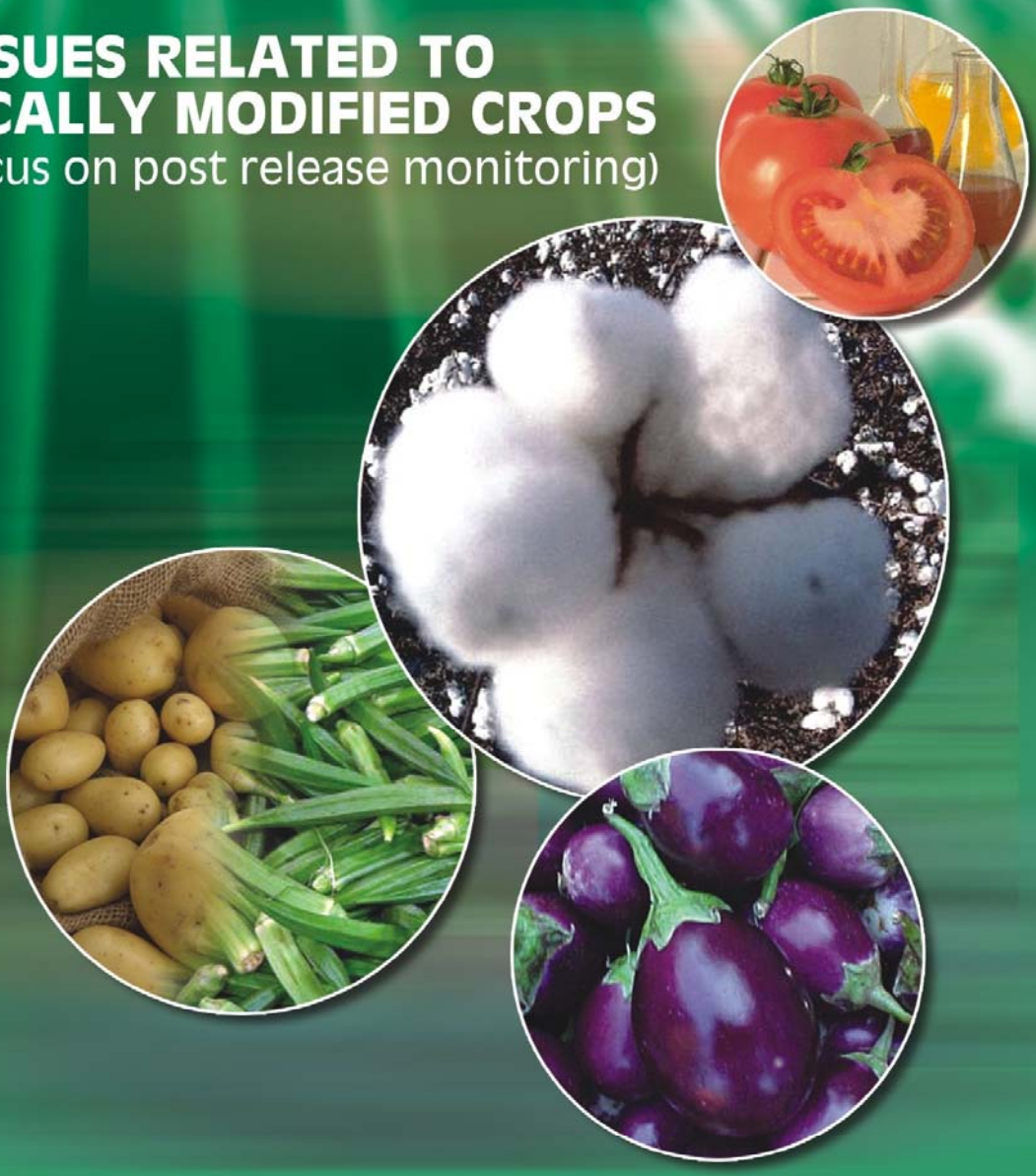
ISSUES RELATED TO GENETICALLY MODIFIED CROPS

(With a focus on post release monitoring)



Biotech Consortium India Limited
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Department of Agriculture & Cooperation
Ministry of Agriculture
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FOREWORD

India is one of the major countries which has released Genetically Modified cotton for commercial cultivation. The area under the cultivation of Bt.cotton has increased rapidly to reach the figure of 1.4 million hectares. Many more transgenic crops are at different levels of development, trial and evaluation. With these developments it is necessary that seed quality law enforcement is improved. It is for this purpose that the Department of Agriculture & Cooperation, Ministry of Agriculture, has initiated a programme of training for the law enforcement agencies including Seed Inspectors, Certification Agencies, Seed Testing Laboratories etc. The programme is being executed through the BCIL.

I am glad that the BCIL has taken up the execution of the programme in right earnest. The training programmes will be conducted in different places in the country and on the basis of experience gained in these programmes, new strategies will be evolved for improving the quality of law enforcement. I would like to compliment the BCIL for bringing out relevant and comprehensive material for the benefit of the trainees.

(S.L.Bhat)
Joint Secretary (Seeds)

1 INTRODUCTION

In agriculture genetic modifications has been taking place with time by domestication, selection and controlled breeding of crops for thousands of years. However, in modern science, new recombinant DNA (rDNA) or genetic engineering technologies are now used to transfer genes within and across plant species to generate genetically modified (GM) plants/crops, also described as transgenic crops.

Genetic engineering or transgenic technology is similar to conventional breeding in terms of the objective of generating more useful and productive crop varieties containing new combination of genes, but it expands the possibilities by enabling introduction of useful genes not just from within the crop species or from closely related plants, but from a wide range of other organisms. It allows the transfer of one or more genes, in a controlled and predictable way than is achievable in conventional breeding.

GM crops incorporate traits such as pest and disease resistance and herbicide tolerance, product quality improvement and abiotic stress tolerance. As of now, 19 crops have been approved for commercial cultivation in the world. The global area under cultivation of GM crops has increased to 90 million hectares in 2005 from 1.7 million hectares in 1996 when the first GM crop was commercially cultivated.

In India, Bt cotton containing the cry1Ac gene from *Bacillus thuringiensis* was approved by Government of India in March 2002 as the first GM crop for commercial cultivation for a period of three years in six states i.e., Madhya Pradesh, Gujarat, Maharashtra, Andhra Pradesh, Karnataka and Tamil Nadu. In 2005, it was approved in three more states i.e., Punjab, Haryana and Rajasthan. The area under Bt cotton increased from 72,000 acres in 2002 to 31,00,000 acres in 2005.

Apart from cotton, there are more than 10 GM crops under development and field trials in India. These are mostly related to insect resistance. These GM crops are expected to offer higher crop productivity, reduced farm costs, increased profit and improvement in the environment. However, as more and more GM crops are being released for field-testing and commercialization, concerns have been expressed about the potential risks associated with their impact to human health, environment and biological diversity.

India has a well-defined regulatory mechanism for development and evaluation of genetically modified organisms (GMOs) including GM crops and the products thereof. Rules notified in 1989 under Environment (Protection) Act, 1986 (EPA) define the competent authorities and composition of such authorities for handling regulation of GMOs and products thereof. There are elaborate steps to manage these risks through the involvement of Ministry of Environment and Forests (MoEF), Department of Biotechnology (DBT), Ministry of Agriculture (MoA) and State and district level authorities.

Bt cotton, the first GM crop being commercially cultivated in India has been subject to extensive monitoring both at central and state levels during the last four years. However, in spite of the fact that available scientific data indicates no serious adverse impact on the environment when necessary safeguards are observed, there are considerable apprehensions in certain quarters about the impact of GM crops. Further, there are many misconceptions among the optimistic user segments that these crops particularly Bt cotton will bring in an end to all their problems whereas these are actually developed for one particular trait and can solve only that problem. There have also been reports about production, supply and marketing of unapproved (illegal) and spurious Bt cotton seeds for short term economic gains. Therefore, there is a need that State authorities be actively involved in both pre and post-release monitoring and management of GM crops and their products.

Keeping in view the above, Department of Agriculture & Cooperation, Ministry of Agriculture (MoA), Government of India in association with Biotech Consortium India Limited has initiated training and awareness campaign in Bt cotton growing states to inform concerned state government officials, scientists, NGOs and other stakeholders including farmers at state and district levels. State level events have been planned to focus on train the trainers approach followed by district level meetings to apprise all concerned about this new technology and associated agronomic practices so that benefits could be reaped in a safe and sustainable manner.

2 DEVELOPMENT OF GM CROPS

Selective breeding and cross-fertilization have been used to impart desirable traits in plants such as higher yields and resistance to pests for thousands of years. Through trial and error, plant varieties have been developed with altered and stable genetic traits. However, over the past 30 years, the ability to alter life forms has been revolutionized by modern biotechnology. Using sophisticated techniques of genetic engineering or recombinant DNA technology, it is now possible to precisely manipulate the intricate genetic structure of individual living cells by incorporating genes from totally different species. Bacterial genes can be used to make insect resistant crops or genes from a coldwater fish can be used to create frost resistant plants. The resulting organisms are known as genetically modified organisms (GMOs) or living modified organisms (LMOs). When the GMO is a crop plant, it is referred to as a GM crop or transgenic crop. An overview of basic science involved in development of GM crops is presented below.

2.1 WHAT IS A GM CROP?

A GM crop contains a gene or genes of a different species artificially inserted in its genome when the inserted gene sequence comes from an unrelated plant or from a completely different species, it is also knows as transgene and the resulting GM crop as a transgenic crop.

2.2 WHY MAKE GM CROPS?

Conventional plant breeding involves exchange of genes between two plants to produce a hybrid for a desired trait by cross pollination. GM technology is similar to conventional plant breeding in terms of the objective of generating more useful and productive crop varieties containing new combination of genes, but it expands the possibilities by enabling introduction of useful genes not just from within the crop species or from closely related plants, but from a wide range of other organisms. It allows the transfer of one or more genes, in a controlled and predictable way than is achievable in conventional breeding. GM crop plants can therefore incorporate the desired traits more quickly and more reliably than through conventional methods.

2.3 HOW IS GENETIC MODIFICATION POSSIBLE?

Genetic modification involving the copying and transfer of genes from one organism to another is possible because the genetic code is universal i.e. the DNA of all organism is made up of the same building blocks and is encoded in exactly the same way. Therefore, it is possible to transfer a copy of

DNA sequence (or gene) that codes for a particular characteristics into the cell of a different organism. Once the gene is incorporated into the genome of recipient, the resulting organism is considered to be genetically modified and the new characteristics coded by that gene is inherited by subsequent generations.

2.4 WHAT IS DNA?

All the living organisms can be modified because of presence of a molecule called Deoxyribonucleic acid (DNA) in every cell of all the organisms (Figure 2.1). DNA is the molecule that 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. DNA exists in the nucleus of each cell.

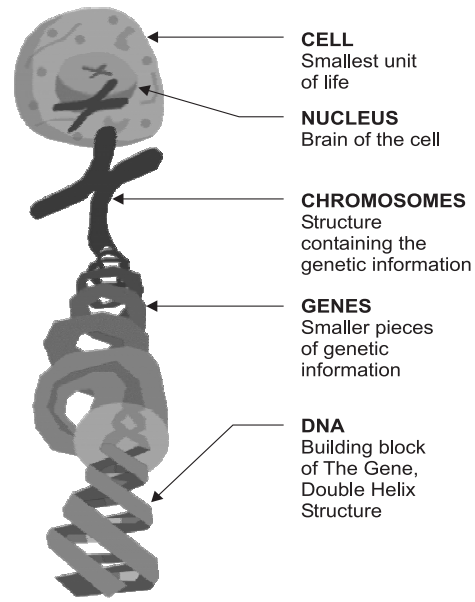


Figure 2.1 Organization of DNA in the cell

The building blocks of DNA are called bases and they come in four types that can link together in different sequences. The four bases also called nucleotides are adenine, cytosine, guanine and thymine. DNA is double stranded with base pairing between adenine and thymine and cytosine and guanine forming the rungs between the phosphate backbones of the two DNA strands. These two long strands wound around each other in a spiral shape called the double helix. The order of bases on each strand makes up the DNA sequence. The number of possible sequences is almost endless because an individual strand of DNA may contain millions of bases.

2.5 WHAT IS A GENE?

A gene is basically a discrete segment of DNA encoding for set of instructions in the cell and contains all information concerning the form and functions of all living cells that give characteristics to an organism (Figure 2.2).

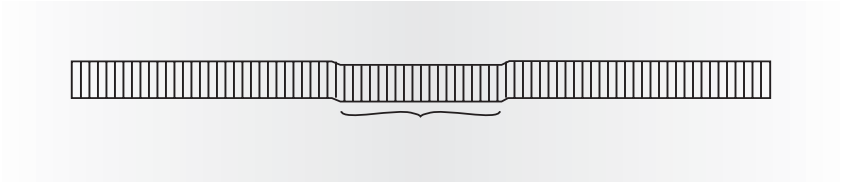


Figure 2.2 : Gene as segment of DNA

2.6 WHAT IS A GENOME?

An organism's complete set of genes is called the genome. All the cells in an organism carry and identical and complete genome, which means every cell contain at least one copy of every gene, although it may not be active. By switching different combinations of genes on or off cells develop into different types e.g. leaf, root and flower cells in plants or heart, lung and skin cells in animals.

All organisms have genomes of varying sizes; for instance, the human genome has an estimated 60,000 – 100,000 genes, most plants have about 20,000, a nematode (a microscopic creature) has about 18,000; and the single celled *Escherichia coli* bacterium just over 4,000. The genetic differences among different species as well as organisms within a species lie in the difference in number and sequence of these genes in the DNA/genome.

2.7 WHAT IS A PROTEIN?

Proteins are made up of long chains of amino acids and have a variety of roles in the cell such as structural proteins or enzymes that carry out many of the life processes in plants and animals.

2.8 HOW IS PROTEIN MADE FROM DNA?

Genes contain the information necessary for assembly of a specific protein. The proteins 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 the form of proteins is via messenger Ribonucleic acid (mRNA) intermediate as shown in the diagram below (Figure 2.3).

Figure 2.3 : Sequence of events from DNA to protein expression
Source: http://cls.casa.colostate.edu/TransgenicCrops/how.html

The transcription and translation processes are controlled by a complex set of regulatory mechanisms, so that a particular protein is produced only when and where it is needed.

2.9 WHAT IS GENETIC ENGINEERING OR RECOMBINANT DNA TECHNOLOGY (rDNA TECHNOLOGY)?

Genetic engineering or rDNA technology involves artificial transfer of genes or gene fragments from one organism to another to produce novel traits in the recipient living organism. The important tools used include enzymes for DNA manipulation, vectors, expression hosts and marker genes.

