delivers it into single cells of the plant being engineered. Another technique, called the gene gun method, shoots microscopic gold particles coated with copies of the transgene into single cells of the recipient organism. During such genetic engineering, there is no control over where or whether the transgenes are inserted into the genome. As a result, it takes hundreds of attempts to produce just a few transgenic organisms.

6. Identification of transformed cell lines or seedling with the help of 'marker genes' and regeneration of fertile plants from the transformed cells.

7. Analyses of transformed plants for several features such as stable integration, expression and genetic behavior of the transgene.

8. Once a transgenic plant has been created, traditional breeding is used to improve its characteristics. Genetic engineering does not replace but complement traditional breeding. It is simply an advanced technology to add genes with new traits to the gene pool of that organism.

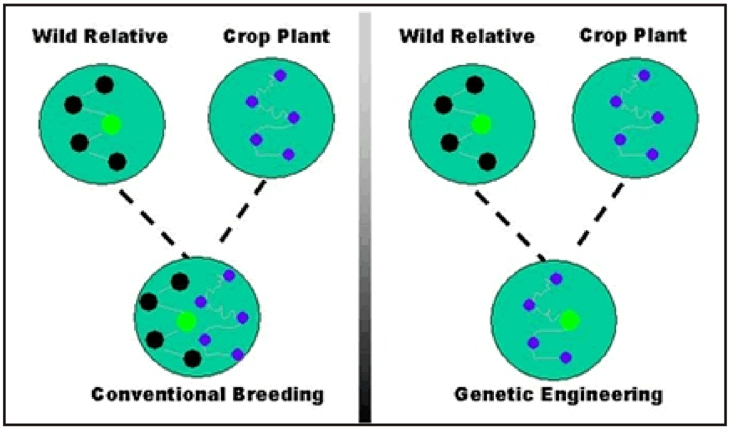
Plant Genetic Engineering



Developing plant varieties expressing good agronomic characteristics is the ultimate goal of plant breeders. With conventional plant breeding, however, there is little or no guarantee of obtaining any particular gene combination from the millions of crosses generated. Undesirable genes can be transferred along with desirable genes; or, while one desirable gene is gained, another is lost because the genes of both parents are mixed together and re-assorted more or less randomly in the offspring. These problems limit the improvements that plant breeders can achieve.

In contrast, genetic engineering allows the direct transfer of one or just a few genes of interest, between either closely or distantly related organisms to obtain the desired agronomic trait. Not all genetic engineering techniques involve inserting DNA from other organisms. Plants may also be modified by removing or switching off their own particular genes.

Comparing conventional breeding and genetic engineering



Source: ISAAA Mentor's Kit, 2003.

Although the traditional breeding and genetic engineering have the same objective to enhance the beneficial traits of the desired plant, there are a few basic differences between the two.

Conventional Breeding vs. Genetic Engineering	
Conventional Breeding	**Genetic Engineering**
• Required genes may be introduced only from closely related plant species.	• Required genes may be introduced from any source including totally unrelated organisms.
• Very little control over how or where a protein is expressed.	• Precise control over how or where a protein is expressed.
• Along with the desired gene, several unwanted genes also get introduced.	• Only the desired gene(s) can be added or inactivated.
• Some unsafe traits can be bred out.	• Increased number of ways to make food safer.
• Slow	• Quick

6. WHAT IS Bt AND HOW ARE Bt-CROPS USEFUL?

Bacillus thuringiensis (Bt)

Bt is the popular abbreviation for *Bacillus thuringiensis*, a bacterium commonly found in soil with ubiquitous distribution. Hence it is popularly called a 'soil bacterium.' The insecticidal property of *Bt* was first discovered way back in 1901 in Japan. More than 90 varieties or sub-species of *Bt* have been described so far.

A unique feature of Bt is that each variety possesses a distinct gene encoding an insecticidal protein that can affect only a narrow range of insects belonging to a particular group. Thus, there are Bt proteins harmful to certain larvae of only Lepidoptera (moths and butterflies), Coleoptera (beetles), Hemiptera (bugs), Diptera (flies) and so on. A particular Bt protein active on one group of insects generally does not affect other insects or other organisms. Currently about 250 such proteins have been characterized.

Bt-proteins require certain specific conditions for their activity. In the first place, the protein has to be ingested by the target insects and this happens when they feed on transgenic plant tissues. It requires an alkaline intestine with a pH of at least 9.5 for its activation and there should be specific receptors in the insect mid-gut for protein-binding before it can kill the insect. All these conditions are available in the susceptible insects and therefore they succumb when they feed on Bt-plants. Such proteins cannot act in human, animal or other non-target organisms as they lack these specific conditions.

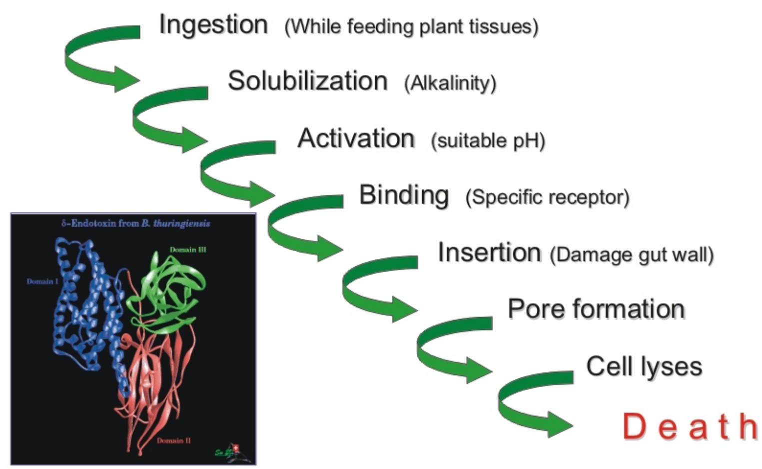
Development of Bt-plants

Depending upon the type of pests to be controlled - whether it is Lepidoptera, Coleoptera etc. - the relevant genes from the soil bacterium, Bacillus thuringiensis (Bt), are isolated, studied, suitably modified and introduced into the desired plant species by genetic engineering. The new Bt-gene gets stably integrated into the host genome and becomes an inheritable trait. Such transgenic plants containing the Bt-gene(s) are popularly called 'Bt-plants.' For example, Bt-cotton is incorporated with the lepidopteran specific gene(s) as it is designed to control bollworms, which belong to this insect order. Similarly we have Bt-corn, Bt-potato, Bt-brinjal (egg-plant), Bt-rice etc. with their encoded proteins providing insect control.

In the commercialized transgenic Bt-cotton plants, the expression of Bt protein is constitutive i.e., the protein is expressed in all parts of the plant. When the larvae feed on Bt plants, they ingest Bt protein along with the plant tissues. If it is a susceptible insect like bollworms, the Bt protein gets activated in the mid-gut and the activated molecules bind themselves to certain receptors present on the gut membrane, very much like a specific key fitting into a lock. Such a specific interaction between the activated Bt protein and receptor results in 'holes' being formed in the insect intestine, causing destruction of the gut lining. The haemolymph (insect blood) carrying ions and vital nutrients leak into the intestine. This leads to paralysis of the insect gut as a result the insect stops feeding. This sequence of events can take place within a few hours. The affected larvae may die after a day or two, but since it stops feeding, any further damage to plants is prevented (see figure). Bt proteins can affect only those insect species possessing the specific receptors and conditions for toxin activation and, therefore, pose no threat to those insects and higher order organisms which do not possess these specific conditions in their gut.