2.10 HOW TO DEVELOP GM CROPS?

GM crops are produced through genetic engineering in which genes that code for desirable traits are transferred from one organism to another. There are four steps in developing a GM crop.

a. **Identification of a gene:** The first step is to identify a particular characteristic from any organism (plant, animal or microorganism) and find out which gene or genes in the organism are responsible for producing that characteristic. This is followed by the use of molecular biology techniques to isolate and copy the gene of interest. Identifying and locating genes for the required traits is currently the most limiting step in the development of GM crops. Relatively little is known about the specific genes required to enhance yield potential, improve stress tolerance, modify chemical properties etc. Further, identifying a single gene involved with a trait is not sufficient and it is important to understand how the gene expression is regulated, what other effects it might have on the plant, and how it interacts with other genes active in the same biochemical pathway.

b. **Designing Genes for Insertion:** Once a gene has been isolated and cloned (amplified in a bacterial vector), it must undergo several modifications before it can be effectively inserted into a host. A simplified representation of a constructed transgene, containing necessary components for successful integration and expression is given below (Figure 2.4) along with the description of components:

Figure 2.4 : Components of a constructed transgene for integration and expression

- A **promoter sequence** must be added for the gene to be correctly expressed (i.e., translated into a protein product). The promoter is the on/off switch that controls when and where in the plant the gene will be expressed.
- The **termination sequence** signals to the cellular machinery that the end of the gene sequence has been reached.
- A **selectable marker gene** is added to the gene "construct" in order to identify plant cells or tissues that have successfully integrated the transgene. This is necessary because achieving incorporation and expression of transgenes in cells is a rare event, occurring in just a small portion of the targeted tissues or cells. Selectable marker genes encode proteins that provide resistance to agents that are normally toxic to plants, such as antibiotics or herbicides. Only those plant cells that have integrated the selectable marker gene will survive when grown on a medium containing the appropriate antibiotic or herbicide. As for other inserted genes, marker genes also require promoter and termination sequences for proper function.

c. **Transformation:** Transformation is the heritable change in a cell or organism brought about by the uptake and establishment of introduced DNA. There are two main methods of transforming plant cells

and tissues (Figure 2.5). The first one is **The Gene Gun method** (also known as microprojectile bombardment or biolositics). The DNA to be introduced into the plant cells is coated onto tiny particles such as that of tungsten. These particles are then physically shot onto plant cells. Some of the DNA comes off and is incorporated into the DNA of the recipient plant. The second one is **The *Agrobacterium* method.** This method uses a bacterium i.e. *Agrobacterium tumefaciens* to introduce the gene(s) of interest into the plant DNA. *Agrobacterium* is a plant pathogen capable of causing tumors in plants through large plasmids called Ti plasmids. When infection occurs, a portion of the Ti plasmid is transferred to the plant cells and is incorporated into the plant genome.

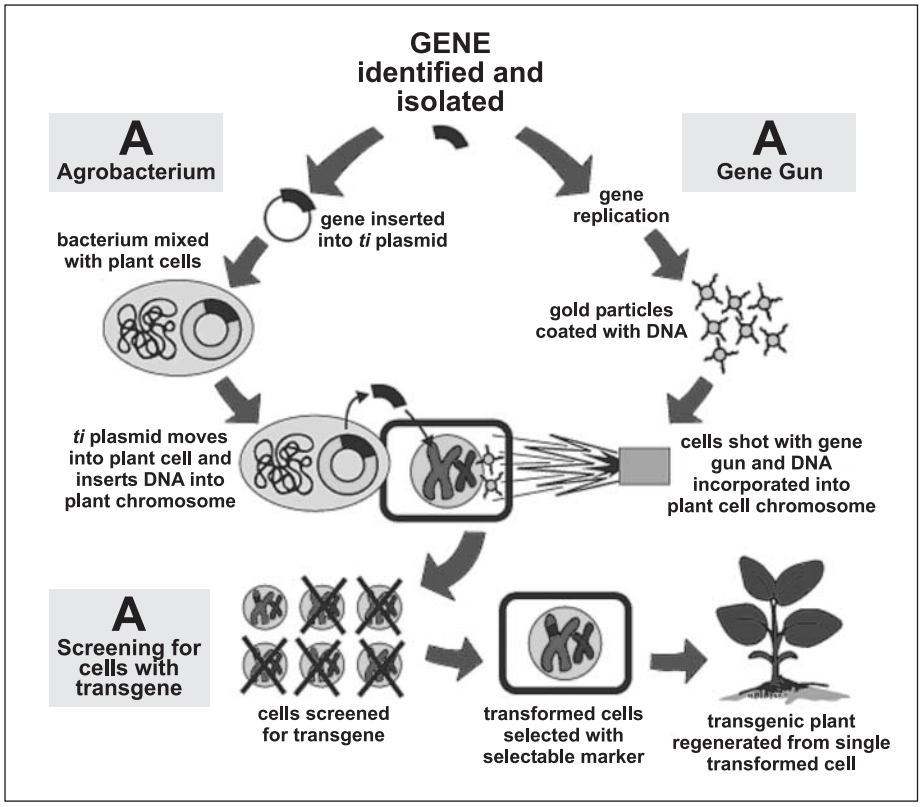


Figure 2.5 : Methods of producing transgenic plant
Source: Peel, M.D. (2001). A Basic Primer on Biotechnology North Dakota State Univ., Fargo.

d. **Selection:** Following the gene insertion process, plant tissues are transferred to a selective medium containing an antibiotic or herbicide, depending on which selectable marker was used. Only plants expressing the selectable marker gene will survive and it is assumed that these plants will also possess the transgene of interest. Thus, subsequent steps in the process use these surviving plants.

To obtain whole plants from transgenic tissues such as immature embryos, they are grown under controlled environmental conditions in a series of media containing nutrients and hormones by tissue culture. Once whole plants are generated and they produce seeds, evaluation of the progeny begins.

To verify whether the inserted gene has been stably incorporated without detrimental effects to other plant functions, product quality, or the intended agro ecosystem, initial evaluation includes attention

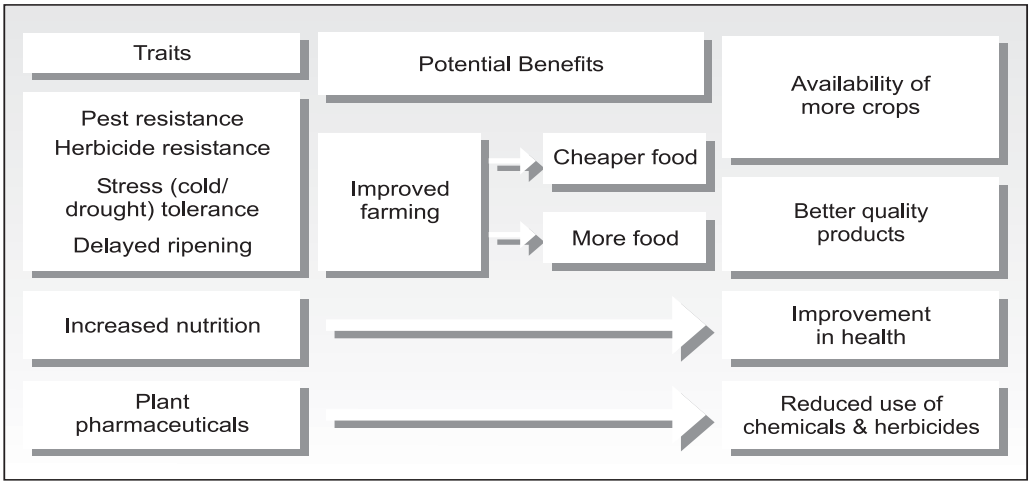
to activity of the introduced gene; stable inheritance of the gene and unintended effects on plant growth, yield, quality etc.

The plant is then crossed with improved varieties of the crop because only a few varieties of a given crop can be efficiently transformed, and these generally do not possess all the producer and consumer qualities required of modern cultivars. The initial cross to the improved variety must be followed by several cycles of repeated crosses to the improved parent, a process known as back crossing. The goal is to recover as much of the improved parent's genome as possible, with the addition of the transgene from the transformed parent. The next step in the process is multi-location and multi-year evaluation trials in greenhouse and field environments to test the effects of the transgene and overall performance. This phase also includes evaluation of environmental effects and food safety.

3 APPLICATIONS OF GM CROPS

GM crops have been developed to incorporate various traits such as insect pest resistance, herbicide tolerance, disease resistance, altered nutritional profile, enhanced storage life etc. The benefits of their use include increased crop yields, reduction in farm costs and thereby increase in farm profit as well as protection of the environment. Research is focused on a second generation of GM crops that feature increased nutritional and/or industrial traits such as easy processability. These varieties are expected to bring in more direct benefits to consumer such as correction of dietary deficiencies. Figure 3.1 summarizes the potential benefits of various traits incorporated in the GM crops.

Figure 3.1 Potential Benefits of Transgenic Crops



The range of crops being targeted for genetic improvement include several commercially important crops such as maize, soybean, tomato, cotton, potato, mustard, rice etc.

3.1 INSECT RESISTANCE

Insect pest menace is one of the major factors that destabilize crop productivity. Insects have been known to damage the crops in the field and during storage. Crop productivity is under constant threat of pest and disease incidence all over the globe.

Biotechnology has opened up new avenues for natural protection for plants by providing new biopesticides, such as microorganisms, that are toxic to targeted crop pests but do not harm humans, animals, fish, birds or beneficial insects.

One of the best-known examples is that of commonly found soil bacterium *Bacillus thuringiensis*. The spores of *Bacillus thuringiensis* (Bt) contain a crystalline protein (*cry*), which breaks down to release a toxin, known as delta-endotoxin, is highly toxic to lepidopteran larvae (Figure 3.2). Different *cry* genes, also known as Bt genes have been identified, cloned and characterized. Effective gene constructs have made it possible to deliver these genes into plant tissues so that they are expressed at levels high enough to kill the insects. Bt cotton and maize which have increased resistance to bollworms have been developed and cultivated since 1996.

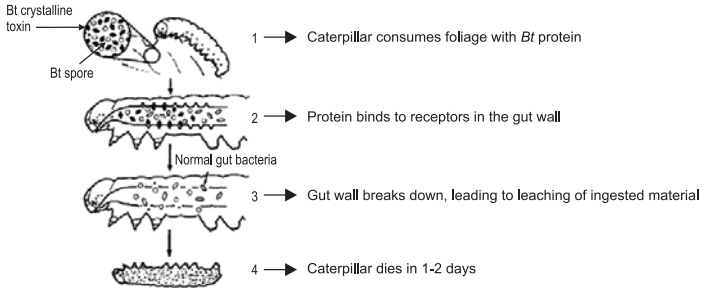


Figure 3.2 : Bt toxin: Mechanism of action

3.2 HERBICIDE TOLERANCE

Good planting conditions for crops also sustain weeds that can reduce crop productivity as they compete for the same nutrients the desired plant needs. To prevent this, herbicides are sprayed over crops to eliminate the undesirable weeds. As the crop plants themselves are affected by a high concentration of herbicides, these herbicides are required to be applied several times during the growth cycle leading to not only increased expenditure to the farmers but also harmful effects to the environment. Further, many effective broad spectrum herbicides do not distinguish between weeds and crops.

Crop plants can be modified to make them resistant to herbicides, so as to eliminate weeds more selectively. For example-GM cotton and soyabean resistant to herbicide Roundup TM have been developed. Genes that provide resistance to other herbicides such as sulfonyl ureas, gluphosinates etc have also been identified and transferred to produce various GM plants. When the herbicide is sprayed, it will kill the weeds but have no effect on the crop plants. Therefore, the herbicide can be applied in a single dose or a fewer doses of higher concentration. For example, genetically modified soyabean of Monsanto requires only one application of weed killer "Roundup" instead of multiple applications, reducing farming cost and environmental damage (Figure 3.3).

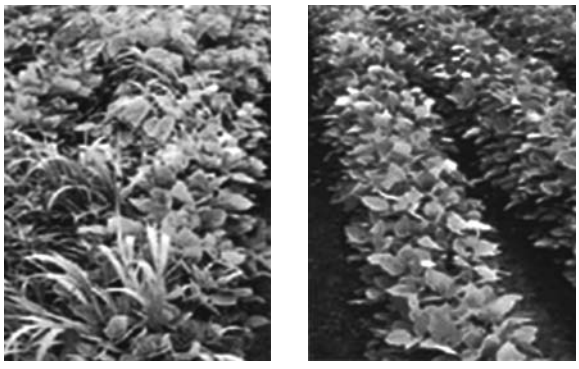


Figure 3.3 : Comparison of a weed-infested soybean plot (left) and Roundup Ready soybean after Roundup treatment (right)
Source: http://www.colostate.edu/programs/lifesciences/Transgenic/Crops/current.html#Bt/Monsanto

3.3 DISEASE RESISTANCE

Plants are susceptible to viral, bacterial and fungal diseases. Much progress has been made in evolving GM plants resistant to viruses. For example, expression of a gene that encodes the coat protein of tobacco mosaic virus (TMV) in GM tobacco plants has been shown to enable the plants to resist TMV infection. A number of other viral resistant plant species have been developed including squash and potatoes.

Genetic engineering of crop plants for resistance to fungal and bacterial infections has been more difficult. However, by studying the defensive genes that are expressed in naturally disease-resistant plants, encouraging progress has been made.

3.4 PRODUCT QUALITY IMPROVEMENT

There are several areas where GM techniques are being applied to improve product quality as well as improved nutritional profiles such as:

i. Improved flavour
ii. Increased shelf life
iii. High nutritional value
iv. Greater processability
v. Changes in composition

One of the most successful and initial research efforts to change the characteristics of a plant product was carried out with tomatoes. Tomatoes need to be picked while still green so that they are firm enough to withstand mechanical handling and transport. Unfortunately, they do not develop the same flavor and texture of vine-ripened tomatoes. GM tomatoes have been developed that have normal color and flavor but they soften more slowly and can be picked and processed after they are ripe. They also have higher content of soluble solids and are, therefore, better than normal tomatoes for further processing.

Improvement in nutritional characteristics includes increasing the contents of vitamins, minerals and other micronutrients, modifying fats and oils, altering the starch and sugar content or protein/amino acid profiles etc. Transgenic lines of potato with increased levels of starch have been developed by introducing a gene from bacteria for enhancing starch biosynthesis. A promoter from a potato gene that encodes the major protein in potato tubers has been used, so that the expression of the introduced gene is limited to the tuber. Tubers accumulate approximately 3 to 5% more starch than normal potatoes and when they are deep-fried absorb less oil and yield chips having fewer calories.

Rice with enhanced level of beta carotene (the precursor of vitamin A) and iron are being developed to address the problems of vitamin A deficiency. Other products in the pipeline include canola containing high levels of oleic and lauric acids, staple crops with improved protein content and vegetable and fruits with delayed ripening as well as modified flavor characteristics.

3.5 RESISTANCE TO ENVIRONMENTAL STRESSES

In addition to the biological challenges to plant growth and development, crops plants need to cope up with abiotic stresses such as drought, cold, heat and soils that are too acidic or saline to support plant growth. While plant breeders have successfully incorporated genetic resistance to biotic stresses such as diseases into many crop plants through cross breeding, their success at creating crops resistant to abiotic stresses has been more limited, largely because few crops have close relatives with genes for resistance to these stresses.

Therefore crop biotechnology is being increasingly used to develop crops that can tolerate difficult growing conditions. For example, researchers have genetically modified tomato and canola plants that tolerate salt levels 300 percent greater than non-genetically modified varieties. Other researchers have identified many genes involved in cold, heat and drought tolerances found naturally in some plants and bacteria and are trying to incorporate them in crops.

3.6 PLANT BASED PHARMACEUTICALS

Plants are among the most efficient bioreactors, which produce quantities of material with sunlight, and soil based nutrients as inputs. Attempts are being made to replace the traditional fermentation procedure for the production of biopharmaceuticals to plant based production. The benefits of using plants are the ability to increase production at low cost by planting more acres, rather than building fermentation capacity, lower capital and operating cost, simplified downstream processing etc.

Therapeutic drugs to treat cancer, infectious diseases, autoimmune deficiencies, cardiovascular diseases and several vaccines can potentially be grown in plants. Transgenic technology is being used to produce a plant that will generate a seed that expresses a desired therapeutic protein. This seed can propagate under the right growing conditions to yield plants and seed stock for producing the desire protein. The desired protein can be extracted from the seed to make a biopharmaceutical. Plant based therapeutics are expected to be highly cost effective.

4 SAFETY CONCERNS

Although the development of GM crops using recombinant DNA techniques is relatively recent, their applications and use is increasing because of advantages over the conventional crops. However as more and more GM crops are being released for field-testing and commercialization, concerns have been expressed regarding the risks arising from their use due to potential risks to both human health and environment.

These apprehensions arise because GM technology crosses the species barrier as compared to classical selection techniques, thereby permitting the gene transfer among microorganisms, plants and animals. There is no evidence that any unique hazards exist in the development of GM crops, because of novel combinations of genes. It is not true that all GM crops are toxic or are likely to proliferate in the environment. However, specific crops may be harmful by virtue of novel combinations of traits they possess. This means that the concerns associated with use of GMOs can differ greatly depending on the particular gene-organism combination and therefore a case-by-case approach is required for assessment of safety concerns.

Potential risks from the use of GM crops broadly fall under two categories as described below:

4.1 RISKS TO HUMAN AND ANIMAL HEALTH

Risks to human health are related mainly to toxicity, allergenicity and antibiotic resistance of the new products.

The risk of toxicity may be directly related to the nature of the product whose synthesis is controlled by the transgene or the changes in the metabolism and the composition of the organisms resulting from gene transfer. Most of the toxicity risks can be assessed using scientific methods both qualitatively and quantitatively.

The introduction of newer proteins in GM crops from the organisms, which have not been consumed as foods, sometimes has the risk of these proteins becoming allergens. However, it may be noted that there is no evidence that GM crops pose more risks than conventional products regarding the development of allergies. Further, the new GM crops can be tested for allergens prior to the commercial release. For example, when it was found that the consumption of GM soybean with a methionine producing gene from the Brazil nut could trigger an allergic response in those sensitive subjects who were allergic to Brazil nut, the product was not released for sale.

The use of genes for antibiotic resistance as selectable markers have also raised concerns regarding the transfer of such genes to microorganisms and thereby aggravate the health problems due to antibiotic resistance in the disease causing organisms. Although, the probability of such transfer is extremely rare, steps are being taken to reduce this risk by phasing out their use.

There have been apprehensions about danger from eating the foreign DNA in foods derived from GM crops i.e. the pieces of DNA that did not originally occur in that food plant. DNA being present in all living things such as plants, animals, microorganisms is eaten by human beings with every meal. Most of it is broken down into more basic molecules during the digestion process whereas a small amount that is not broken down is either absorbed into the blood stream or excreted. So far there is no evidence that DNA from GM crops has any additional risk to human health than DNA from conventional crops, animals or associated microorganisms that are normally eaten. In cases where the GM crops is to be used for animal feed, the similar concerns as explained above are addressed.

4.2 RISKS TO ENVIRONMENT

Risks to environment due to release of GM crops include impact of introduced traits on the other related species, the potential build up of resistance in insect populations, effect on biodiversity and unintended effects on non-targeted organisms.

Accidental cross breeding between GM crops and traditional varieties through pollen transfer can contaminate the traditional local varieties with transgenes. The consequences associated with such gene transfer may impact intellectual property, increase weediness if transferred to compatible weedy relatives or lead to extinction endangered varieties of the same genera. However, these risks can be anticipated easily and then evaluated by experiments prior to any commercial release.

The gene transfer into a crop or the resultant products can actually remain in environment leading to environmental problems e.g. in case of Bt crops, it was suspected that insecticidal proteins can persist in the environments but experiments have proved that these are degraded in the soil. Further there are concerns about possible interaction that may occur between other organisms in the environment following the release of a GM crop.

Environmental concerns have also been raised about the development of increased insect resistance, virus resistance and weediness following the introduction of GM crops.

5 REGULATORY FRAMEWORK FOR GM CROPS IN INDIA

Safety concerns have led to the development of regulatory regimes in various countries for research, testing, safe use and handling of GM crops and their products. An overview of the regulatory framework in India governing GM crops is given below:

5.1 GOVERNMENT RULES FOR GMOs

The Ministry of Environment & Forests had enacted Environment and Protection Act in 1986 to provide for the protection and improvement of environment and the related matters (Annex-1). Environment includes water, air and land and the interrelationship, which exists among and between water, air and land, and human beings, other living creatures, plants, microorganism and property. Some important section of EPA are listed in Table 5.1.

Table 5.1: Important sections of Environment (Protection) Act (EPA), 1986

Section	Details
3	Central Government shall have the powers to take all such measures for the purpose of protecting and improving the quality of the environment and preventing, controlling and abating environmental pollution
6	Central Government has powers to:· ➢ make rules on environmental safety issues. These include powers to maintain standards of quality of air, water and soil. ➢ Can set limits of pollutants. ➢ Can set procedures and safe guards for handling hazardous substances ➢ Can prohibit or restrict use in locations. ➢ Can set procedures for containing / minimizing risks. ➢ order that no person can violate the rules and procedures.
7	No person carrying on any industry, operation or process shall discharge or emit or permit to be discharged or emitted any environmental pollutants in excess of such standards as may be prescribed
8	No person shall handle or cause to be handled any hazardous substance except in accordance with such procedure and after complying with such safeguards as may be prescribed

Section	Details
15	Whoever fails to comply with or contravenes the act or any rules can be punished with imprisonment for a term up to 5 years, or with a fine up to Rs. 100,000 or with both. If failure or contravention continues beyond one year, the offender may be punishable with imprisonment which may extend up to 7 years
25	The Central Government can make rules for the purpose of this act.The rules may contain standards, producers for handling, authorities to intimate, manner of collecting samples, the intention of collecting samples, functions of authorized laboratories, qualifications of analysts, the manner of making complaints to the governments, the authority/authorities implementing the rules and related matters, and the powers of the authority/authorities for directing the generation of information in open environment·

Under this act, the rules and procedures for the manufacture, import, use, research and release of GMOs as well as products made by the use of such organisms were notified by MoEF through their Notification No. 621 in Official Gazette of Govt. of India on December 5, 1989 (Annex-2). These rules and regulations, commonly referred as Rules 1989 cover areas of research as well as large scale applications of GMOs and its products. These Rules and Guidelines are implemented by the Ministry of Environment & Forests and the Department of Biotechnology, Government of India. There are 20 paras in the Rules 1989 and some of the important paras alongwith relevant details given here (Table 5.2):

Table 5.2: Important paras of Rules 1989

Para	Deals with
7	Approvals to individuals on the import, export, transport, manufacture, process, use or sell of GMOs and use of GMOs for research
8	Authorisation for production of genetically modified microorganisms, plants and animals
9	Approval for deliberate or unintentional release of GMOs into the open environment
10 & 11	Approval for substances, which may contain GMOs
12	Procedures for obtaining approvals in different conditions
13	Conditions of approval of GMOs
14	Mechanism for supervising the implementation of term and conditions given with authorization for commercial use
15	Penalties that can be levied for non compliance of measures for safe use of GMOs and products thereof
19	Redressal mechanism through appellate authority

These rules also defined the competent authorities and composition of such authorities for handling of various aspects of the rules. Presently there are six Competent Authorities as per the rules, brief description of their broad responsibilities is as described below:

(i) **Recombinant DNA Advisory Committee (RDAC):** This committee constituted by the Department of Biotechnology, which takes note of developments in biotechnology at national and international levels.

The RDAC recommendations, from time to time, the technologies/processes suitable for implementation for upholding the safety regulations in research and applications of GMOs and products thereof. This Committee prepared the Recombinant DNA Biosafety Guidelines in 1990, which was adopted by the Government for conducting research and handling of GMOs in India.

(ii) **Institutional Biosafety Committee (IBSC):** It is necessary that each institution intending to carry out research activities involving genetic manipulation of microorganisms, plants or animals should constitute the IBSC. All the IBSCs, *inter alia*, need to have one nominee from the DBT. The IBSC is the nodal point for interaction within the institution for implementation of the guidelines. The main activities of IBSCs are:

- To note and to approve r-DNA work.
- To ensure adherence of r-DNA safety guidelines of government.
- To prepare emergency plan according to guidelines.
- To recommend to RCGM about category III risk or above experiments and to seek RCGM's approval.
- To inform DLC and SBCC as well as GEAC about the experiments where ever needed.
- To act as nodal point for interaction with statutory bodies.
- To ensure experimentation at designated location, taking into account approved protocols.

(iii) **Review Committee on Genetic Manipulation (RCGM):** The RCGM functions as a body under the Department of Biotechnology and has the following functions:

- To bring out manuals of guidelines specifying producers for regulatory process on GMOs in research, use and applications including industry with a view to ensure environmental safety.
- To review all on going r-DNA projects involving high risk category and controlled field experiments.
- To lay down producers for restriction or prohibition, production, sale, import & use of GMOs both for research and applications.
- To permit experiments with category III risks and above with appropriate containment.
- To authorize imports of GMOs/ transgenes for research purposes.
- To authorize field experiments in 20 acres in multi-locations in one crop season with up to one acre at one site.
- To generate relevant data on transgenic materials in appropriate systems.
- To undertake visits of sites of experimental facilities periodically, where projects with biohazard potentials are being pursued and also at a time prior to the commencement of the activity to ensure that adequate safety measures are taken as per the guidelines.

(iv) **Genetic Engineering Approval Committee (GEAC):** Genetic Engineering Approval Committee (GEAC) functions as a body under the Ministry of Environment and Forests and is responsible for approval of activities involving large scale use of hazardous microorganisms and recombinant products in research and industrial production from the environment angle. GEAC, *inter alia*, has the following functions:

- To permit the use of GMOs and products thereof for commercial applications.
- To adopt producers for restriction or prohibition, production, sale, import & use of GMOs both for research and applications under Environment (Protection)Act, 1986..
- To authorize large-scale production and release of GMOs and products thereof into the environment.
- To authorize agencies or persons to have powers to take punitive actions under the under Environment (Protection)Act, 1986.

(v) **State Biotechnology Coordination Committee (SBCC):** SBCC is constituted in each State where research and applications of GMOs are contemplated. SBCC is headed by the Chief Secretary of the State and has the following functions:

- Powers to inspect, investigate and to take punitive action in case of violations of statutory provisions through the State Pollution Control Board or the Directorate of Health etc.
- To review periodically the safety and control measures in various institutions handling GMOs.
- To act as nodal agency at State level to assess the damage, if any, due to release of GMOs and to take on site control measures.
- The Committee coordinates the activities related to GMOs in the State with the Central Ministries. This committee also nominates State Government representatives in the activities requiring field inspection of activities concerning GMOs.

(vi) **District Level Committee (DLC):** This Committee, constituted at the district level, is considered to be smallest authoritative unit to monitor the safety regulations in installations engaged in the use of GMOs in research and applications. The DLC is headed by the District Collector who can induct representatives from State agencies to enable smooth functioning and inspection of the installations with a view to ensure the implementation of safety guidelines while handling GMOs, under the Indian EPA. Its functions are:

- To monitor the safety regulations in installations.
- Has powers to inspect, investigate and report to the SBCC or the GEAC about compliance or non compliance of r-DNA guidelines or violations under EPA.
- To act as nodal agency at District level to assess the damage, if any, due to release of GMOs and to take on site control measures.

In addition, Monitoring and Evaluation Committee (MEC) set up by RCGM visits field trial sites and recommends safe and agronomically viable transgenic crops to RCGM/GEAC.

The notification orders compliance of the safeguards through voluntary as well as regulatory approach and any violation and non-compliance including non-reporting of the activity in this area would attract punitive actions provided under the EPA.

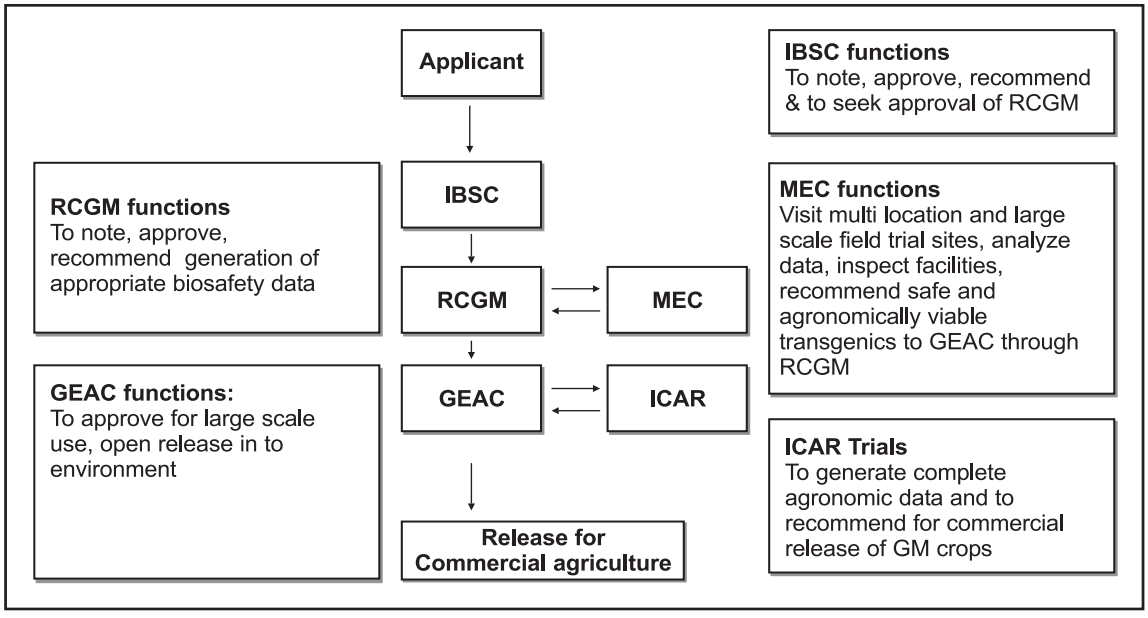
The approvals and prohibitions under Rules 1989 are summarized below:

- No person shall import, export, transport, manufacture, process, use or sell any GMOs, substances or cells except with the approval of the GEAC.

- Use of pathogenic organisms or GMOs or cells for research purpose shall be allowed under the Notification, 1989 of the EPA, 1986.
- Any person operating or using GMOs for scale up or pilot operations shall have to obtain permission from GEAC.
- For purpose of education, experiments on GMOs IBSC can look after, as per the guidelines of the Government of India.
- Deliberate or unintentional release of GMOs not allowed.
- Production in which GMOs are generated or used shall not be commenced except with the approval of GEAC
- GEAC supervises the implementation of rules and guidelines.
- GEAC carries out supervision through SBCC, DLC or any authorized person.
- If orders are not complied, SBCC/DLC may take suitable measures at the expenses of the person who is responsible.
- In case of immediate interventions to prevent any damage, SBCC and DLC can take suitable measures and the expenses incurred will be recovered from the person responsible.
- All approvals shall be for a period of 4 years at first instance renewable for 2 years at a time.
- GEAC shall have powers to revoke approvals in case of:

  i. Any new information on harmful effects of GMOs.
  ii. GMOs cause such damage to the environment as could not be envisaged when approval was given.
  iii. Non-compliance of any conditions stipulated by GEAC.

To summarize, under Rules, 1989, IBSC, RCGM and GEAC are involved in approval process of LMOs/ GMOs and SBCC and DLC have monitoring functions. The procedures involved in the approval of GMOs in India are summarized below:



5.2 RECOMBINANT DNA GUIDELINES, 1990

With the advancement of research work initiated in biotechnology in the country by various Indian institutions and industry, Department of Biotechnology had formulated Recombinant DNA Guidelines in 1990. These guidelines were further revised in 1994. The revised guidelines includes guidelines for R&D activities on GMOs, transgenic crops, large-scale production and deliberate release of GMOs, plants, animals and products into the environment, shipment and importation of GMOs for laboratory research. The issues relating to genetic engineering of human embryo, use of embryos and fetuses in research and human germ line, and gene therapy areas have not been considered while framing the guidelines.

The research activities have been classified into three categories based on the level of the associated risk. Accordingly, the requirement for the approval of competent authority is envisaged. Category I activities include those experiments involving self cloning using strains and also inter-species cloning belonging to organism in the same exchanger group which are exempt for the purpose of intimation and approval of Competent Authority. Category II activities which require prior intimation of Competent Authority and include experiments falling under containment levels II, III and IV (details of each containment level provided separately in the guidelines). Category III activities that require review and approval of competent authority before commencement include experiments involving toxin gene cloning, cloning of genes for vaccine production, and other experiments as mentioned in the guidelines. The levels of risk and classification of the organisms within these categories have been defined in these guidelines. Appropriate practices, equipment and facilities necessary for safeguards in handling organisms, plants and animals in various risk groups have been recommended. The guidelines enumerate the concept of physical and biological containment and the principles of good laboratory practices. For containment facilities and biosafety practices, recommendations of the WHO laboratory safety manual on genetic engineering techniques involving microorganisms of different risk groups have been incorporated therein.