The first genes encoding the insecticidal Bt proteins were cloned early in the 1980s. This paved the way for

SELECTIVE ACTION OF BT IN INSECTS



constructing recombinant bacterial insecticides containing novel combinations of these proteins and to the development of Bt-plants. The first Bt-cotton plants were developed by the Chinese Academy of Agricultural Sciences (CAAS) in China and by Monsanto Company in the USA in the early 1990s. However, regulatory approval and large scale commercial cultivation of Bt-crops which included Bt-cotton along with Bt-corn and Bt-potato developed by Monsanto took place in the USA in 1996. Thus, 1996 marked the beginning of commercialization of transgenic crops. This approval was preceded by a large number of biosafety tests and agronomic trials carried out for 13 to 14 years to establish the safety and benefits of these biotech crops.

Bt-cotton has several advantages. Some of these are:

- Bt-technology for control of bollworms is made available in the seed itself. Farmers have to just sow the Bt-cotton seeds as they do with conventional seeds. The resulting plants have the in-built ability to produce Bt-protein within their body and defend themselves from bollworms. No extra efforts or equipment are needed to utilize this technology.
- Bt protein is expressed in all parts of the plant (i.e., constitutive expression), providing bollworm control day and night, almost throughout the plant life. No need to monitor the bollworms to initiate control measures.
- The newly hatched larvae feeding on any part of the plant will ingest Bt-protein and die within one or two days, thereby preventing any potential serious damage to the crop.
- Bt-proteins, being lepidopteran specific, affect only the bollworms and are safe to biological control agents and other non-target beneficial organisms, higher animals and plants.
- Bt-cotton is compatible with other control measures such as biological control, pheromones, botanical insecticides and also chemicals that are recommended for Integrated Pest Management. In fact, Bt-cotton can serve as a major component of IPM in cotton crops.

- Bt-cotton helps to avoid or minimize chemical sprays, thus contributing to cleaner environment and conservation of biological control agents and biodiversity.
- Bt-cotton offers protection from bollworms right from the early days of the crop, leading to a healthy crop, better boll retention, greater harvest and more profit.
- The Bt-farmers experience a far lower tension and are certainly better off than the earlier scenario of "spray and pray."
- In other words, Bt-cotton provides social, economic and environment benefits.

It is important to know that Bt-cotton offers protection only against bollworms, not sucking pests and other non-lepidopteran pests. Therefore, separate control measures have to be taken against such pests as and when required. It is always necessary to understand clearly the scope of a particular technology for its proper utilization.

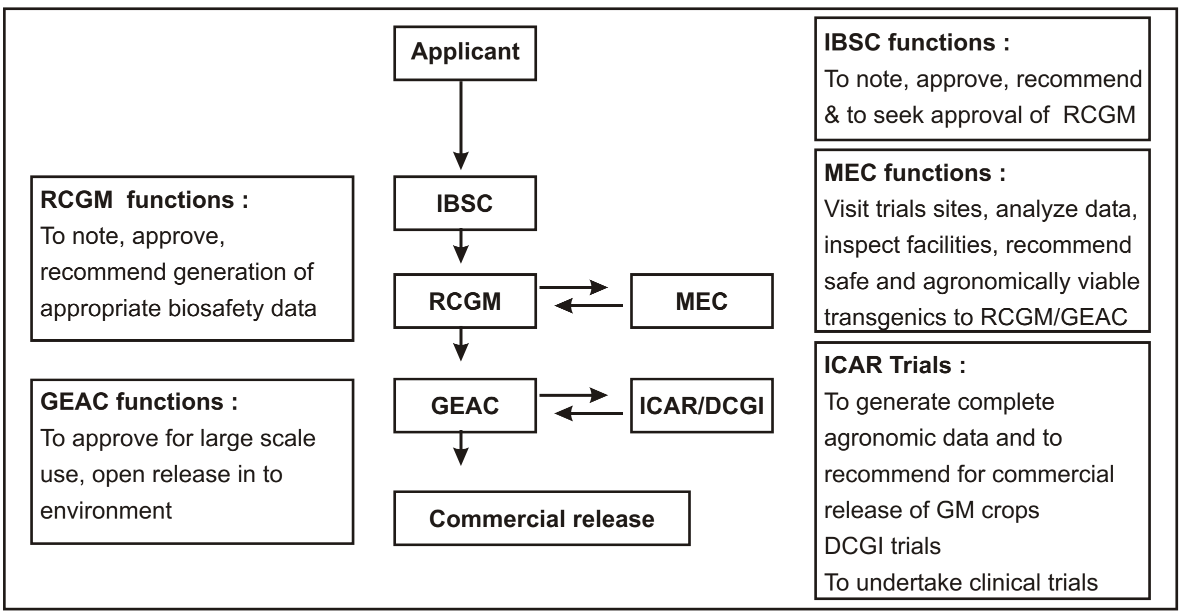
7. REGULATORY FRAMEWORK FOR BIOTECH CROPS

A biotech product has to pass through a series of rigorous biosafety tests and field trial to prove its safety and agronomic advantages before it is approved for commercialization or large-scale use. Biosafety refers to certain policies and procedures framed by the government regulatory authorities, in consultation with various experts, to ensure overall safety from the biotech products during the course of their development and commercialization. Every country has set up such regulatory bodies. For example, in the USA, the GMO regulatory body is comprised of three federal agencies, namely Environmental Protection Agency (EPA), Federal Drug Administration (FDA), and United States Dept of Agriculture (USDA).

The Government of India has adopted a policy of precautionary principles, on a case by case basis, for careful evaluation of the risks and benefits of biotech crops and other GM products, at various stages of their development, before they are approved for commercialization. Such rules were framed and guidelines notified in 1989 under the Environment Protection Act 1986 (EPA) of the Ministry of Environment and Forest (MOEF), Govt of India. The guidelines were amended in 1990, 1994 and 1998 to keep pace with the progress made in the GMO research.

Two nodal agencies, the Dept of Biotechnology (DBT) under the Ministry of Science and Technology (MoST) and Ministry of Environment and Forests (MoEF) are responsible for implementation of the biotech policies in India. They have constituted four major committees to handle various issues: Recombinant DNA Advisory Committee (RDAC), Institutional Bio-Safety Committee (IBSC), Review Committee on Genetic Manipulation (RCGM) and Genetic Engineering Approval Committee (GEAC). These committees are supported by several other committees such as the State Biotechnology Coordination Committee (SBCC), District Level Coordination Committee (DLCC) and Monitoring and Evaluation Committee (MEC). All these committees have specific responsibilities as indicated in the figure and table below.

The major committees are comprised of eminent experts drawn from various fields from various organizations across the country.



Biosafety Committees in India		
Committees	**Composition**	**Responsibilities**
RDAC: DNA Advisory Committee	Constituted by DBT with experts in the relevant fields	RDAC prepared the Recombinant Recombinant DNA Bio Safety Guidelines in 1990 To suggest improvements from time to time for research and handling of GMOs Keep track of biotechnology developments at national and international levels
IBSC: Institutional Bio-Safety Committee	Every institute intending to work on GMOs should have this committee Head of the institution as Chairman One nominee from DBT One biosafety or medical officer Internal and external scientists engaged in r-DNA work	To examine and approve any r-DNA work To ensure adherence of safety guidelines To recommend to RCGM about category III and above risks and seek approval To inform DLC, SBCC and GEAC about experiments where needed To act a nodal point for interaction with statutory bodies
RCGM: Review Committee on Genetic Modification	Constituted by DBT Member secretary of DBT Indian Council of Medical Research Indian Council of Agricultural Research Council of Scientific and Industrial Research Other experts in their individual capacity.	Prepare guidelines to ensure environmental safety To authorize imports of GMOs/ transgenes for research To authorize small scale field trials (up to one acre at each site) and generate scientific safety data Visit experimental sites and review all r-DNA projects and controlled field experiments to ensure compliance of safety guidelines
MEC: Monitoring and Evaluation Comittee	Constituted by RCGM	To visit field trials and inspect facilities

	Representatives from state governments, ICAR, universities and other public institutions	Report to RCGM on the status of safety and agronomic impact of GMOs Recommend improvements
GEAC: Genetic Engineering Approval Committee	Constituted by the Union Ministry of Environment & Forestry (MoEF) Chair - Additional Secretary, -MoEF Co-chair: Nominee from DBT Representatives from Ministry of Industrial Development; Departments of Biotechnology and Atomic Energy; Indian Council of Agricultural Research; Indian Council of Medical Research; Council of Scientific and Industrial Research; Directorate of Plant Protection; Central Pollution Control Board; other experts by invitation	To authorize large scale production and release of GMOs into the environment To permit commercial application of GMOs Mandate restriction or prohibition on production, sale, import or use of GMOs, if required, under Environment Protection Act To authorize punitive action for violation of Environment Protection Act
SBCC: State Biotechnology Coordination Committee	Constituted by the concerned State Govt Chair - Chief Secretary of the State Representatives from State Govts and Universities	To act as a nodal agency at the state level to ensure compliance of safety regulations To nominate representatives to the committee constituted by Central Ministry to inspect field and laboratory trials on GMOs To review periodically the safety measures taken by various institutions handling GMO research in the state To assess the damage, if any, due to release of GMOs and take appropriate damage control measures To take punitive action against violation of safety regulations
DLCC: District Level Coordination Committee	Constituted by the state govt at the district level Chair District Collector Members from state govts and universities	Monitor safety regulations at the district level and report to SBCC or GEAC on the status To assist SBCC in assessing the damage, if any, due to release of GMOs and take damage control measures

The biosafety committees examine the safety of a product from different perspectives at various levels. Biosafety concerns generally include testing the proteins for potential allergenicity, toxicity, out-crossing, effects on non-target organisms, effect on soil and its micro-fauna, potential pest resistance and all perceived adverse effects. The safety assessments are made through experiments based on scientific principles under their expert guidance. Regulatory approval is given only if the concerned product satisfies all the prescribed biosafety norms. The biosafety regulations in India are as stringent as anywhere else in the world. However, there is scope for implementing these more effectively and strictly. If any one has any specific suggestions for improvement, these can be communicated to the regulatory authorities. The broad idea is to strive for excellence.

8. GLOBAL STATUS OF BIOTECH CROPS

The year 1996 can be considered a landmark in agricultural biotechnology in general and crop protection in particular as four transgenic crops comprising three insect-resistant crops and a herbicide tolerant soybean, developed by Monsanto Company, received regulatory approvals and these were commercially grown and harvested for the first time in the USA. These approvals were preceded by about 14 years of intensive research and data generation that demonstrated these crops to be beneficial to farmers while, at the same time, being safe to humans, animals as well as other non-target beneficial organisms, plants and environment.

All three insect-resistant crops were incorporated with genes that produce insecticidal proteins derived from the ubiquitous soil bacterium, Bacillus thuringiensis, popularly referred to as Bt. The proteins are expressed in planta. These crops were Bt-corn for protection against the notorious European corn borer - Ostrinia nubilalis, Bt-potato against the hardy Colorado potato beetle - Leptinotarsa decemlineata, and Bt-cotton against the dreaded cotton bollworm complex which includes the tobacco budworm - Heliothis virescence, bollworm - Helicoverpa zea and pink bollworm - Pectinophora gossypiella. The transgenes incorporated in these crops were the modified cry1Ab in corn, modified cry1Ac in cotton and modified cry3Ab in potato. The gene EPSP synthase, also derived from a bacterium, was deployed in the herbicide tolerant soybean. In 1996, these crops were commercially cultivated not only in the USA, but also in Argentina and Canada on 1.7 million hectares. Although some products were formally approved for sale in limited areas prior to 1996, it was only in 1996 that farmers planted such large areas of biotech crops and continued to do so year after year in several countries. Thus, 2005 will be the 10th consecutive year of commercial planting of biotech crops on a significant scale. Meanwhile, herbicide tolerant canola as well as transgenic crops where both insect-resistant and herbicide tolerant genes were stacked in the same plant were also developed and commercialized. More countries started adopting transgenic crops. Further progress made in this area is described below.

Global Adoption :

The global adoption rates for biotech crops have been very encouraging.

Consistent increase in biotech area:

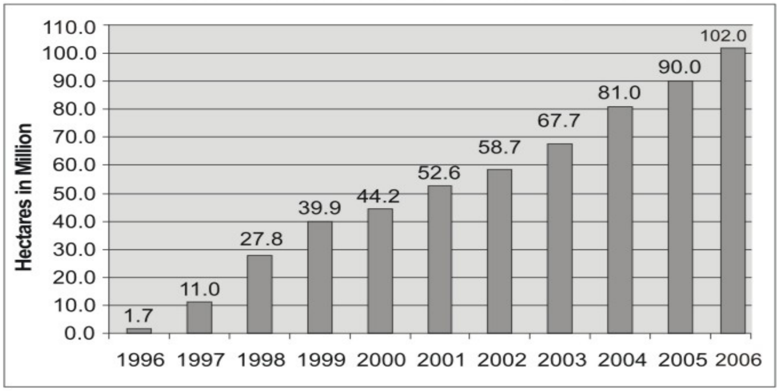
The area planted with transgenic crops in 1996, the first year, was only 1.7 million hectares. It increased significantly from year to year to reach 102 million hectares in 2006 as depicted in the Table below. Thus, in a span of about 11 years, the area increased by more than 60 times, an unprecedented adoption record for any crop technology in agriculture! Of the 102 million hectares, 61.1 million hectares (60%) were grown in industrial countries while 40.9 million hectares in developing countries.

More countries adopt biotech crops:

The number of countries growing transgenic crops, which was only 6 in 1996, increased to 22 (11 industrial and 11 developing countries including India) in 2006.

The US continues to be the leading country in the commercial cultivation of transgenic crops, occupying 54.6 m ha (53%) of the total 102.0 m ha in 2006 followed by Argentina 18.0 m ha (18%), Brazil 11.5 (11%), Canada 6.1 (6%), India 3.8 (4%), China 3.5 (3%), Paraguay 2.0 (2%), South Africa 1.4 (1%), Uruguay 0.4, Philippines 0.2,

GLOBAL AREA OF BIOTECH CROPS, 1996-2006



60-fold increase in 11 years

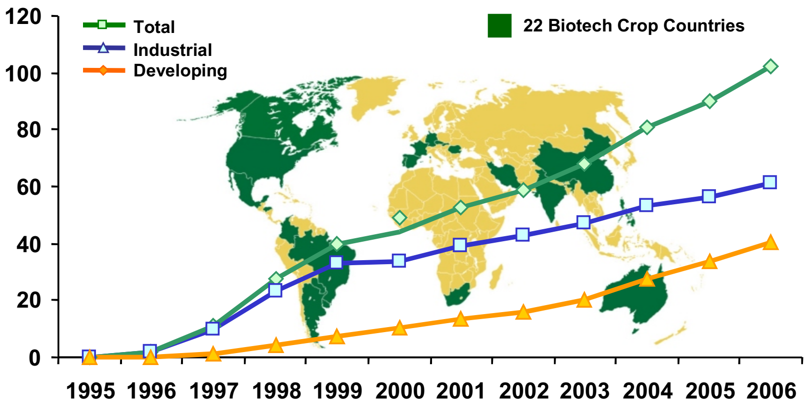
Australia 0.2, Romania 0.1, Mexico 0.1, Spain 0.1 and other countries like Colombia, Iran, Honduras, Portugal, Germany, France, Czechia and Slovakia occupying less than 50,000 ha each.