The guidelines require the interested party to evaluate GMOs for potential risk prior to application in agriculture and environment i.e properties of the organism, possible interaction with other disease causing agents and the infected wild plant species. An independent review of potential risks should be conducted on a case-to-case basis.

5.3 REVISED GUIDELINES FOR RESEARCH IN TRANSGENIC PLANTS, 1998

In 1998, DBT brought out separate guidelines for carrying out research in transgenic plants called the "Revised Guidelines for Research in Transgenic Plants". These also include the guidelines for toxicity and allergenicity of transgenic seeds, plants and plant parts.

These guidelines cover areas of recombinant DNA research on plants including the development of transgenic plants and their growth in soil for molecular and field evaluation. The guidelines also deal with import and shipment of genetically modified plants of research use.

To monitor over a period of time, the impact of transgenic plants on the environment, a special Monitoring cum Evaluation Committee (MEC) has been set up by the RCGM. The committee

undertakes field visits at the experimental sites and suggests remedial measures to adjust the trial design, if required, based on the on-the-spot situation. This committee also collects and reviews the information on the comparative agronomic advantages of the transgenic plants and advises the RCGM on the risks and benefits from the use of transgenic plants put into evaluation.

The guidelines include complete design of a contained green house suitable for conducting research with transgenic plants. Besides, it provides the basis for generating food safety information on transgenic plants and plant parts.

5.4 NATIONAL SEED POLICY, 2002

National Seed Policy, 2002, has a separate section (No. 6) on transgenic plant varieties which states that all genetically engineered crops/varieties will be tested for environment and biosafety before their commercial release as per the regulations and guidelines under the EPA, 1986 (Annex-3). Seeds of transgenic plant varieties for research purposes will be imported only through the National Bureau of Plant Genetic Resources (NBPGR) as per the EPA, 1986. Transgenic crops/varieties will be tested to determine their agronomic value for at least two seasons under the All India Coordinated Project Trials of ICAR, in coordination with the tests for environment and bio-safety clearance as per the EPA before any variety is commercially released. Once the transgenic plant variety is commercially released, its seed will be registered and marketed in the country as per the provisions of the Seeds Act. The performance of the commercially released variety in the field will be monitored for at least 3 to 5 years by the Ministry of Agriculture and State Departments of Agriculture.

It has also been mentioned that transgenic varieties can be protected under the Plant Varieties & Farmers Rights Protection (PVP) legislation in the same manner as non-transgenic varieties after their release for commercial cultivation.

5.5 PREVENTION OF FOOD ADULTERATION ACT, 1955

As the Government has the prime responsibility for the establishment and operation of national food safety programs and quality control systems that must ensure safe and wholesome food to meet the nutritional needs of consumers and do not endanger the consumer's health through chemical, biological or other contaminants, it has set up a 'food control system' that includes the national, state and municipal organizations involved in either the regulation, inspection or analysis of food and agricultural products, together with their supporting legislation and rules and compliance activities.

The Ministry of Health and Family Welfare (MOH&FW) in the Central Government is the nodal Ministry for ensuring the quality and safety of food marketed in the country. A comprehensive legislation called the Prevention of Food Adulteration Act (PFA Act) has been enacted in 1954, which came into effect from June 1, 1955, with the objective of assuring the quality and safety of food as well as to encourage fair trade practices.

The Act has been amended a number of times to make the provisions more practical and consumer-oriented. This Act is the basic statute intended to protect the consumer from the supply of adulterated

food and it specifies food safety and quality standards for consumer protection. The definition of 'adulteration' includes the addition of cheaper or inferior substances to deceive the consumer and the presence of contaminants, which may make the food, unfit for human consumption. The objective of this legislation is, therefore, not only to ensure pure and wholesome food to the consumers, but also to prevent fraud or deception. It lays down that no person shall manufacture, sale, store, or distribute adulterated or misbranded food products not conforming to the standards laid down in the rules. The provisions apply to imported food as well as to food produced in India.

The responsibilities of the PFA cell in food control system are as follows:

- Enhance the availability of safe and wholesome food.
- Consumer protection from deception, fraud and food-borne diseases.
- Risk analysis, risk management and risk communication.
- Ensure safety of genetically modified food.
- Enhance the involvement of NGOs and Home Science Institutes.
- Educational authorities to ensure better consumer protection.
- Promote a voluntary management system, the Code of Ethics, through principles of GMPs and the HACCP.

Regarding laboratory facilities under the PFA Act, there are approximately 80 food laboratories in the country undertaking the analysis of samples of food articles under the provisions of the PFA Act, out of which 13 are managed by local bodies (municipalities). These are known as Public Analyst Laboratories. In addition, there are four Central Food Laboratories notified under the PFA Act to carry out an analysis of appeal samples whenever the report of the public analyst is challenged in the court of law. These are situated in Kolkata, Ghaziabad, Mysore and Pune. These laboratories analyze the bulk of the samples under the PFA Act.

Details may be seen at http://www.mohfw.nic.in

5.6 THE FOOD SAFETY AND STANDARDS BILL, 2005

The Ministry of Food Processing Industries has introduced "The Food Safety and Standards Bill, 2005" which seeks to consolidate the laws relating to food and establish the "Food Safety and Standards Authority of India". This step has been taken keeping in view the fact that presently eight ministries are administering food laws in diverse ways, which has been found to be not conducive to the growth of the food processing industry.

The proposed "Food Safety and Standards Authority of India" would facilitate scientific standards for food articles and regulate their manufacture, storage, distribution, sale and import to ensure the availability of safe and wholesome food for human consumption. The authority will consist of members from various ministries, and representatives from State Governments, the food industry, consumer organisations and even farmers' organisations. Scientific committees and panels will assist it in fixing standards, while a Central Advisory Committee will prioritise the work.

The enforcement of the legislation will be through the State Commissioner for Food Safety and Panchayati Raj/municipal bodies. The Food Bill not only incorporates the salient provisions of the Prevention of Food Adulteration (PFA) Act, but is also based on international legislations, instrumentalities and Codex Alimentaries Commission (related to food safety norms).

The proposed body will regulate the limits on the usage of food additives, crop contaminants, pesticide residues, heavy metals, processing aids, myco-toxins, antibiotics and pharmacological active substances.

It will formulate mechanisms and guidelines for the accreditation of bodies engaged in the certification of a food safety management system for the food business. It will also set up food labelling standards, including claims on health, nutrition and special dietary uses. The Bill seeks to regulate nutraceuticals and dietary supplements. It has stressed on proper labelling and has said that information should not be misleading. Imposing restrictions on advertising, it specifies, "No advertisement shall be made of any food, which is misleading or contravenous to the provisions of this Act." The Bill has imposed safeguards on imports of food products. No person shall be allowed to import unsafe, misbranded or sub-standard food and importing would require a license. Stringent penalties have also been proposed in the Bill.

The Bill has also mooted the establishment of a Food Safety Appellate Tribunal to hear the appeals of disputed parties.

The "genetically modified food" has been defined in the Bill as the food, which is produced through techniques in which the genetic material has been altered in a way that does not occur naturally by mating or having adequate human intervention or both. Techniques of Genetic Engineering or modification include, but are not limited to recombinant DNA, cell fusion, micro and macro injection, encapsulation, gene deletion, addition and doubling.

There is a provision for a separate scientific panel on genetically modified organisms. As per the provisions of the Bill, no person shall manufacture, process, export, import or sell genetically modified articles of food, organic foods, functional foods, neutraceuticals, health supplements etc. except in accordance with the regulations made there for under this Act.

Various Acts/Orders which would stand repealed on commencement of this Act, include the Prevention of Food Adulteration and sections relating to food under the Environment (Protection) Act, 1986 and Rules, 1989.

Details may be seen at http://www.mofpi.nic.in.

5.7 TASK FORCE ON APPLICATION OF AGRICULTURAL BIOTECHNOLOGY, 2005

Ministry of Agriculture had set up a Task Force under the chairmanship of Prof. M.S. Swaminathan, Chairman, MSSRF to formulate a draft long-term policy on applications of biotechnology in agriculture and suggest modifications in the existing administrative and procedural arrangements for the approval of GM crops. The report covered issues related to biotechnology applications in agriculture, animal husbandry and fishery sectors. It has been suggested that transgenic approach should be considered as

complimentary and resorted to when other options to achieve the desired objectives are either not available or not feasible. There is a need to priortise and reorient research programmes relating to transgenic research in crops, animals and fishes as per national requirements. An illustrative list of specific targets/traits has been included in the report that can be further revised/expanded on the basis of national and international data

The Task Force suggested of setting up of National Biotechnology Regulatory Authority, a statutory and autonomous body with two wings -one for agricultural and food biotechnology and the other for medical and pharmaceutical biotechnology. The report has underlined the need for clear-cut policy, guidelines and protocols for various GM products and their uses such as national food safety protocol, feeding of GM foods to livestock, use of livestock products from animals fed with GM foods, extensive biosafety guidelines for transgenic animals and fish etc.

Regarding awareness generation of matters relating to agricultural biotechnology, the task force report has indicated that an effective communication strategy must be developed and a cohesive mechanism established to ensure that messages are consistent with National policy on agricultural biotechnology and also that all target groups are reached. Education and development communication must receive high priority. Field research may be required to ensure that the concerns of various groups of population are understood and addressed to see that the messages are evidence based, simple and effective.

The issues in regard to the release of GM crops are not understood correctly owing to the lack of information on this subject even amongst the otherwise well-informed members of the public. An information campaign needs to be conducted to generate public awareness on the benefits and risks associated with biotechnology and the social, ethical, economic, scientific, environmental and health issues which are addressed by regulatory bodies before allowing the cultivation of GM crops.

Active cooperation of various scientific organizations/institutions/ universities/NGOs may be sought to generate public awareness in the country on the following specific aspects of agricultural biotechnology:

- Concept of plant breeding, pressures on modern plant breeding and the need for novel genetic enhancement strategies
- Introduction to genetic engineering technology
- The benefits, risks and constraints of agricultural biotechnology
- Current status of national and global GM crops and other biotechnological applications in agriculture
- Risk assessment procedures (regulatory mechanisms) for environmental and food safety, and related legislations
- Social, economic, ethical, scientific, environmental and health issues which are addressed by regulatory bodies before allowing release of GM crops.
- Current GM products under evaluation in India under biosafety, VCU and other regulatory trials
- Community and Farmers' Rights and benefit sharing related to agro-biotechnological applications

Post-release monitoring and management of GM crops and their products, such as insect resistance management, transgene stability at the farm level, use of transgenic diagnostic kits, and maintenance of transgenic seed quality, should be organized with effective involvement of State Level and District Level Coordination Committees of the existing transgenic biosafety evaluation and management mechanism.

Details may be seen at http://www.agricoop.nic.in.

5.8 DRAFT NATIONAL BIOTECHNOLOGY STRATEGY (2005)

DBT has brought out a National Biotechnology Strategy in 2005 which covers regulatory mechanisms as well. The policy indicates that it has to be ensured that research and application in biotechnology is guided by a process of decision-making that safeguards both human health and the environment with adherence to the highest ethical standards.

Choices are required to be made that reflect an adequate balance between benefit, safety, access and the interest of consumers and farmers. It is also important that biotechnology products that are required for social and economic good are produced speedily and at the lowest cost. It stresses on a scientific, rigorous, transparent, efficient, predictable, and consistent regulatory mechanism for biosafety evaluation and release system/protocol for achieving these multiple goals. Strategic actions include the implementation.

(i) It is proposed to set up an inter-ministerial group chaired by a reputed scientist to address anomalies and issues that arise in regulation from time to time. The mandate of the committee should be to vet any changes in policies, procedures, protocols by departments dealing with regulation in biotech products and processes; resolve issues emanating from the overlapping/conflicting rules in various acts related to regulation of biotechnology activities in research and development, import, export, releases etc. and to review guidelines, protocols, standard operating procedures and ensure their dissemination to all stakeholders from time to time

(ii) It is proposed to establish a competent single National Biotechnology Regulatory Authority with separate divisions for agriculture products/transgenic crops, pharmaceuticals/drugs and industrial products; and transgenic food/feed and transgenic animals/aqua culture. The authority is to be governed by an independent administrative structure with common chairman. The inter-ministerial group will evolve suitable proposals for consideration of the government.

(iii) A centre for in-service training of all professionals, irrespective of their location, engaged in the regulatory process to be established by the Department of Biotechnology in close collaboration with other concerned departments and institutions.

(iv) All existing guidelines are to be updated and made consistent with the recommendations of the Swaminathan and Mashelkar committees in 2005. New guidelines on transgenic research and product/process development in animal, aqua culture, food, phyto-pharma and environmental application to be put in place in 2005 by the concerned ministries/departments

(v) As an interim measure, a special regulatory cell will be created by the DBT to build capacity in the country for scientific risk assessment, monitoring and management, to foster international linkages, support biosafety research; to obtain and review feedback from different stakeholders and provide support to industry and R&D institutions. This cell will only have a promotional and catalytic role

Regarding public communication and participation proposed strategic actions include providing credible information based on scientific data, training media personnel through Institutes of Mass Communication, colleges of journalism and others and capacity building among extension personnel in agricultural, fisheries, veterinary and medical sectors.

Involvement of *Panchayati Raj* institutions in the process of analysis and understanding the risks and benefits associated with GMOs has been suggested as they will be playing an important role in the local level management of bio-diversity, access to benefit sharing etc.

Awareness generation among undergraduate and post-graduate students in universities, colleges etc on issues related to biosafety and promoting a genetic literacy movement within government and public schools through 50 genome club nature clubs each year are some of other recommendations.

It has been proposed to create a media resource network to facilitate access to information and empower policy makers by participation in regular training programs.

Details may be seen at http://www.dbtindia.nic.in.

5.9 REFERRAL LABORATORY FOR Bt COTTON

Ministry of Agriculture has issued a Notification on November 12, 2003 nominating Central Institute of Cotton Research (CICR), Nagpur to act as a referral laboratory for ascertaining the presence or absence of *cry1Ac* gene in cotton seeds for the whole of India. Copy of the notification is placed in Annex-4.

5.10 QUALITY CONTROL IN GM SEEDS

The State Governments have indicated their inability in the quality enforcement of the Bt cotton seeds due to the fact that the Seeds Act, 1966 does not cover transgenic seeds. The Department of Agriculture and Cooperation, Ministry of Agriculture, therefore, had requested the Ministry of Environment and Forests to notify the Seed Inspectors under Section 13 of the Seeds Act and Section 12 of the Seeds (Control) Order to draw the seed samples of transgenic seeds as mentioned under Section 10 of the Environment (Protection) Act, 1986. Accordingly, the Ministry of Environment & Forests in consultation with Ministry of Law & Justice has issues several Gazette Notifications wherein Seed Inspectors have been given adequate power to draw seed samples of transgenic seeds for the purpose of Quality Control and to get it tested in the notified seed testing laboratories and prosecute in case of spurious Bt cotton seeds (Annex-5). With the promulgation of the said notification, the seed law enforcement agencies are empowered to take necessary punitive action against the offenders.

In addition to the above, Seeds Division has issued minimum limits of purity in respect of Bt cotton seeds as 90% (Bt. Protein-toxin) under Section 6 of the Seeds Act, 1966 in the Gazette Notification issued vide SO No. 1567 (E) dated 5th November, 2005, a copy of the same is placed at Annex-6.