Although only 22 countries are currently involved in the commercial cultivation of only four major transgenic crops that have been approved, altogether 63 countries are engaged in transgenic research on some 57 plant species comprising field crops, vegetables, fruits and other crops. These are in various stages of development and regulatory approval.

Major biotech traits:

The first generation of major transgenic crops that are currently under commercial cultivation is dominated by crop protection traits. Among these, the most dominant trait is herbicide tolerance (HT), which constituted 69.9% of the 102.0 m ha of the total transgenic area, followed by insect resistance (IR) with 19% and both HT and IR stacked in the same plant with 13.1%. Virus resistance and others occupied very little area (see table).

GLOBAL AREA OF BIOTECH CROPS
Million Hectares (1996 to 2006)



Increase of 13%, 12 million hectares or 30 million acres, between 2005 and 2006.

Source: Clive James, 2006.

Dominant biotech crops:

The principal transgenic crop was soybean followed by maize, cotton and canola. These crops were either herbicide tolerant (HT) or insect resistant with Bt (IR) or both the traits stacked in the same plant (HT + IR). The area occupied by each of these crops is given in the table below.

Global biotech area, trait & % adoption of main biotech crops in 2006

Crops	HT	IR (*Bt*)	HT + IR	Total biotech area (Mha)	Global crop area (Mha)	Biotech area as % of global area
Soybean	58.6	-	-	58.6	91	64
Corn	5.0	11.1	9.0	25.1	148	17
Cotton	1.4	8.0	4.0	13.4	35	38
Canola	4.8	-	-	4.8	27	18
Others	<0.1	<0.1	-	0.1	-	-
Total (Mha)	69.8	19.1	13.1	102.0	301	34.0
Trait %	68.5	18.7	12.8	100		

Gene stacking (or gene pyramiding) is receiving greater attention in recent years due to obvious benefits.

Global value of biotech crops:

The estimated value of transgenic crops grown globally in 2006 was US$ 6.15 billion (about 16% of the $38.5 billion global crop protection market and 21.0% of the $30 billion global commercial seed market).

Ever increasing biotech-farmers:

The number of farmers adopting transgenic crops has been steadily increasing from year to year. For example, it increased from 8.5 million in 2005 to 10.3 million in 2006. Of these, about 9.3 m or 90% were resource-poor farmers planting Bt-cotton 6.8 m in China, 2.3 m in India, 100,000 from the Philippines, several thousand in S. Africa and the rest from other seven developing countries.

9. Bt-COTTON AND THE INDIAN SCENARIO

India made its long-awaited entry into commercial agricultural biotechnology in March 2002 with the regulatory approval of three Bt-cotton hybrids developed by Mahyco-Monsanto for control of bollworms. These contain Monsanto's lepidopteron specific Bollgard® Bt gene, cry1Ac, which offers protection against all the major species of Indian bollworms - Helicoverpa armigera, Pectinophora gossypiella, Earias vittella and E. insulana. These bollworms, especially H. armigera, have been very destructive pests, causing an estimated annual loss of about US$ 300 million despite repeated spraying of insecticides (6 to 16 times or more for each crop). It is estimated that insecticides valued at $700 million are used on all crops annually in India, of which about 50% are used on the cotton crop alone especially to control bollworms.

Old world bollworm, *Helicoverpa armigera*

Pink bollworm, *Pectinophora gossypiella*

Spotted bollworm, *Earias vittella*

Even then, the control was not satisfactory owing to several factors such as abuse of insecticides, spurious products and, moreover, H. armigera, the major pest, has developed resistance to most of the recommended insecticides. However, since dependable alternative methods are not available, farmers continue to spray chemicals. The approval of Bt-cotton at this juncture brought a ray a hope to the farmers.

What it took to get the approval?

The approval of Bt-cotton in India was preceded by about 500 field trials carried out in different agro-climatic regions between 1998 and 2001 to assess its efficacy against bollworms and the concomitant agronomic benefits. Experimental data on the bio-safety of Bt-cotton were generated by several public funded research institutions as per the direction of the Ministry of Environment and Forest (MOEF) and the Department of Biotechnology (DBT), Government of India.

Chronology of Development and Approval of Bt-Cotton in India	
1995	Mahyco applied to DBT for permission to import a small stock of Bollgard® (Bt-cotton) seeds from Monsanto Company, USA. DBT gave permission.
1996	A nucleus stock of 100 gms of cottonseeds of the American variety Coker 312 containing the Bollgard® Bt gene, cry1Ac, was received by Mahyco from Monsanto, USA. Mahyco initiated crossing Coker 312 with the Indian cotton breeding lines to introgress cry1Ac gene. 40 elite Indian parental lines were converted for Bt trait.
1996-1998	Risk-Assessment Studies were conducted, using Indian Bt-cotton hybrids, in laboratories and fields designated by RCGM/GEAC. These included pollen escape, aggressiveness and persistence, biochemical analysis, toxicity and allergenicity.
1998 -1999	Multi-location field trials at 40 locations in 9 states to assess agronomic benefits and safety. Data submitted to RCGM.
1999 -2000	Field trials repeated at 10 locations in 6 states. Data submitted to RCGM.
2000	July 2000 Based on the recommendations of RCGM, the GEAC gave permission for large-scale field trials in 85 ha and seed production in 150 ha.
2001	*Kharif* 2001 Large-scale field trials covering 100 ha. Field trials were also conducted by All India Coordinated Cotton Improvement Project (AICCIP) of the Indian Council of Agricultural Research (ICAR).
2002	On 26 March 2002, GEAC approved Mahyco's three Bt-cotton hybrids, viz. MECH-12, MECH-162 and MECH-184, for commercial cultivation in India. This approval was initially valid for three years and it came with certain conditions. **It was a landmark decision as Bt-cotton is the first-ever biotech crop to receive such a regulatory approval in India.**
2004	One more hybrid Bt-cotton containing cry1Ac gene was approved by GEAC.
2005	16 additional Bt-cotton hybrids containing cry1Ac gene were approved.
2006	A second event featuring staked genes, cry1Ac and cry2Ab, developed by MMB (7 hybrids); a third event featuring fusion genes, cry1Ab and cry1Ac, developed by Nath Seeds (3 hybrids) and a fourth version featuring cry1Ac with a different event (Event 1) (4 hybrids) were approved for commercialization. 28 more hybrids with the single gene, cry1Ac, were also approved. **In 2006, altogether 62 Bt-cotton hybrids representing 4 events from 15 companies were approved for commercialization.**

In addition to many trials conducted by MAHYCO as per DBT's guidelines and supervision, the Bt-cotton hybrids were also evaluated by ICAR (India Council of Agricultural Research) in multi-location field trials in 2001. These trials have indicated that Bt-cotton provided effective control of bollworms, requiring no or fewer application of chemical insecticides. The approval by GEAC was based on the strength of such scientific data. The Bt-cotton hybrids approved were MECH 12, MECH 162 and MECH 184. Following the approval, Mahyco-Monsanto Biotech Limited (MMB), a joint venture of Mahyco and Monsanto, which had only a limited stock of the Bt cotton seeds, sold these in six states of south and central India (Andhra Pradesh, Karnataka, Tamil Nadu, Maharashtra, Madhya Pradesh and Gujarat) to cover about 29,000 hectares. Thus, the first commercial planting of Bt-cotton occurred in the second half of 2002. Following its success, there has been an increasing demand for Bt-cotton seeds in India.

More Bt-cotton hybrids approved

Realizing the potential of Bt-cotton, reputed seed companies like Rasi, Ankur, Nuziveedu, and several others, totaling more than 20, have already become sub-licensees of MMB for this technology. Meanwhile, MMB has come out with a more effective second generation Bt-cotton, stacked with two genes, cry1Ac and cry2Ab2, which was approved for commercial cultivation in Australia and the USA in 2002. Besides, two other companies, namely J.K. Seeds and Nath Seeds, have proposed newer versions of Bt-cotton. All these have been approved by GEAC in 2006 after they have completed satisfactorily the stipulated regulatory trials. All these companies who have their own germplasm will introduce the Bt-gene(s) into their own cotton hybrids developed for different agroclimatic regions and seek regulatory approvals. In fact, by 2006, altogether 62 Bt-cotton hybrids from 15 companies have officially approved by GEAC for commercial cultivation. These include 52 hybrids with only a single Bt-gene (48 from MMB and its sub-licensees and 4 from J.K.Seeds) and 10 hybrids with dual genes (7 from MMB and its sub-licensees and 3 from Nath Seeds). The names of these hybrids and zones where they are grown are depicted in the map.

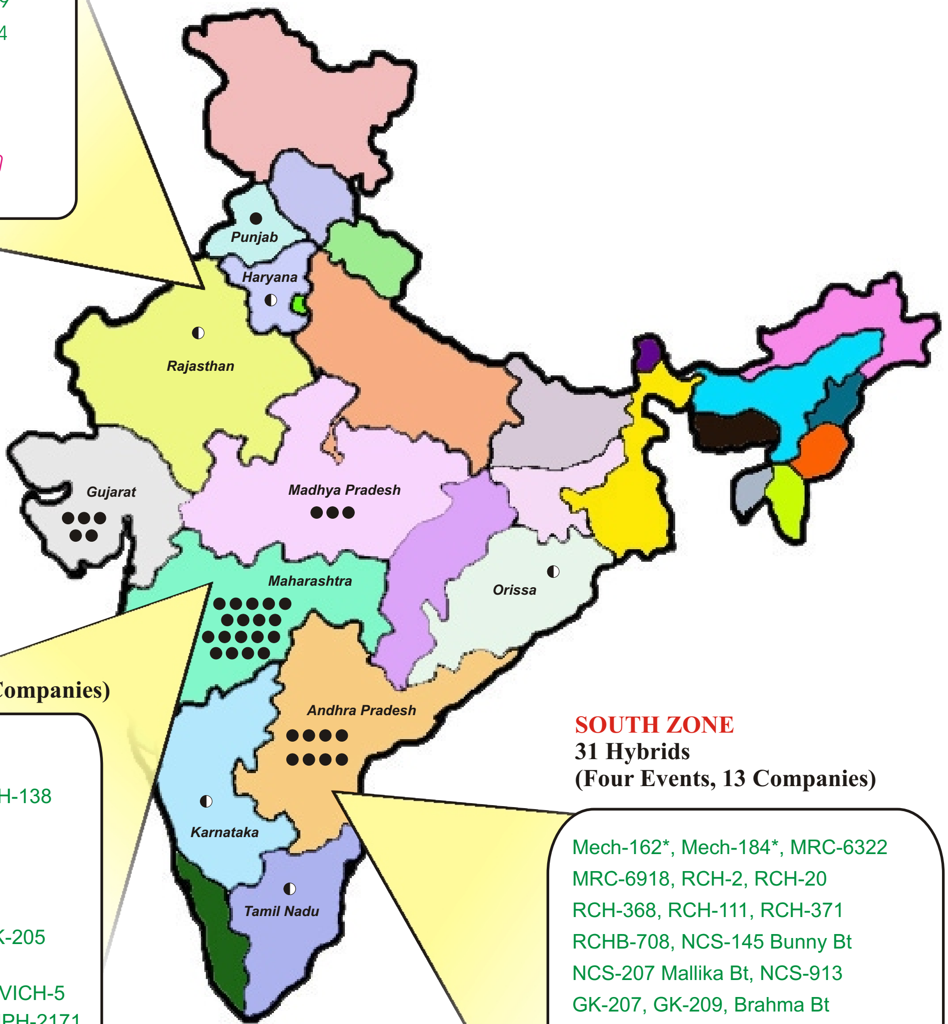
Adoption of Bt-cotton in India

Farmers' response to Bt-cotton has been overwhelming. The area under Bt-cotton in 2002, the first year of introduction, was about 29,000 hectare (72,000 acres). It increased significantly from year to year to reach 3.8 million hectare (9.4 million or 94 lakh acres) in 9 cotton-growing states in 2006 a remarkable growth rate in a short period of five years. Similarly, the number of farmers who adopted this technology has also increased from a few thousand in 2002 to 2.3 million (23 lakhs) in 2006 (see table). Such growths clearly reflect the farmers' confidence in this technology. Similar trends have been recorded in other countries also.

Approved Bt Cotton Hybrids in India (2006)

NORTH ZONE
14 Hybrids (Three Events, 6 Companies)

MRC-6301, MRC-6304
MRC-6025, MRC-6029
Ankur-651, Ankur-2534
RCH-134, RCH-317
RCH-308, RCH-314
NCS-913, NCS-138
NCEH-6R (GFM Event)
JKCH-1947 (Event-1)



CENTRAL ZONE
36 Hybrids
(Four Events, 15 Companies)

Mech-12, Mech-162,
Mech-184, MRC-6301
RCH-2, RCH-118, RCH-138
RCH-144, RCH-377
Ankur-09, Ankur-651
NCS-145 Bunny Bt
NCS-207 Mallika Bt
NCS-913, GK-204, GK-205
Tulasi-4, Tulasi-117,
Brahma Bt, VCH-111, VICH-5
VICH-9, PRCH-102, NPH-2171
ACH-33-1, ACH-155-1
KDCHH-9632, KDCHH-9810
KDCHH-9821
MRC-7301 (BG-II)
MRC-7326 (BG-II)
MRC-7347(BG-II)
ACH-11-2(BG-II)
KDCHH-441 (BG-II)
NCEH-2R (GFM Event)
JK Varun (Event-1)

SOUTH ZONE
31 Hybrids
(Four Events, 13 Companies)

Mech-162*, Mech-184*, MRC-6322
MRC-6918, RCH-2, RCH-20
RCH-368, RCH-111, RCH-371
RCHB-708, NCS-145 Bunny Bt
NCS-207 Mallika Bt, NCS-913
GK-207, GK-209, Brahma Bt
PRCH-102, PRCH-103
ACH-33-1, NPH-2171
PCH-2270, KDCHH-9632
Tulasi-4, Tulasi-117
VICH-5, VICH-9
MRC-7351 (BG-II), MRC-201 (BG-II)
NCEH-3R (GFM Event)
JK-Durga (Event-1)
JKCH-99 (Event-1)

* Mech 162 & Mech 184 are not approved for AP.

Event	Color Code
BG-I	Green
BG-II	**Brown**
GFM Event	*Pink*
Event-1	***Blue***

● For 100,000 hectares of Bt cotton
◐ For < 100,000 hectares of Bt cotton

Bt Cotton (2002-2006): 62 Bt cotton hybrids commercially released, 106 in large-scale trials (LST)

Compiled by ISAAA, 2006

Adoption of Bt Cotton in India (2002-06)		
Year	**Area under Bt Cotton (ha)**	**Nos. of Farmers**
2002-03	44,500	-
2003-04	100,000	-
2004-05	500,000	300,000
2005-06	13,00,000	10,00,000
2006-07	38,00,000	23,00,000

Source: ISAAA 2006

Bt-cotton is presently cultivated in 9 states. The area has consistently increased from year to year in almost every state. The figures for 2005 and 2006 are given in the table below to exemplify this.