6 CARTAGENA PROTOCOL ON BIOSAFETY

6.1 INTRODUCTION

Although many countries have enacted national biosafety legislations to ensure the safe use of GMOs and products thereof, biotechnology being a global industry and GMOs traded across borders, international rules are needed as well. Cartagena Protocol on Biosafety is an attempt to produce a globally harmonized regime for biosafety under the Convention on Biological Diversity (CBD). Named after the Colombian city where the final round of talks was launched, the Cartagena Protocol on Biosafety sets out a comprehensive regulatory system for ensuring the safe transfer, handling and use of GMOs subject to transboundary movement.

The Protocol deals primarily with GMOs that are to be intentionally introduced into the environment (such as seeds, trees or fish) and with genetically modified farm commodities (such as corn and grain used for food, animal feed or processing). It does not cover pharmaceuticals for humans addressed by other international agreements and organizations or products derived from GMOs, such as cooking oil from genetically modified corn.

The protocol entered into force from September 11, 2003. As of May, 2006, 132 countries have ratified the protocol. India ratified the protocol in January 2003.

6.2 OBJECTIVE

The objective of the Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

6.3 SALIENT FEATURES

The Protocol promotes biosafety by establishing rules and procedures for the safe transfer, handling, and use of LMOs, with specific focus on transboundary movements of LMOs.

It features a set of procedures including one for LMOs that are to be intentionally introduced into the environment (advance informed agreement procedure, and one for LMOs that are intended to be used directly as food or feed or for processing as indicated below :

♦ ADVANCE INFORMED AGREEMENT (AIA) PROCEDURE

The AIA procedure applies only to the first intentional transboundary movement of any particular GMO intended for introduction into the environment. These include seeds, live animals and other organisms that are destined to grow and that have the potential to pass their modified genes on to succeeding generations. The exporter must provide a notification to the importing country containing detailed information about the LMO, previous risk assessments of the LMO and its regulatory status in the exporting country. The importing country must acknowledge receiving the information within 90 days and whether the notifier should proceed under a domestic regulatory system or under the Protocol procedure. In either case, the importing country must decide whether to allow the import, with or without conditions or deny it within 270 days. Consecutive shipments are not subject to the AIA requirement.

Further the Protocol's AIA procedure does not apply to LMOs in transit; destined for contained use and LMOs intended for direct use as food or feed or for processing.

♦ PROCEDURES FOR LMOs INTENDED FOR DIRECT USE AS FOOD OR FEED FOR PROCESSING (LMOs – FFP)

Instead of requiring the use of the AIA procedure, the Protocol establishes a simpler system for the transboundary movement of LMOs intended for direct use as food or feed or processing (LMOs – FFPs) and not as seeds for growing new crops. Under this procedure, governments that approve these commodities for domestic use must communicate this decision to the world community via the Biosafety Clearing- House within 15 days of its decision. They must also provide detailed information about their decision.

Decisions by importing countries on whether or not to import these LMO-FFPs are taken under its domestic regulatory framework.

♦ RISK ASSESSMENTS

The Protocol empowers governments to make its decisions in accordance with scientifically sound risk assessments. These assessments aim to identify and evaluate the potential adverse effects that a LMO may have on the conservation and sustainable use of biodiversity in the receiving environments. They are to be undertaken in a scientific manner using recognized risk assessment techniques. While the country considering permitting the import of a LMO is responsible for ensuring that a risk assessment is carried out, it has the right to require the exporter to do the work or to bear the cost. This is particularly important for many developing countries.

♦ RISK MANAGEMENT AND EMERGENCY PROCEDURES

The Protocol requires each country to manage and control any risks that may be identified by a risk assessment. Key elements of effective risk management include monitoring systems, research programmes, technical training and improved domestic coordination amongst government agencies and services. The Protocol also requires each government to notify and consult other affected or potentially affected governments when it becomes aware that LMOs under its jurisdiction may cross international borders

due to illegal trade or release into the environment. This will enable them to pursue emergency measures or other appropriate action. Governments must establish official contact points for emergencies as a way of improving international coordination.

♦ HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION OF LMOs

The Protocol provides for practical requirements that are deemed to contribute to the safe movement of LMOs. Parties are required to take measures for the safe handling, packaging and transportation of LMOs that are subject to transboundary movement. The Protocol specifies requirements on identification by setting out what information must be provided in documentation that should accompany transboundary shipments of LMOs. It also leaves room for possible future development of standards for handling, packaging, transport and identification of LMOs by the meeting of the Parties to the Protocol.

Each Party is required to take measures ensuring that LMOs subject to intentional transboundary movement are accompanied by documentation identifying the LMOs and providing contact details of persons responsible for such movement. The details of these requirements vary according to the intended use of the LMOs,

For LMOs intended for direct introduction into the environment, the accompanying documentation must clearly state that the shipment contains LMOs. It must specify the identity and relevant traits and characteristics of the LMO; any requirements for its safe handling, storage, transport and use; a contact point for further information; and the names and addresses of the importer and exporter. In cases where a government agrees to import LMO-FFPs the shipment must clearly indicate that it "may contain" living modified organisms and that these organisms are not intended for introduction into the environment.

♦ BIOSAFETY CLEARING HOUSE (BCH)

The Protocol established a Biosafety Clearing-House (BCH) as part of the clearing-house mechanism of the Convention, in order to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and to assist Parties to implement the Protocol. In addition to enabling governments to inform others about their final decisions regarding the import of GMOs, the Biosafety Clearing- House contains information on national laws, regulations, and guidelines for implementing the Protocol. The Biosafety Clearing-House also includes information required under the AIA procedure, summaries of risk assessments and environmental reviews, bilateral and multilateral agreements, reports on efforts to implement the Protocol, plus other scientific, legal, environmental and technical information. Common formats are used to ensure that the information collected from different countries is comparable. The Biosafety Clearing-House has been developed as an Internet-based system and can be found at http://bch.biodiv.org.

♦ UNINTENTIONAL TRANSBOUNDARY MOVEMENTS OF LMOs

When a country knows of an unintentional transboundary movement of LMOs that is likely to have significant adverse effects on biodiversity and human health, it must notify affected or potentially

affected States, the Biosafety Clearing-House and relevant international organizations regarding information on the unintentional release. Countries must initiate immediate consultation with the affected or potentially affected States to enable them to determine response and emergency measures.

♦ ISSUE OF NON-PARTIES

The Protocol addresses the obligations of Parties in relation to the transboundary movements of LMOs to and from non-Parties to the Protocol. The transboundary movements between Parties and non Parties must be carried out in a manner that is consistent with the objective of the Protocol. Parties are required to encourage non-Parties to adhere to the Protocol and to contribute information to the Biosafety Clearing House.

♦ CAPACITY BUILDING

Countries that trade in GMOs need to have the capacity to implement the Protocol. They need skills, equipment, regulatory frameworks and procedures to enable them to assess the risks, make informed decisions, and manage or avoid any potential adverse effects of GMOs on their natural relatives. The Protocol promotes international cooperation to help developing countries and countries with economies in transition to build human resources and institutional capacity in biosafety. Parties are encouraged to assist with scientific and technical training and to promote the transfer of technology, know-how, and financial resources. Parties are also expected to facilitate private sector involvement in capacity building. Biosafety activities under the Cartagena Protocol are eligible for support from the Global Environment Facility – an international fund that was established to help developing countries protect the global environment.

♦ PUBLIC AWARENESS AND PARTICIPATION

It is clearly important that individual citizens understand and are involved in national decisions on GMOs. The Protocol therefore calls for cooperation on promoting public awareness of the safe transfer, handling and use of GMOs. It specifically highlights the need for education, which will increasingly have to address GMOs as biotechnology becomes more and more a part of our lives. The Protocol also calls for the public to be actively consulted on GMOs and biosafety. Individuals, communities and non-governmental organizations should remain fully engaged in this complex issue. This will enable people to contribute to the final decisions taken by governments, thus promoting transparency and informed decision-making.

♦ LIABILITY AND REDRESS

The Protocol contains an enabling provision by which the Conference of the Parties serving as the meeting of the Parties shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms. The Parties shall endeavor to complete this process within four years.

♦ INSTITUTIONAL ARRANGEMENTS AT THE NATIONAL LEVEL

Parties are required to designate national institutions to perform functions relating to the Protocol. Each Party needs to designate one national focal point to be responsible on its behalf for liaison with the Secretariat. Each Party also needs to designate one or more competent national authorities, which are responsible for performing the administrative functions required by the Protocol and which shall be authorized to act on its behalf with respect to those functions. A Party may designate a single entity to fulfill the functions of both focal point and competent national authority.

♦ GOVERNING BODY OF THE PROTOCOL

The governing body of the Protocol is the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol (COP-MOP). The main function of this body is to review the implementation of the Protocol and make decisions necessary to promote its effective operation.

6.4 BENEFITS OF BECOMING A PARTY TO THE PROTOCOL

Becoming a Party to the Protocol presents a number of benefits, such as the following:

- Influence on the implementation of the Protocol and shaping of its further development through participation in the decision-making processes of the Conference of the Parties serving as the meeting of the Parties to the Protocol;
- For developing country Parties and Parties with economies in transition, eligibility for financial support from the Global Environment Facility (the financial mechanism for the Protocol) for capacity-building, as well as other support for implementation of the Protocol and participation in its processes;
- Enhanced visibility and credibility of national systems for regulating biosafety within the global community;
- Contribution to harmonized rules, procedures and practices in managing the transboundary movement of LMOs;
- Facilitation of mechanisms and opportunities for governments to collaborate with other governments, the private sector and civil society on strengthening biosafety;
- Improved access to relevant technologies and data, and benefiting from a regular exchange of information and expertise; and
- Demonstration of commitment to conservation and sustainable use of biological diversity through the implementation of biosafety measures.

The full text of the protocol may be seen at http://www.biodiv.org/biosafety/protocol.asp.

7 SAFETY ASSESSMENT OF GM CROPS

Commercial GM crop production is the final stage of a four step process. The first step begins in government and private sector laboratories and greenhouses, where scientists investigate potential biotech traits and undertake genetic transformations. If these lab results are successful, the plant may advance to the second step i.e. open field trials, where breeding and testing continue in a real life environment. The third step to commercialization is securing regulatory approval in a country where the plant will be grown, and/or consumed by humans or animals. The fourth and final step is market acceptance and widespread production.

Safety assessment of a GM crop is the most important step in this development process. Extensive testing and a long approval process accompany every GM crop introduction. The approval process includes comprehensive risk analysis to ensure food, feed and environmental safety before entering the market place.

7.1 CONCEPT OF RISK ANALYSIS

Risk assessment evaluates and compares the scientific evidence regarding the risks associated with alternative activities. Risk management develops strategies to prevent and control risks within acceptable limits and relies on risk assessment. In addition to the scientific assessment, it also takes into consideration various factors such as social values and economics. Risk communication involves an ongoing dialogue between regulators and the public about risk and options to manage risk so that appropriate decision can be made.

7.2 APPROACH TO RISK ASSESSMENT, MANAGEMENT AND COMMUNICATION

Risk assessment is a scientific process that makes use of the best up-to-date knowledge and experience. Broad methodologies for risk assessment for modern biotechnology products have been outlined in several international and national guidelines.

It has been generally accepted that details of risk assessment procedures may vary from case to case but there are few logical steps that need to be followed. These are:

(i) Identification of potential adverse effects on human health and/or environment

(ii) An estimation of likelihood of these adverse effects being realized

(iii) An evaluation of the identified risks

(iv) Considerations of appropriate risk management strategies

(v) Assessment of the overall potential environmental impact, including a consideration of the potential impacts that may be beneficial to human health or the environment.

The methodology of risk assessment of GMOs generally covers the characterization of the organisms, effects on pathogenicity, toxigenicity, allergenicity etc., substantial equivalence, effects related to gene transfer and marker genes and ecological effects.

Risk management is the use or application of procedures and means to reduce the negative consequences of a risk to an acceptable level. The risks can be limited by proper handling and use of various preventive measures. Risk management is employed during the development and evaluation of an organism in a systematic fashion in the laboratory, through stages of field-testing to commercialization.

Whereas risk assessment and management procedures are intended to identify and minimize potential negative effects on human health and the environment, risk communication is an integral part of biosafety procedures to ensure public acceptance of GMOs. It is important to interact with public at large about the specific risks and actions taken to alleviate them as insufficient or inaccurate information needs to misperceptions of risk resulting in adverse public opinion.

7.3 SAFETY ASSESSMENT PROCEDURES

Generally safety assessment of a transgenic crop is initiated by determining if the product is substantially equivalent (except for defined differences) to conventional counterpart varieties. Further analysis than focuses on the evaluation of the defined differences by assessing potential safety risks of host plan, gene donor(s) and introduced protein.

Experiments are designed to systematically identify the hazards, to assess risks and to take steps to manage the risk by applying logically valid strategies. The information on the following aspects is required to be generated on a case-to-case basis:

i. Characteristics of the donor organisms providing the target gene such as identification, pathogenicity, toxicity and allergenicity, the geographical origin, distribution pattern and survival mechanisms and the method of transfer of its genetic materials to other organisms.

ii. Characteristics of the vectors used such as the origin, identity and habitate, sequence, frequency of mobilization and the ability to get established in other hosts.

iii. Characteristics of the transgenic inserts such as the specific functions including the marker gene inserts, the expression levels and the toxicity of the expressed product on the host plant, human or animals, if any.

iv. Characteristics of the GM plants including methods of detection of the GM plant as well as the escaped transgenic traits in the environment, toxicity and pathogenicity of the transgenic plants

and their fruits to other plants, possibility of and the extent of transgenic pollen escape and pollen transfer to wild near relatives, and the consequences to the environment, pathogenicity, toxicity and allergenicity of the transgenic plants and their fruits to human and animals.

Although, information on some of these questions may be available but many questions need to be investigated using appropriate experimental designs in the laboratory greenhouse and field trials in a systematic fashion. Toxicity and allergenicity data are generated using the standard protocols devised by national and international agencies.

All the data generated by the developing organizations is then submitted in the detailed formats to the government for seeking permission for commercial release of target transgenic crop. The initial risk assessment begins at the institutional level itself. The Institutional Biosafety Committee evaluates the proposal for research or commercialization following which it is passed on to Review Committee on Genetic Manipulation and then Genetic Engineering Approval Committee. At the commercialization phase, another round of assessments with respect to agronomic benefits is undertaken under the ICAR system. In fact, even after the release of the crop there is a continuance monitoring by Monitoring and Evaluation Committees at center and state levels.

8 GLOBAL STATUS OF GM CROPS

8.1 CROPS APPROVED FOR COMMERCIAL USE

Since the introduction of first GM crop for commercial use in 1995 in USA i.e. the Flavr Savr tomatoes with delayed ripening, extensive research and development efforts were initiated all over the world. The areas of crop improvement currently being targeted using transgenic techniques include resistance to a variety of pests, pathogens and weed control agents, improvement in nutritional content and improved survival during environmental stress. Research is also carried out into production of new and improved raw materials for a wide range of products including medicines.

Approval for commercial planting and use of GM crops follows many years of research involving laboratory and field-testing, peer review and government regulatory procedures. Nineteen crops have so far been approved for planting in various countries across the world incorporating one or more of the basic phenotypic characteristics such as fatty acid composition, fertility restoration, herbicide tolerance, insect resistance, male sterility, modified color, mutations, reduced nicotine, delayed ripening and virus resistance.

Table 8.1 lists these products along with the genetically improved trait and countries where they have been approved.

Table 8.1: GM crops approved for commercial use

S. No.	Crop	Traits	Countries where approved
1.	**Alfalfa**	Herbicide tolerance	U.S., Canada, Mexico
2.	**Argentine Canola**	Herbicide tolerance and improved protection against weeds	Canada, US, Japan, Australia
3.	**Carnation**	Increased shelf life by delayed ripening, modified flower colour and herbicide tolerance	Australia, European Union
4.	**Chicory**	Herbicide tolerance, improved protection against weeds and higher yields	European Union
5.	**Cotton**	Improved insect protection, herbicide tolerance and improved protection against weeds	Japan, Australia, US, China, Mexico, South Africa, Argentina, India, Indonesia, Philippines, Brazil
6.	**Flax, Linseed**	Herbicide tolerance, antibiotic resistance and improved weed protection	Canada, US

Contd...