State-wise adoption of Bt-cotton in India, 2005 & 2006

The distribution of Bt cotton in the major growing states in 2004, 2005 and 2006 is shown in table below. The major states growing Bt cotton in 2006, listed in order of hectarage, are Maharashtra (18,40,000 hectares representing almost half, 48% of all Bt cotton in India in 2006) followed by Andhra Pradesh (830,000 hectares or 22%), Gujarat (470,000 hectares or 12%), Madhya Pradesh (310,000 hectares or 8%), and 215,000 hectares (6%) in the Northern Zone and the balance in Karnataka and Tamil Nadu and other states.

State	2004 (ha)	2005 (ha)	2006 (ha)
Maharastra	200,000	607,000	18,40,000
Gujarat	122,000	150,000	470,000
Madhya Pradesh	80,000	146,000	310,000
Andhra Pradesh	75,000	280,000	830,000
Karnataka	18,000	30,000	85,000
Tamil Nadu	5,000	27,000	45,000
Northern Zone	-	60,000	215,000
Other	-	-	5,000
Total	**500,000**	**13,00,000**	**38,00,000**

Source: DBT 2006, ISAAA, 2006

Cotton Yield and Production: Pre & Post Release of Bt Cotton in India :

Over the last few years, India has achieved significant quantitative increase in cotton yield and production. Until recently, India used to import massive quantities of cotton in the range of 8 to 9 lakh bales per year. Coincidental with the steep increased adoption of Bt cotton between 2002 and 2006, the average yield of cotton in India, which had one of the lowest yields in the world, increased from 308 kg per hectare in 2001-02 to 467 kg per hectare in 2005- 2006 and 501 kg per hectare in 2006-07, with most of the increase in yield of up to 50%, or more, attributed to Bt cotton. At a national level, this is a major factor in higher cotton production increasing from 158 lakh bales in 2001-02 to 244 lakh bales in 2005-06 and 270 lakh bales in 2006-07, which is a record cotton crop for India.

Year	Production (Lakh Bales)	Yield (Kg/hectare)
2000-01	140	278
2001-02	158	308
2002-03	136	302
2003-04	179	399
2004-05	243	470
2005-06	244	467
2006-07	270	501

Source: CCI, Textile Commissioner, Mumbai

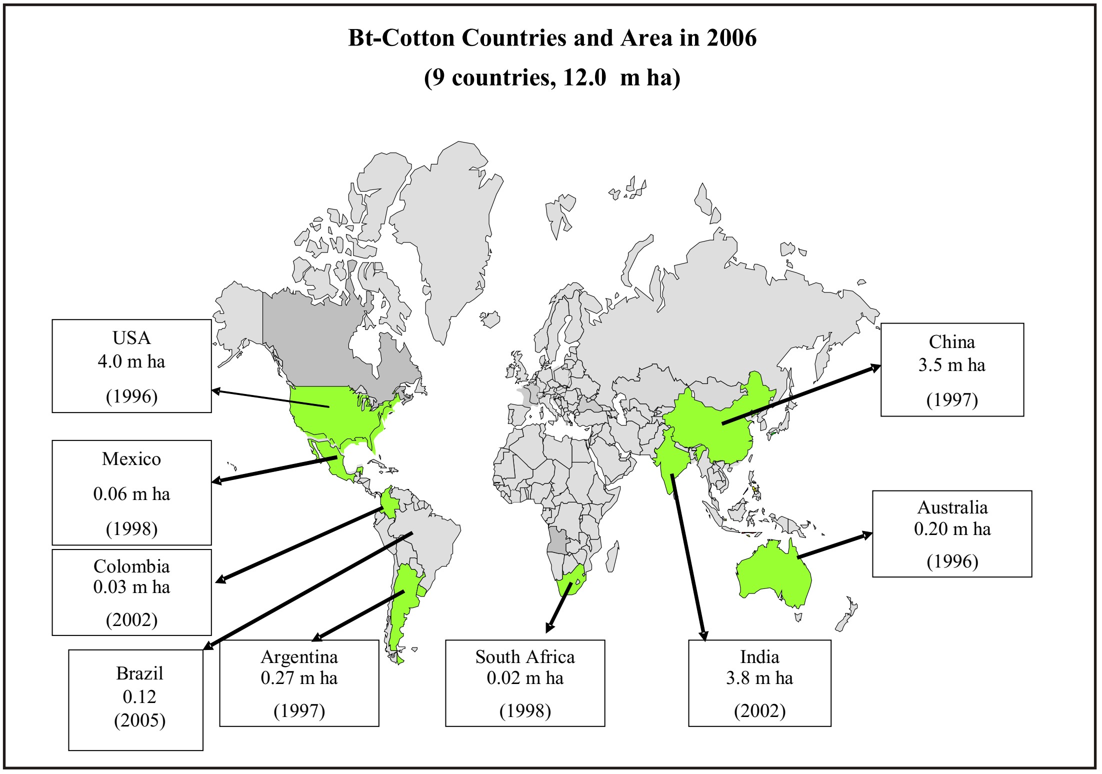
Status in other countries

As of 2006, genetically modified cotton was cultivated by 9 countries on 13.4 million hectares. Of this, 8.0 m ha had only the Bt gene(s) (including 3.8 m ha in India) while 4.0 m ha had Bt stacked with herbicide tolerance and another 1.4 m ha had only herbicide tolerance. The USA, India, China, Argentina, Australia, Mexico, South Africa, Colombia and Brazil were the countries that grew Bt-cotton. The area occupied by the genetically modified (GM) cotton in these countries from 2004 to 2006 is indicated in the table.

Country	Year Introduction	2004	2005	2006
United States	(1996)	4.2	4.60	5.30
India	(2002)	0.5	1.30	3.80
China	(1997)	3.7	3.30	3.50
Argentina	(1998)	0.02	0.07	0.36
Australia	(1996)	0.2	0.30	0.18
Brazil	(2005)	-	-	0.12
Mexico	(1996)	0.07	0.12	0.06
Columbia	(2002)	<0.02	<0.10	0.03
South Africa	(1998)	0.02	0.03	0.02
Total (Mha)	9.0	9.8	13.4	

Source: James, 2002, 2006

The reduction in area in 2006 over 2005 in Mexico was due to seed import constraints and in Australia due to reduction of total plantings of cotton owing to drought. In all other countries there was a significant increase in area with India recording an unprecedented 192% growth over the previous year. The country-wise break up of Bt-cotton area in 2006 is shown in the map.



* Includes 8.0 m ha with Bt (insect tolerance) alone and 4.0 m ha with Bt stacked with herbicide tolerance (1.4 m ha with herbicide tolerance alone is not included here)

More countries and farmers are expected to adopt this technology in the coming years.

10. SAFETY ASPECTS RELATED TO TECHNOLOGY

Transgenic technology particularly Bt-cotton has undergone all the prescribed tests and received approval by the regulatory authorities as safe both in India and other countries. The major issues addressed include those related to the potential of cry proteins for toxicity, allergenicity, effect on non-target beneficial organisms including biological control agents, feed safety, cross pollination, fate of protein in the soil, pest resistance etc. Even then, several doubts have been raised in certain quarters about its safety and benefits. Some of these are clarified below.

Safety of Bt cry proteins:

The cry 1 class of proteins expressed in Bt-cotton have selective toxicity to certain category of insects, in this case bollworms, and require certain specific conditions for their effective action. The protein has to be ingested by the target insects which happens when the caterpillars feed on the transgenic plant tissues. It requires an alkaline pH of 9.5 or above for effective processing and also specific receptors (on the brush-border membrane of mid-gut epithelium cells of target insect) for binding before it can kill the target insect. All these conditions are available in bollworms and therefore the caterpillars succumb when they feed on Bt-cotton plant. The protein cannot act in the human or animal intestine because their intestine is acidic, pH is about 1.5 and there are no receptors. Hence, Bt protein is safe to such non-target organisms.

Cross-pollination and gene flow:

The potential movement of transgenes from Bt-plants into related plants or weeds, through pollen flow, has been one of the concerns. This issue has been addressed for each Bt-crop that has been approved and experimentally demonstrated that there is no significant risk of capture and expression of any Bt cry gene by wild or weedy relatives of cotton, corn, or potato. The low risk has been ascribed to sexual incompatibility (due to differences in chromosome number) and differences in crop phenology (i.e., periodicity or timing of events within an organism's life cycle as related to climate, e.g., flowering time) and habitat.

In India, Bt gene has been introduced into hybrids developed from the new world cotton species (Gossypium hirsutum and G. barbadens) which are tetraploid. These cannot cross pollinate with the 'Desi' (local) cotton (G. arboreum and G. herbaceum) as they are diploid and lack reproductive compatibility. Further, cotton pollen is heavy and cannot travel beyond a few meters.

The potential for horizontal gene transfer from Bt-crops was also considered and evaluated. Various sub-species or strains of Bacillus thuringiensis already naturally occur in soil and therefore various cry genes have been available for long periods of time for any potential horizontal transfer from this bacterium to other soil species. Therefore, Bt crops, including cotton, are not adding anything new to the already existing flux of cry genes among the soil micro-organisms. There is no evidence that horizontal gene transfer has occurred from plants to microbes.

Fate of Bt proteins in soil:

It is feared that soil organisms may be affected on being exposed to cry proteins that may be incorporated into the soil through crop residues (through roots, pollen deposits, fallen leaves etc). Studies have been conducted to determine the amount of Bt-protein leached by roots and as also from other plant parts incorporated in the soil and its effect on soil rhizosphere and non-rhizosphere microflora, soil Collembola, earthworms etc. It was found that there was no adverse effect. In fact, there was no difference between the soils obtained from the Bt and non-Bt plots in this respect. It was also found that Bt insecticidal proteins are readily susceptible to metabolic, microbial and abiotic degradation once they are ingested or excreted into soil. The half-life of the Cry1Ac protein has been found to be a maximum of 41 days. Therefore, it cannot bio-accumulate causing delayed effects.

Effect on non-target organisms:

Another apprehension is that non-target organisms exposed to Bt cry proteins expressed in transgenic plants may suffer from undesirable deleterious effects. Several experimental studies were carried out to examine this issue.

Experimental animals like mice, rats, rabbits and sheep fed with unusually high doses (500, 1000 and 4300 mg/kg body weight) of cry1Ac protein showed no acute toxic effect on their health. These animals were found to be substantially equivalent to those not fed with cry 1Ac in respect of body weight, food consumption and other respects.

Proximate analysis showed that there was no difference between Bt-cotton and its non-Bt counter part in terms of protein, carbohydrates, ash and moisture contents. Forage composition of Bt-cotton is substantially equivalent to non-Bt cotton in respect of gossypol and other acid contents.

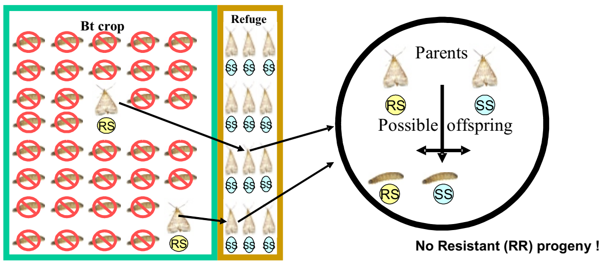
The U.S. Environmental Protection Agency (EPA) has concluded "that toxicity and infectivity risks of cry proteins to non-target organisms like avian, freshwater fish, freshwater aquatic invertebrates, estuarine and marine animals, arthropod predators/parasitoids, honey bees, annelids, and mammalian wildlife will be minimal to non-existent at the label use-rates of registered B. thuringiensis active ingredients." This provides strong support that cry proteins produced in Bt-crops approved for commercial cultivation will pose low risk to non-target organisms. A published report of toxicity to monarch butterfly caterpillars when force-fed with un-naturally high doses of Bt protein from Bt corn in the laboratory does not hold good for the natural situation where such high levels on plants are highly improbable.

In India, as per the direction of Department of Biotechnology (DBT), several studies relating to bio-safety were conducted. Feed-safety studies of Bt cottonseed meal were carried out with goats, buffalos, cows, rabbits, birds and fish. The results revealed that the animals fed with Bt-cottonseed meal showed no ill-effects and were comparable to control animals in the various tests. These studies were carried out at the Industrial Toxicological Research Institute (ITRC), Lucknow; National Dairy Research Institute, Karnal; Central Institute of Fisheries Education, Mumbai; Central Avian Research Institute, Bareily; National Institute of Nutrition, Hyderabad: and Govind Vallabh Pant University for Agriculture and Technology, Pantnagar. In short, the various feed-safety studies conducted showed Bt cottonseed meal to be substantially equivalent to the non-Bt counterpart.

Insect resistance management (IRM):

Pest populations exposed to Bt-crops continuously for several years have the potential to develop resistance to cry proteins. This phenomenon is not unique to Bt. In view of this, proactive insect resistance management (IRM) strategies have been developed and are in place so as to prevent or delay resistance development. A key element of these plans is that growers should plant sufficient non-Bt crops to serve as a refuge for producing Bt-susceptible insects. The recommendation includes growing 20% non-Bt cotton in the periphery of Bt-cotton as refuge and taking necessary control measures against bollworms in the refuge crop as and when required. The alternative is to grow only 5% non-Bt as refuge without taking any control measure. The refuge strategy is designed to ensure that Bt-susceptible insects will be available to mate with Bt-resistant insects, should they arise. The offspring of these mating will be Bt-susceptible, thus mitigating the spread of resistance in the population. Gene stacking or pyramiding, expression of optimum dose of Bt protein, and deployment of Bt-crops as one of the components of integrated pest management are the other options for IRM. Bollgard® II developed by Monsanto which has been approved for commercialization in Australia and the USA in 2002 is an example for gene stacking. This contains two Bt genes, cry 1Ac and cry 2Ab2. The proteins produced by these have different mode of action, thus making it very difficult for the pest to develop resistance to both the proteins simultaneously.

How a refuge crop helps in insect resistance management



On Bt-Crop:
- Freshly hatched larvae while feeding on Bt plant ingest Bt protein and nearly all of them die within one or two days.
- A scant few may survive and develop into moths (RS).

On Refuge:
- Freshly hatched larvae feed on plant and a large number of them successfully complete their life cycle and develop into moths. All of them will be susceptible to Bt protein (SS).

The no. of resistant moths (RS) is extremely low whereas that of susceptible moths very high. When a resistant moth (RS) looks for a mate, odds are greatly in favour of its finding a susceptible moth from the refuge. Pairing RS & SS results in susceptible progeny. Thus refuge helps in maintaining susceptible population.

Planting refuge is mandatory in India as in the USA, Australia and other countries. In India, Helicoverpa armigera, by far the most predominant bollworm, besides cotton, has a large number of alternative host crops like chickpea, pigeonpea, tomato, sunflower, maize and sorghum which are substantially grown around the same area at the same time as cotton. These crops, especially chickpea and pigeonpea, support large populations of H. armigera, thereby serving as natural refuge and helping IRM. Further, as the area presently occupied by Bt-cotton is very small (about 6% of the total cotton area), a huge crop of non-Bt hybrids and varieties are also available as refuge. In view of this, whether there is need to deliberately grow non-Bt cotton as refuge needs to be re-examined.