7.	**Green pepper**	Virus resistance	China
8.	**Maize**	Herbicide tolerance, improved weed protection, resistance against insects and restored fertility of seeds	Canada, Japan, US, Argentina, European Union, South Africa, Philippines, Switzerland, Taiwan, China, U.K., Korea, Russia, Uruguay
9.	**Melon**	Delayed ripening	U.S.A
10.	**Papaya**	Virus Resistance	U.S.A., Canada
11.	**Polish Canola**	Herbicide tolerance and improved weed control	Canada
12.	**Potato**	Improved protection from insect and leaf roll virus	US, Canada, Japan, Australia, Philippines
13.	**Rice**	Herbicide resistance	US
14.	**Soybean**	Improved weed control and herbicide tolerance, increased cooking quality	US, Argentina, Japan, Canada, Uruguay, Mexico, Brazil and South Africa, Czech Republic, European Union, Korea, Russia, Switzerland, Taiwan, U.K., Philippines and Australia
15.	**Squash**	Resistance against watermelon mosaic virus and zucchini yellow mosaic virus	US, Canada
16.	**Sugar beet**	Herbicide tolerance	US, Canada, Japan, Philippines, Australia
17.	**Sunflower**	Herbicide tolerance	Canada
18.	**Tobacco**	Herbicide tolerance	US
19.	**Tomato**	Improved shelf life, taste, color and texture, improved insect resistance, virus resistance	US, Mexico, Japan, China, Canada

Source: *http://www.agbios.com/*

8.2 AREA UNDER CULTIVATION

In the ten-year period since the commercial cultivation of transgenic crops started, the global area under these crops increased by more than 47 fold, from 1.7 million hectares in 1996 to 90.0 million hectares in 2005 (Figure 8.1). There has been 11% increase in 2005 in the area over the same in 2004 equivalent to 9.0 million hectares.

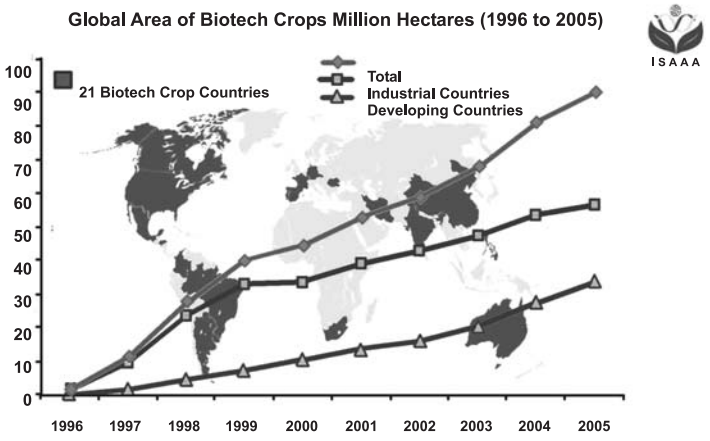


Figure 8.1: Global Area of Biotech crops

In 2005, more than one third of the global biotech crop area, equivalent to 33.9 million hectares, was grown in developing countries. There were 21 countries planting 50,000 hectares or more to biotech crops in 2005 (Figure 8.2). These mega-countries included the USA, Argentina, Brazil, Canada, China, Paraguay, India, South Africa, Uruguay, Australia, Mexico, Romania, the Philippines, Spain, Colombia, Iran, Honduras, Portugal, Germany, France, and the Czech Republic, reflecting a more balanced and stabilized participation of a broader group of countries adopting biotech crops. India had the highest percentage year-on-year growth in 2005, with an increase of 160% in Bt cotton area over 2004, followed Brazil (88%), Paraguay (50%), Canada (7%), Argentina (6%), and the USA at 5%.

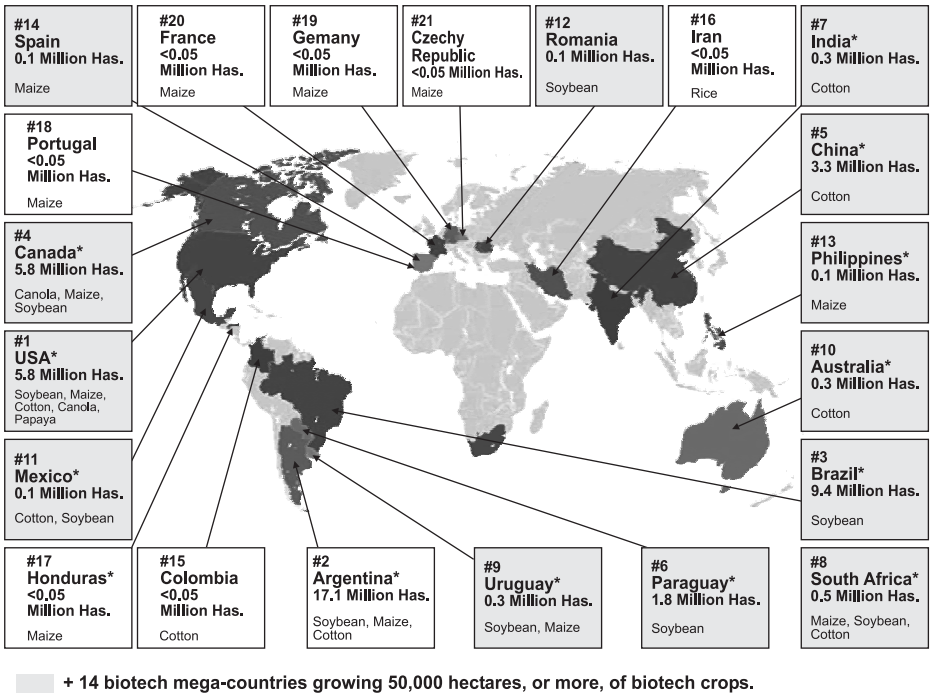


Figure 8.2: Biotech crop countries and mega countries, 2005
Source: International Service for the Acquisition of Agri-biotech Applications (http://www.isaaa.org)

There is cautious optimism that the global area and the number of farmers planting GM crops will continue to grow as new and novel products become available for commercialization in the coming years.

8.3 CROPS UNDER RESEARCH

There is intensive research going on to develop GM crops with more direct benefits to consumers. It has been reported that 63 countries are in GM crop research and development programs ranging from laboratory/greenhouse experiments, to field trials, to regulatory approval and commercial production. 57 plants divided into four groups i.e. field crops, vegetables, fruits and other plants, have been identified for further research and are listed below:

Table 8.2: GM crops under research and development

Field Crops (16)	**Vegetables** (14)	**Fruits** (16)	**Miscellaneous** (11)
Alfalfa	Broccoli	Apple	Chicory
Barley	Cabbage	Banana	Cocoa
Canola	Carrot	Cantaloupe	Coffee
Cassava	Cauliflower	Cherry	Garlic
Clover	Cucumber	Citrus	Lupins
Cotton	Eggplant	Coconut	Mustard
Flax	Lettuce	Grape	Oil palm
Maize	Onion	Kiwi	Oilseed poppy
Rice	Pea/Bean	Mango	Olive
Safflower	Pepper	Melon	Peanut
Sorghum	Potato	Papaya	Tobacco
Soybean	Spinach	Pineapple	
Sugar beet	Squash	Plum	
Sugar cane	Tomato	Raspberry	
Sunflower		Strawberry	
Wheat		Watermelon	

A variety of traits are targeted for these crops. Some of products that are likely be available to consumers in the near future are Soybean and canola oils containing more unsaturated fatty acids, high protein rice, fruits and vegetables with higher levels of vitamins, salt tolerant crops etc

9 STATUS OF GM CROPS IN INDIA

In view of the importance and potential of GM crops, extensive efforts have been initiated in India for development of GM crops.

9.1 CROPS APPROVED FOR COMMERCIAL USE

As of now, Bt cotton containing the *cry1Ac* gene from *Bacillus thuringiensis* is the only GM crop approved for commercial cultivation in India. The approval was first accorded to M/s Maharashtra Hybrid Seeds Company Limited (MAHYCO) in 2002. Subsequently, several other companies have taken sub-licenses from MAHYCO and developed Bt hybrids by back crossing their germplasm.

Taking into consideration the need for introducing diversity in the gene as well as germplasm as a tool to contain the development of insect resistance, hybrids containing three new Bt cotton genes/events have been approved in 2006. These are:

i. *Cry1Ac* gene (event 1) by M/s. J.K. Agri Seeds Ltd.

ii. Fusion genes (*cry1Ab+cry1Ac*) GFM by M/s Nath Seeds

iii. Stacked genes *cry1Ac* and *cry1Ab* by M/s MAHYCO

As of now 62 Bt hybrids approved for commercial cultivation in India as given below:

Table 9.1 : Bt cotton hybrids approved for commercial cultivation in india

Zone	Company	Hybrid
North	Ankur Seeds Ltd J.K. Agri Genetics Seeds Ltd. MAHYCO Nath Seeds Ltd. Nuziveedu Seeds Ltd Rasi Seeds Ltd	Ankur 2534 Bt JKCH 1947 Bt MRC – 6304 Bt, MRC 6029 Bt., MRC-6025 Bt. NCEH-6R NCS 138 Bt. RCH – 134 Bt, RCH 308 Bt., RCH – 317 Bt, RCH 314 Bt.
Central & North	Ankur Seeds Ltd MAHYCO	Ankur – 651 Bt MRC – 6301 Bt
Central	Ajeet Seeds Ltd. Ankur Seeds Ltd Ganga Kaveri Seeds Pvt. Ltd. J.K.Agri Genetics Seeds Ltd. Krishidhan Seeds Pvt. Ltd. MAHYCO Nath Seeds Ltd.	ACH-11-2 BG II Ankur – 09 GK 205 Bt., GK 204 Bt. JK Varun Bt. KDCHH 9821 Bt., KDCHH-441 BG II MECH 12 Bt *, MRC 7301 BG II, MRC-7326 BG II, MRC-7347 BG II NCEH-2R

	Pravardhan Seeds Ltd. Rasi Seeds Vikki Agrotech Pvt. Ltd.	PRCH-102 Bt. RCH 377 Bt., RCH –144 Bt, RCH –118 Bt, RCH - 138 Bt VCH-111 Bt.
Central & South	Ajeet Seeds Ltd. Emergent Genetics Krishidhan Seeds Pvt. Ltd. MAHYCO Nuziveedu Seeds Ltd. Prabhat Seeds Ltd. Rasi Seeds Ltd Tulasi Seeds Pvt. Ltd. Vikram Seeds Pvt. Ltd.	ACH-33-1 Bt., ACH-155-1 Brahma Bt. KDCHH 9810 Bt., KDCHH 9632 Bt. MECH 162 Bt* , MECH 184 Bt* NCS – 207 Mallika, NCS – 145 Bunny NPH 2171 Bt. RCH 2 Bt Tulasi 4 Bt., Tulasi 117 Bt. VICH 5 Bt., VICH 9 Bt.
North/Central/South	Nuziveedu Seeds Ltd	NCS-913 Bt.
South	Ganga Kaveri JK Agri Genetics Ltd. MAHYCO Nath Seeds Ltd. Prabhat Seeds Ltd. Rasi Seeds Ltd	GK-209 Bt., GK-207 Bt. JK Durga Bt, JKCH-99 Bt MRC – 6322 Bt, MRC – 6918 Bt, MRC-7351 BG II, MRC 7201 BG II NCEH-3 R PCH-2270 Bt. RCH – 20 Bt, RCH – 368 Bt, RCH 111 BG I, RCH-371 BG I, RCHB-708 BG I

**Approval not renewed for Andhra Pradesh.*

North zone: Haryana, Punjab & Haryana
Central zone: Gujarat Madhya Pradesh and Maharashtra
South Zone: Andhra Pradesh, Karnataka and Tamil Nadu

9.2 AREA UNDER CULTIVATION

The total area under Bt cotton has increased from 72,000 acres in 2002 to 31 lakh acres in 2005 as seen from the sale of Bt cotton seed packets (Figure 9.1).

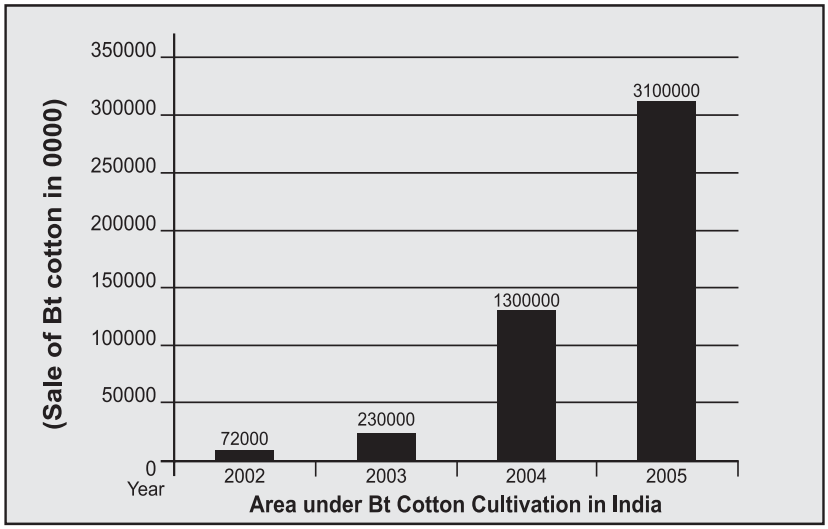


Figure 9.1: Area under Bt cotton cultivation in India

9.3 CROPS UNDER FIELD TRIALS

In addition to Bt cotton, ten crops are under development and field trials in India (Table 9.2). The trials are being conducted by both public and private sector institutions and are mainly for insect resistance using Cry genes.

Table 9.2: GM crops under development and field trials in 2005

S.No.	Crop	Organization	Transgene
1.	Brinjal	Mahyco, Mumbai Sungro Seeds Ltd, New Delhi IARI, New Delhi	*cry1Ac* *cry1Ac* *cry1F*
2.	Cabbage	Sungro Seeds Ltd, New Delhi	*cry1Ac*
3.	Cauliflower	Sungro Seeds Ltd, New Delhi	*cry1Ac*
4.	Corn	Monsanto, Mumbai	Cry1Ab
5.	Cotton	Ajeet Seeds, Aurangabad Ankur Seeds P. Ltd., Nagpur Bioseed Research India Pvt Ltd, Hyd Emergent Genetics India P. Ltd, Hyd Ganga Kaveri Seeds Ltd, Hyderabad Green Gold Seeds Ltd, Aurangabad JK Agri Genetics, Hyderabad Kaveri Seeds Co. P. Ltd, S'bad Krishidhan Seeds, Jalna Mahyco, Mumbai Metahelix Life Sciences, Bangalore Nandi Seeds Pvt. Ltd Mehbubnagar Namdhari Seeds Pvt. Ltd, Bangalore Nath Seeds, Aurangabad Nuziveedu Seeds, Hyderabad Prabhat Agri Biotech Ltd. Hyderabad Pravardhan Seeds Pvt. Ltd Hyderabad Proagro Seeds Co. Ltd Hyderabad Rasi Seeds Ltd., Attur Syngenta India Ltd., Pune Tulasi Seeds, Guntur UAS, Dharwad Vibha Agrotech Ltd. Hyderabad Vikki's Agrotech, Hyderabad Vikram Seeds Ltd, Ahmedabad Zuari Seeds Ltd. Bangalore	*cry1Ac, cryX* *cry1Ac, cryX* *cry1Ac, cryX* *cry1Ac, cryX* *cry1Ac* GFM *cry1Aa* *cry1Ac* *cry1Ac* *cry1Ac, cryX* *cryX* *cry1Ac* *cry1Ac* *cry1Ac* GFM *cry1Aa* *cry1Ac, cryX* *cry1Ac* *cry1Ac* cry1Ac *cryX* *Vip-3A* *cry1Ac, cryX* *cry1Ac* *cry1Ac* *cry1Ac* *cry1Ac* GFM *cry1Aa*
6.	Groundnut	ICRISAT, Hyderabad	Coat protein of *IPCV* Nucleo Capsid Protein of PBNV
7.	Mustard	UDSC, New Delhi	*barnase & barstar*
8.	Okra	Mahyco, Mumbai	*cry1Ac,*
9.	Pigeonpea	ICRISAT, Hyderabad	*cry1Ac,*
10.	Rice	IARI, New Delhi	*cry1Ac, cry1Aa + cry1B* Mahyco, Mumbai *cry1Ac*
11.	Tomato	IARI, New Delhi Mahyco, Mumbai	*antisense replicase gene of tomoto leaf curl virus* cry1Ac

Source: *Department of Biotechnology, Government of India*

10 CASE STUDY OF Bt COTTON

10.1 BACKGROUND

Cotton is a very important commercial crop in India. Nearly nine million hectares of land in India is used to produce 14.2 million bales of cotton lint under diverse agro climatic conditions. Cotton contributes to 29.8% of the gross Indian agricultural domestic product and provides a livelihood to more than 60 million people by way of support in agriculture, processing and use of cotton in textiles. The major cotton growing states are Andhra Pradesh, Gujarat, Haryana, Karnataka, Madhya Pradesh, Maharashtra, Punjab, Rajasthan and Tamil Nadu.