In the last 8-9 years of large scale commercial cultivation of Bt-cotton in various countries (7.5 million hectares in 8 countries in the year 2004), there has been no evidence of field resistance to the in planta expressed Bt protein by bollworms. This is encouraging and monitoring should be continued.

11. PERFORMANCE OF TECHNOLOGY

Both pre- and post-commercialization studies conducted by several public institutions and private seed companies (under the monitoring of RCGM) have indicated that Bt-cotton has increased farmers' income. For example, the multi-location field trials conducted by ICAR in 2001 with Mahyco's three Bt-cotton hybrids, as a part of the regulatory requirements, revealed that these hybrids yielded 60 to 92% more than the local and national checks and fetched a net profit between Rs.4,633 and Rs.10,205/ha which was about 67% higher.

Post-release, the nationwide surveys conducted by ACNielsen & ORG-MARG in 2003 and by the International Market Research Bureau (IMRB) in 2004 & 2005, revealed that on an average, yield increase owing to effective bollworm control ranged from 29 to 58% (4.25 to 7.4 quintals/ha), pesticide reduction from 60 to 72% (savings of Rs. 2,800 to 3,200 per hectare) and increase in net profit to farmers from 60 to 78% (Rs.7,725 to 14,700 per hectare). In the surveys, more than 90% of the Bt-cotton users and 42% of the non-users expressed their intention to purchase Bt-cotton seeds in the next season. Another survey conducted by the Gokhle Institute of Politics and Economics, Pune, in 2003 in certain parts of Maharashtra has also indicated that Bt-cotton was profitable to farmers.

Another report indicated that the net economic benefits to Indian farmers from Bt-cotton was, on an average, $139 per ha in 2002, $324 per ha in 2003 and $260 per ha in 2004, with a four-year average of $225 per ha. Other studies also reported results in the same range, acknowledging that the benefits will vary from year to year and also from place to place due to varying levels of bollworm infestation, agronomic conditions and cultivation practices.

In a more recent (2006) study conducted in Maharashtra, Gujarat, Andhra Pradesh and Tamil Nadu by the Indian Institute of Management (IIM), Ahmedabad, the profit from Bt-cotton was found to be higher in all the states, both under irrigated and non-irrigated conditions. It reported an yield gain of 31%, reduction in the number of pesticide sprays by 39% and an 88% increase in profit (Rs.11,250 or US$250 per hectare). The farmers found advantage in pest incidence, pesticide cost, cotton quality, yield and profit. Almost all farmers indicated that they plan to plant Bt-cotton in the future. Similar results have been reported from several other countries also.

However, the results of alternative experiments and surveys carried out independently by Gene Campaign; Centre for Sustainable Agriculture; Research Foundation for Science, Technology and Ecology; Greenpeace and a few other NGOs in India who have always been opposed to this technology, found no such benefits. According to them, Bt-cotton suffered more bollworm damage, required more pesticide sprays, yielded less and produced poorer quality cotton than the non-Bt cotton.

The final judgment is best left to farmers. They have the option to choose Bt-cotton or non-Bt cotton whichever is beneficial to them. The fact remains that the number of Bt-farmers is increasing from year to year.

Bt technology is useful to both small farmers and big farmers. It does not distinguish between the two. It controls bollworms no matter who is growing the crop. In India, in 2006, about 2.3 million small cotton farmers were able to derive attractive economic benefits from Bt-cotton. Similarly, thousands of small farmers in China, South Africa, Argentina and other developing countries have been amply benefited by this technology.

12. WAY FORWARD

The Government of India is giving top priority for agricultural biotechnology and has been extending financial and technical support to a number of research institutions.

Several public sector institutions, spearheaded by the Indian Council of Agricultural Research (ICAR), are developing various biotech crops with different traits ranging from insect resistance, salinity and drought tolerance, quality improvement and nutritional enhancement. Such research is at various stages of development. The following table provides some details.

Crop	Trait (Character)	Gene(s)
Cotton	Resistance to boll worm Resistance to leaf curl virus	Cry1Ac, Cry1F, Cry1Aa3 Antisense Cp Sense Cp
Brinjal	Resistance to shoot and fruit borer	Cry1Aa, Cry1abc
Rice	Resistance to Yellow Stem Borer Sheath blight resistance Salinity and drought tolerance Submergence tolerance	Cry1Ac, Cry1Aa3 Chitinase DREB1a, TPSP PDC
Maize	Resistance to stem borer	Cry1Ab
Chickpea	Resistance to pod borer	Cry1Aa3
Pigeonpea	Resistance to pod borer	Cry1Aa3
Soybean	Resistance to mung bean yellow mosaic virus	Rep sense Rep antisense
Mustard	Salinity and drought tolerance Resistance to aphids	Osmotin DREB1a, Zat12 Lectin gene
Tomato	Salinity and drought tolerance Resistance to leaf curl virus Resistance to fruit borer Delayed ripening Improved texture	DREB1a Truncated Rep gene, Antisense rep Cry1Aa3 Antisense ACC synthase Expansin
Banana	Resistance to banana streak virus Resistance to bunchy top virus Resistance to Fusarium wilt	Rep antisense Cp gene Antimicrobial peptide gene
Papaya	Resistance to leaf curl virus Resistance to ring spot virus	Rep antisense, Cp sense Cp antisense

Cassava	Resistance to mosaic virus	Rep antisense
Potato	Quality Improvement Resistance to late blight Resistance to mosaic and leaf curl virus	Ama1 RB gene Cp sense Rep antisense
Groundnut	Resistance to tobacco streak virus	Cp sense Cp antisense
Wheat	Drought tolerance	DREB1a
Sorghum	Resistance to stem borer	Cry1Ab

Source: ICAR, DBT

Some of the research that has generated a lot of interest:include Nutritional enhancement in potato by deploying a non-allergenic seed albumin gene AmaI derived from the plant Amaranthus hypochondriacus; improving the beta carotene level in the Indian mustard; Bt-crops, notably brinjal, totamo, chickpea, pigeon pea, groundnut, cotton (in addition to those already developed and approved) and rice, for protection against serious insect pests; and attempts to develop drought resistant crops. These are at various stages of experimentation or regulatory approvals.

Some of the research institutions involved in these efforts include IARI; various ICAR institutions; ICRISAT; TERI; State Agricultural Universities; Jawaharlal Nehru University, New Delhi; Delhi University, New Delhi; Bose Institute, Kolkata; Madurai Kamaraj University, Madurai, etc.

A number of private companies also have very interesting projects.

Globally, 63 countries are involved in doing research on 57 crop species for various beneficial traits. These products would add value to sustainable agriculture and contribute towards meeting the food demand of the ever-increasing population.

There has been an unending debate over the safety and benefits of Bt-cotton. The fact remains that during the last 11 years of its commercial cultivation on millions of hectares in several countries, and since 2002 in India, there has not been a scientifically proven negative impact related to safety of humans/animals/environment or pest resistance. On the other hand, Bt-cotton has contributed substantially towards yield increase owing to effective control of bollworms, drastic reduction in the application of chemical pesticides and more profit to farmers. Such positive impact should be effectively communicated to the farmers and the general public.

According to ISAAA, the global outlook for the next decade of commercialization, 2006 to 2015, points to continued growth in the global hectarage of biotech crops, up to 200 million hectares, with at least 20 million farmers growing biotech crops in up to 40 countries or more by 2015. Most of this growth is expected to take place in the developing countries of Asia, led by China and India. With its vast resources, India has the potential to emerge as one of the leading agricultural countries in the world if modern technologies are appropriately utilized.

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