Although India ranks first globally area wise but with regard to production it ranks third next to USA and China. The major reason of low productivity is damage by insect pests, notably, *Helicoverpa armigera*, commonly referred to as the American bollworm. It has been estimated that nearly fifty percent of total insecticides used in the country are only for the control of bollworms in cotton crop. Still it is a known fact that all the pesticide molecules except perhaps the latest ones like Spinosad and Indoxacarb have failed to effectively control cotton pests.

In view of the above, alternative ways of dealing with these plant pests were sought. One option is the use of *Bacillus thuringiensis,* which produced insecticidal proteins. Bt is easily cultured by fermentation and over the last 40 years, farmers have used it as an insecticide worldwide. It is applied either as spray or as granules but the efficiency of both applications is quite limited, as the target organism does not often come in contact with the insecticide. This is because the larvae are found on the underside of leaves or have already penetrated the plant. To overcome this problem, transgenic cotton was developed by introducing the insecticidal gene from the bacterium in the cotton plant, commonly referred to as Bt cotton. These plants have a built in mechanism of protection against targeted pests. The protein produced by the plants does not get washed away nor is destroyed by sunlight unlike those applied externally. The plant is thus protected from the bollworm round the clock and throughout its life.

The advantages of Bt cotton with genes integrated in the plant versus the spray of Bt powder are as follows:

- Active protein provides moderate to high dose control that allows fair to excellent control of selected important lepidopteran pests
- Active protein expressed in all plant parts
- Active protein expressed throughout the season, hence timing of insecticide applications in relation to an infestation is not an issue

- Wash off of insecticide during rain, and degradation in sunlight are not issues as they are with spray formulations
- Less farmer exposure to insecticide
- Labor saving technology, due to elimination or reduction of insecticide sprays
- Decreases production risks and provides peace of mind and insurance to farmers at cost-effective control rates
- Contributes to, and provides the foundation for an integrated pest management (IPM) strategy.

10.2 GLOBAL STATUS

Since its introduction in 1996 in USA, Bt cotton has found extensive acceptance world over. Currently, Bt cotton is grown in most of the major cotton growing countries, including USA, Argentina, China, India, South Africa, Australia, Mexico, Thailand and Indoensia. Extensive field-testing is underway in countries such as Brazil, Colombia, Thailand and Zambia. The total area under Bt cotton cultivation has been estimated to be 9.8 million Hectares in 2005 amounting to 28% of the global area under cotton.

Several Bt genes for pest resistance have been identified and commercialized world over. Monsanto Company developed and deployed the *Cry1Ac* gene from the isolate *B.thuringiensis, ssp kurstaki* into Coker 312 cotton designated MON 531 and later named Bollgard® cotton. This has been followed by development of a second generation of Bt technology called Bollgard II containing two different genes i.e. *Cry2Ab* and *Cry1Ac*. The Bollgard II (event 15985) is expected to provide broader control over a wide variety of insects in addition to American Bollworm. Chinese Academy of Agricultural Sciences (CAAS) has developed a modified fusion gene, *Cry1Ab/Cry1Ac* which has been incorporated in several cotton varieties being grown over large areas in China. The fusion gene has also been incorporated in cotton hybrids in India. Syngenta Seeds has commercialized COT102 containing vip3A(a) gene that imparts resistance among others, to cotton bollworm, tabacco budworm, pink bollworm and fall armyworm.

10.3 INDIAN STATUS

In India, Maharashtra Hybrids Seed Company (MAHYCO) first imported the parental cotton cultivar Coker 312 from Monsanto and then carried out a contained breeding programme to incorporate the Bt gene into their elite cotton inbred lines. The Bt trait was successfully transferred into more than 60 cotton lines by the traditional backcrossing method

Bt cotton contains the following three genes inserted via genetic engineering techniques:

- The *Cry1Ac* gene, which encodes for an insecticidal protein, Cry1Ac, derived from the common soil microbe *Bacillus thuringiensis* subsp. k*urstaki (B.t.k.).*
- The *nptII* gene, which encodes the selectable marker enzyme neomycin phosphotransferase II (NPT II), was used to identify transformed cells that contained the Cry1Ac protein. It served no other purpose and has no pesticide properties. The *nptII* gene is derived from the prokaryotic transposon Tn5.

- The *aad* gene which encodes the bacterial selectable marker enzyme 3"(9)-O- aminoglycoside adenyltransferase (AAD) allowed for the selection of bacteria containing the PV-GHBK04 plasmid on media containing spectinomycin or streptomycin. The *aad* gene was isolated from transposon Tn7.

NPT II and AAD proteins are used as a selectable marker and have no pesticidal activity and are not known to be toxic to any species.

Bt cotton being a GM / transgenic crop requires environmental clearance under Rule 7-10 of the 1989 "Rules for Manufacture, Use, Import, Export and storage of hazardous microorganisms/Genetically Engineered Organisms or Cells" notified under the Environment (Protection) Act, 1986. Enough data and information was necessary to evaluate its performance and environmental safety before it was permitted for use in India. Accordingly the biosafety and environmental issues were assessed including pollen escape, out- crossing, aggressiveness and weediness, effect on non-target organisms, presence of Cry 1AC protein in soil, effect of Cry1 AC protein on soil micro-flora, confirmation of the absence of Terminator Gene, and baseline susceptibility studies. MAHYCO conducted these studies as per the Protocol approved by the Review Committee on Genetic Manipulation functioning in the Department of Biotechnology. Brief summary of the biosafety assessment is summarized below:

- **Studies conducted on pollen escape/out crossing:** Multi-location experiments conducted in 1996, 1997 and 2000 revealed that out-crossing occurred only upto 2 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. Also 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 & Weediness:** To assess the weediness of Bt cotton the rate of germination and vigor was compared by laboratory test and in soil to the non-transformed parental line. The results demonstrated that there are no substantial differences between Bt and non-Bt cotton for germination and vigor. This also indicates that there is no substantial difference between transgenic Bt and control non-Bt cotton with regard to their weediness potential.

- **Studies conducted on the effect of Bt on non-target organisms:** Studies conducted during the multi-location field trials revealed that the Bt cotton hybrids do not have any toxic effects on the non-target species, namely sucking pests (aphids, jassids, white fly 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 beetle, spiders) remained active in both Bt and non Bt varieties.

- **Studies conducted regarding presence of Bt gene in soil:** Studies were conducted to assess the possible risk of accumulation of Bt gene in the soil, by insect bioassays. Bt protein was not detected in soil samples indicating that Bt protein is rapidly degraded in the soil on which Bt cotton is grown. This study showed that the Cry 1AC 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 Cry 1AC protein in plant tissue was calculated to 41 days which is comparable to the degradation rates reported for microbial formulations of Bt.

- **Studies to evaluate the effect of Bt gene on soil micro-flora:** Studies were conducted to evaluate any impact of Bt protein leached by roots of Bt cotton on the soil micro-flora. There was no significant difference in population of microbes and soil invertebrates like earthworm and Gllembola between Bt and non-Bt soil samples.

- **Studies to evaluate the Food Safety:** For evaluating food safety, the studies conducted include: compositional analysis, allergenicity studies, toxicological study, presence of Bt gene and protein in Bt cottonseed oil and feeding studies on fish, chicken, cows and buffaloes. Salient features of these studies are as follows:

  i. *Compositional analysis:* The studies revealed that there is no change in the composition of Bt and non Bt seeds, with respect to proteins, carbohydrates, oil, calories and ash content.

  ii. *Allergenicity studies:* Allergenicity studies were conducted in Brown Norway rats. No significant differences in feed consumption, animal weight gain and general animal health were found between animals fed with Bt cotton seed and no 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 is no significant change in endogenous allergens of Bt cottonseed compared to non-Bt cotton seed.

  iii. *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.

  iv. *Presence of Cry 1AC gene and Bt protein in Bt cotton seed oil:* Studies have indicated that Cry 1AC gene and protein are not found in refined oil obtained from Bt cotton seeds.

  v. *Feeding studies on fish, chicken, cows and buffaloes:* Feeding experiments conducted with Bt cotton seed meal on fish chicken, cows and buffaloes indicated that Bt cotton seed meal is nutritionally equivalent, wholesome and safe as the non-Bt cotton seed meal. The feeding experiments on poultry, fish, cows and buffaloes were conducted at National Dairy Research Institute (NDRI), 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 (CARI), Izzatnagar on poultry; and Central Institute of Fisheries Education (CIFE), Mumbai on fish.

MAHYCO conducted extensive field trials throughout India under different agro-climatic conditions including under the All India Coordinated Cotton Improvement Project of ICAR. Government of India through GEAC, Ministry of Environment & Forests has approved on March 26, 2002, three Bt cotton hybrids (MECH12Bt, MECH162Bt and MECH184Bt) for commercial cultivation for a period of three years with the following conditions.

(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 labeled 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 based methods.

The chronology of Bt cotton development by MAHYCO is as follows:

1994	Formation of IBSC and application for transgenic Bt cottonseed import.
1995	Permit from DBT received to import 100 g. Bt Cotton seed of Coker 312 from Monsanto, USA.
1996	Imported seed and Green House trial initiated.
1996	Limited field trial (1 Location) to assess pollen escape.
1996	Back crossing (Ongoing) breeding for transfer of Bt gene into elite parental lines in green house.
1997/98	Limited field trials (5 locations) to assess pollen escape.
1998	Toxicological (Ruminant goat model) and Allergenicity (BNR model) studies.
1998/99	Multi-centric research trials (15 +25 locations) to assess efficacy of Bt gene in Indian elite germplasm.
1999	Multi-centric research trials (11 locations) to assess efficacy of Bt gene in Indian elite germplasm.
2000/01	(a) Large-scale trials (100ha) to assess efficacy of Bt gene in Indian elite germplasm and the performance of Bt hybrids. (b) Hybrid seed production (150 ha) (c) Various biosafety studies. (d) ICAR trials at 6 locations.
2001-02-	(a) Large-scale trials (100ha) to assess efficacy of Bt gene in Indian elite germplasm and the performance of Bt hybrids, (b) Hybrid seed production (300 ha) (c) Biosafety studies. (d) ICAR Trials at 11 locations.
April 2002	Commercial cultivation in Six States (Andhra Pradesh, Gujarat, Karnataka, Madhya Pradesh, Maharashtra, Tamil Nadu)

The Bt transgene in the converted Indian inbred lines behaves as a single dominant -Mendelian factor and is stably integrated in the plant genome. The advantages of Bt cotton include improved pest management, reduction in insecticide use and therefore greater net return to the farmers. Healthy growth of the plants yields a better boll size and quality as well as reduction in picking costs.

Bt cotton has been grown in six states i.e. Madhya Pradesh, Gujarat, Maharashtra, Andhra Pradesh, Karnataka and Tamil Nadu since 2002. Approximately 72,000 packets of seeds (for covering one acre each) containing Bt cotton hybrids and its non Bt cotton hybrid counterparts was sold by MAHYCO in the Kharif season 2002-2003. In the second year of launch, the acreage under Bt cotton increased to three fold of the last year and approximately 2,30,000 packets of seeds were sold. In 2004, one more company M/s Rasi Seeds got approval for its hybrids. The total sales of Bt cotton in 2004 were to the tune of 13 lakhs packets, an increase of six times over the previous year. In 2005, around 13,00,000 hectares of cotton land were planted with 20 Bt cotton hybrids by more than one million farmers from different states. The state wise sale of Bt cotton hybrids is given in Table 10.1.

Table 10.1: State wise sale of approved Bt cotton hybrids in last four years (in numbers)

State	No. of packets sold			
	2002	**2003**	**2004**	**2005**
Andhra Pradesh	12,894	13,000	1,80,000	5,62,176
Madhya Pradesh	3,676	33,000	2,20,000	3,52,313
Gujarat	22,577	103,000	3,30,000	3,65,392
Maharashtra	30,699	54,000	5,10,000	15,40,355
Karnataka	5,401	7,500	45,000	71,642
Tamil Nadu	925	19,000	25,000	45,655
Haryana				33,007
Punjab				1,27,533
Rajasthan				3,994
Total	**72,682**	**2,30,000**	**13,10,000**	**31,02,067**

Source: MAHYCO

With the introduction of Bt technology, there has been a significant change in the cotton cultivation scenario in the country. Within a period of four years after the approval of Bt cotton with *cry1Ac* (Mon 531 event) ,62 hybrids have been released by the GEAC and about 121 Bt cotton hybrids are under various stages of field trials and the area under Bt cotton in India has increased from 72,682 acres in 2002 to 31,00,000 acres in 2005. This area is expected to increase substantially over 50 lakh acres during 2006. In addition to Bt hybrids containing the *cry 1Ac* gene (MON 531 event), which was earlier approved by the GEAC and is in commercial cultivation since 2002, the GEAC approved hybrids with three new gene/event namely Bt hybrids expressing fusion genes *(cry 1Ab+cry 1Ac*) "GFM *cry 1*A" developed by M/s Nath Seeds, Bt hybrids expressing *cry 1Ac* gene (Event-1) by M/s JK Seeds Ltd and Bt hybrids expressing stacked genes *cry 1Ac* and *cry 2Ab* (MON 15985 event)—BG-II by M/s Mahyco.

The benefits of Bt cotton in India are in line with those enjoyed by farmers worldwide who have cultivated Bt cotton. The area under Bt cotton cultivation is expected to increase further in coming years leading to increased production and reduced costs in an environment friendly manner. This will have a positive effect on the livelihood of millions of farmers by improving their net incomes.

The safety aspects of Bt cotton have been most extensively studied. Rigorous scientific studies conducted in India and abroad demonstrate that Bt cotton and its products are safe for the environment, humans, animals, and agriculture. In fact, the use of Bt cotton is a positive step towards environmental protection because it makes possible the reduction of the insecticide load in the environment and reduces handling of such chemicals by farmers. Reduced use of insecticides will enhance the effectiveness of biological controls and implementation of Integrated Pest Management (IPM) programs. The higher farm income observed in the experiments has now been demonstrated by the large-scale use of Bt cotton by Indian farmers, and the incorporation of the gene is proving an effective and environmentally friendly plant protection tool resulting in greater cultivation of Bt cotton in the coming years. As newer products are approved in the regulatory system, it is likely that farmers will have greater choice of plant hybrids according to the requirements of quality and needs of the market.

There is a misconception among farmers that Bt cotton does not need any other plant protection. Hence, there is an urgent need to make the cotton farmers understand that Bt gene is only one of the most effective tools in pest management and not a panacea for the total pest problem in cotton. Based on the requirements, the use of other IPM technologies such as management of sucking pest through seed treatment or through resistant cultivars has to be suitably used for sustainability of higher crop yields and successful adoption of Bt cotton technologies.

11 DETECTION OF GM CROPS

Generally GM crops are indistinguishable from the non-GM crops to the naked eye. It is even more difficult to identify the novel genes in the products derived from these crops. However, it is extremely important to have the detection methods for ensuring the quality concerns of GM crops and ascertaining the efficacy of products by users i.e. farmers. Seed industry is also concerned about availability of detection methods to ensure quality control and gene introgression. Most important, effective testing methods are required by regulatory authorities including extension workers to ensure compliance of quality standards, define guidelines and track down illegal business.

Testing methods for GM crops look for the genes (DNA) engineered into the particular crop or the proteins produced in the crop by the introduced DNA. Each method is appropriate under certain conditions and it is important to be aware of the same when selecting an appropriate GM testing method. In line with the above, analytical methods to detect (qualitative or yes/no answers) and quantify (percentage content) in a GM crop can be broadly classified into two main categories:

(i) **DNA based methods** look for the specific genes or DNA genetically engineered into the crop. Although, there are number of DNA based methodologies, most commercial testing is conducted using polymerase chain reaction (PCR) technology. PCR is used to detect the specific transgene in the GM crop or specific elements associated with the transgene by targeting and amplifying the same. The amplified DNA can be then seen using a technique known as gel electrophoresis. A positive result is indicated by a band on the gel and a negative result by no band.

The PCR test is highly sensitive as it can detect trace amounts of GM DNA in complex mixtures of DNA, such as a processed food sample. PCR test can be used for multiple GM varieties simultaneously as per the level of specification required such as screening, gene specific, construct specific and event specific detection. PCR based methods can be used on raw and processed products as long as DNA can be extracted from the sample.

Whereas conventional PCR can only provide a 'Yes' or 'No' answer to the presence of GM DNA in a product, real time PCR has been developed to accurately quantify the amount of GMO present. This technology is similar to conventional PCR except that the amount of DNA amplified during each cycle of the PCR is monitored using fluorescent dyes and used for precise information on the amount of starting GM DNA in a sample.

(ii) **Protein based methods** use antibodies to detect or measure the amount of specific proteins expressed by the transgene in the GM crop. They may be divided into two principle types

a. **ELISA:** This test uses antibodies (polyclonal or mammalian) raised against a specific protein encoded by transgene. These antibodies are colour coated to enable them to be easily detected and quantified. This test is conducted in a laboratory.

b. **Strip test:** These tests can be carried out by unskilled personnel in the actual field. Typically, a sample for testing is crushed and mixed with extraction buffer. The strip is dipped into this mixture and the result monitored as the colour of the strip changes and simultaneously a band is developed indicating whether or not the GMO variety is present.

Protein based methods can be used on raw samples i.e. leaves, seeds, grain etc. and semi processed samples as long as protein is not denatured or destroyed by processing. Protein testing is considered reasonably simple to apply but commercial kits are only trait specific and cannot identify event specific GM crops and therefore is used only as screening methods.

To summarize the above and to provide guidance on which test to be used for a product, a comparison of both DNA and protein based method is presented below:

Table 11.1: Comparison of both DNA and protein based method

S. No.	Parameter	DNA based methods	Protein based methods
1.	Products that can be analyzed	Both processed and un processed	Not appropriate for processed products
2.	Sensitivity	Highly sensitive – detects trace amounts of GM DNA	Relatively low sensitivity.
3.	Time	Typically 3-5 days to perform each test	Rapid test: 5 – 20 minutes for strips and 24 hours for ELISA
4.	Facilities and manpower	Highly skilled personnel and laboratory facilities	Strip test possible in the field even by layman and ELISA requires trained personnel and limited laboratory facilities
5.	Cost	Very expensive	Relatively cheap

It is extremely important to select the appropriate test type to detect the GM crop or their products. For example, protein based methods are more appropriate when a product has not undergone extensive processing and DNA based methods are more useful when it is highly processed. However, it may be noted that proper sampling is critical to the final test results and adequate care should be taken by drawing representatives and multiple samples.

Several companies are marketing detection methods for Bt cotton in India. Most commonly used kits as of now are strip based and ELISA tests. The Central Institute of Cotton Research (CICR), Nagpur has also developed three kits for different user levels as explained below:

- **The Cry 1Ac Bt- Quant** is an ELISA Kit, which facilitates a precise quantification of Cry 1Ab or Cry 1Ac, expressed in transgenic plants. The kit is simple, cost effective and very reliable. It takes about four hours for completion of one set of ELISA assay. Each ELISA plate can be used for 96 samples.
- **Cry 1Ac Bt-detect** is a dot-blot assay and enables the user to detect the presence of Bt toxin in seeds or plant tissue. Each kit can be used to test 100 samples. The Kit is fairly simple and can be used by persons with minimum technical capabilities with little training. It takes about 2-3 hrs for completion of one set of test assay.
- **Cry 1Ac Bt express** is a dip-stick format and can be used by even a layman, for instantaneous detection of Bt toxin in either seeds or plant tissue. It takes about 10 minutes for the test to be completed. The test can be used in fields and does not require any additional facilities for use. The kit is rapid, reliable and ready to use.

12 ROLE OF STATE AGENCIES IN MONITORING OF GM CROPS

As per Rules, 1989 notified by Ministry of Environment & Forests, the responsibility of monitoring the activities related to GMOs is vested with State Biotechnology Coordination Committee (SBCC) and District Level Committee (DLC). The SBCC in the states, shall have powers to inspect, investigate and take punitive action in case of violation of statutory provisions through the nodal department and the State Pollution Control Board/Directorate of Health/Medical Services. The DLC is to be set up in the districts wherever necessary under the District Collectors to monitor the safety regulations. The composition of the two committees is given in Box 12.1

Box 12.1: Composition of SBCC and DLC

SBCC	
(i)	Chief Secretary - Chairman
(ii)	Secretary, Department of Environment - Member Secretary
(iii)	Secretary, Department of Health - Member
(iv)	Secretary, Department of Agriculture - Member
(v)	Secretary, Department of Industries and Commerce - Member
(vi)	Secretary, Department of Forests - Member
(vii)	Secretary, Department of Public works/Chief Engineer, Department of Public Health Engineering - Member
(viii)	State microbiologists and Pathologists - Member
(ix)	Chairman of State Pollution Control Board

DLC	
(i)	District Collector - Chairman
(ii)	Factory Inspector - Member
(iii)	A representative of the Pollution Control Board - Member
(iv)	Chief Medical Officer (District Health Officer) – Member (Convenor)
(v)	District Agricultural Officer - Member
(vi)	A representative of the Public Health Engineering Department - Member
(vii)	District Microbiologists pathologist (Technical expert) - Member
(viii)	Commissioner Municipal Corporation - Member

The Committees may co-opt other members/ experts as necessary.

As may be seen above, Secretary, Department of Agriculture in the State is a member of SBCC and District Agriculture Officer is a member of DLC and therefore are responsible for monitoring of GM Crops at State and District level. State Agriculture Department has a major responsibility towards monitoring compliance of conditions stipulated by GEAC for commercial release, field trials and seed production of GM Crops. Annex-8 may be referred to get an overview of conditions for approval of Bt cotton hybrids.

Further, the functionaries from State Agriculture Department implementing the Seed Act including seed laboratories and analyst have been empowered to take punitive action and the sampling procedures

have been notified to ensure uniform action by the field staff. The State Agriculture Departments are also notified about the field trials by GEAC with copies of communications addressed to Secretary, Agriculture and Commissioner, Agriculture, simultaneously.

In addition to the above, the State Agricultural Universities (SAUs) are also being actively involved in pre release and post release monitoring of Bt cotton. The same has been recommended by Sub Committee on Bt cotton and related issues set up by the Ministry of Environment & Forests to look into streamlining the current regulatory framework for transgenic crops as both SAUs and State Agriculture Departments have elaborate establishment in place to monitor the performance of agricultural crops in their jurisdiction. The details of alternate monitoring mechanisms for pre release and post release monitoring are as follows:

i. **Pre release monitoring:** Responsibility of monitoring Multi-location field trials (MLT) and Large Scale field trials (LST) has been entrusted to the State Agriculture Universities (SAU) under the direct supervision of Director of Research of each SAU. Director of Research may be advised to constitute a monitoring team as per the composition give below:

1)	Director of Research, SAU, Nodal person	-	Team Leader
2)	Plant Breeder (concerned crop), SAU	-	Member
3)	Entomologist- Head of the Department or Nominee State Agriculture University	-	Member
4)	Agronomist- Head of the Department or Nominee State Agriculture University	-	Member
5)	Pathologist- Head of the Department or Nominee State Agriculture University	-	Member
6)	Subject matter specialist Relevant to the transgene (Biotechnologist).	-	Member
7)	Joint Director/ Deputy Director, State Agriculture Department	-	Member
8)	Agriculture Officer of the concerned district/ State Agriculture Department	-	Member
9)	Nominee of RCGM	-	Member
10)	Nominee of GEAC	-	Member

The Director of Research may include additional members or drop not relevant Members based on transgenic crop and the trait.

The Nodal person as identified, would be responsible for monitoring of transgenic cotton/ and other field trials conducted in the jurisdiction of State Agriculture University by constituting Monitoring Teams as per the composition given above. The Nodal person shall also be responsible

for maintenance of grants received from the Government of India/ fees collected from the applicants for this purpose.

The monitoring team shall visit the fields for minimum of two times during the cotton crop season matching boll development and other important stages of the cotton crop. All the replicated field trials conducted by the applicants in its SAU jurisdiction and at least 25% of large scale field trials in its jurisdiction would be monitored as per the conditions given in the experimental trial permits issued by DBT/MoEF. The monitoring team(s) shall also observe and advise on collection of data by the applicants on the objectives of large scale and replicated field trials on transgenic crop as mentioned above. The team(s) may advise minor modifications in the collection of data based on the nature of gene expression in transgene and prevailing situation at the site of experimentation. The monitoring team(s) shall collect the data during its visit and a copy of the data sheet shall be handed over to the applicant for their records along with suggestions if any, for improvement on the conduct of the trial. The Team Leader shall submit the monitoring team(s) report on the large-scale field trials to MEC/GEAC and replicated multi-location field trials to RCGM/ MEC within 15 days from conclusion of the last visit. The Director of Research shall maintain the records of monitoring which may be called for by the GOI, if required. The monitoring team(s) shall maintain all the information provided by the applicant and/or collected by the team as confidential.

ii. **Post release monitoring:** Responsibility of post release monitoring has been entrusted to the State Agriculture Universities (SAU) under the direct supervision of Director of Agriculture Extension of each SAU. The Composition of the Monitoring Team shall consist of:

1)	Director of Extension, SAU, Nodal person	-	Team Leader
2)	Plant Breeder (concerned crop), SAU	-	Member
3)	Entomologist- Head of the Department or Nominee State Agriculture University	-	Member
4)	Agronomist- Head of the Department or Nominee State Agriculture University	-	Member
5)	Pathologist- Head of the Department or Nominee State Agriculture University	-	Member
6)	Subject matter specialist relevant to transgene (Biotechnologist)	-	Member
7)	Biostatistician	-	Member

The Director of Extension may include additional members or drop who are not relevant based on GM crop and the trait.

The Nodal person as identified would be responsible for post –release monitoring of transgenic cotton in the jurisdiction of State Agriculture University by constituting Monitoring Team(s) as per the

composition given above. The monitoring should be carried out through a scientifically designed survey. The Nodal person shall also be responsible for maintenance of grants received from the Government of India/ fees collected from the applicants for this purpose.

The monitoring team shall visit the fields for a minimum of two times during the cotton crop season matching boll development and other important stages of the cotton crop. The recorded observations will consist of:

- Date of sowing
- Seed Rate
- Method of Planting
- Spacing
- Fertilizer Application
- Micro-nutrient application
- Irrigation if any
- Control of pest/disease measures undertaken
- IPM practices followed
- Method of harvesting
- Performance of the hybrid
- Economic benefits
- Views of public acceptability / other comments
- Compliance of GEAC conditions.
- Any other parameter of relevance

The monitoring team may also be the focal point for providing feed back on the representations received by the GEAC/RCGM through an on the spot verification. Based on the feed back received from the Monitoring Team(s), the MoEF/DBT may make public the facts of the case through a press release/ website.

The detailed terms and conditions of the monitoring teams including financial support are available at http://www.envfor.nic.in.

To conclude, State Agriculture Departments and State Agriculture Universities have an important role to play in the enforcement and monitoring of regulations regarding GM crops to harness their maximum benefit in a sustainable manner.

The Indian Environment (Protection) Act, 1986 No. 29 of 1986

[23rd May, 1986]

An Act to provide for the protection and improvement of environment and for matters connected therewith.

WHEREAS decision were taken at the United Nations Conference on the Human Environment held at Stockholm in June, 1972, in which India participated, to take appropriate steps for the protection and improvement of human environment.

AND WHEREAS it is considered necessary further to implement the decision aforesaid in so far as they relate to the protection and improvement of environment and the prevention of hazards to human beings, other living creatures, plants and property;

BE it enacted by Parliament in the Thirty-seventh Year of the Republic of India as follows:

CHAPTER 1. PRELIMINARY

1. (1) This Act may be called the Environment (Protection) Act, 1986.

   (2) It extends to the whole of India.

   (3) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint and different dates may be appointed for different provisions of this Act and for different areas.

2. In this Act, unless the context otherwise requires:-

   (a) "environment" includes water, air and land and the interrelationship which exists among and between water, air and land, and human beings, other living creatures, plants, microorganism and property;

   (b) "environmental pollutant" means any solid, liquid or gaseous substance present in such concentration as may be, or tend to be, injurious to environment;

   (c) "environment pollution" means the presence in the environment of any environmental pollutant;

   (d) "handling", in relation to any substance, means the manufacture processing, treatment, package, storage, transportation, use, collection, destruction, conversion, offering for sale, or the like of such substance;

   (e) "hazardous substance" means any substance or preparation which, by reason of its chemical or physico-chemical properties or handling, is liable to cause harm to human beings other living creatures, plants, micro-organism, property or the environment;

(f) "occupier", in relation to any factory or premises, means a person who has control over the affairs of the factory or the premises and includes, in relation to any substance, the person in possession of the substance;

(g) "prescribed" means prescribed by rules made under this Act.

CHAPTER 2. GENERAL POWERS OF THE CENTRAL GOVERNMENT

3. (1) Subject to the provisions of this Act, the Central Government shall have the power to take all such measures as it deems necessary or expedient for the purpose of protecting and improving the quality of the environment and preventing, controlling and abating environmental pollution.

(2) In particular, and without prejudice to the generality of the provisions of sub-section (i), such measures may include measures with respect to all or any of the following matters, namely:

(i) Co-ordination of actions by the State Governments, officers and other authorities:-

(a) under this Act, or the rules made thereunder; or

(b) under any other law for the time being in force which is relatable to the objects of this Act;

(ii) planning and execution of a nation-wide programme for the prevention, control and abatement of environmental pollution;

(iii) laying down standards for the quality of environment in its various aspects;

(iv) laying down standards for emission or discharge of environmental pollutants from various sources whatsoever;

Provided that different standards for emission or discharge maybe laid down under this clause from different sources having regard to the quality or composition of the emission or discharge of environmental pollutants from such sources;

(v) restriction of areas in which any industries, operations, or processes or class of industries, operations or processes shall not be carried out or shall be carried out subject to c certain safeguards;

(vi) laying down procedures and safeguards for the prevention of accidents which may cause environmental pollution and remedial measures for such accidents;

(vii) laying down procedures and safeguards for the handling of hazardous substances;

(viii) examination of such manufacturing processes, materials and substances as are likely to cause environmental pollution;

(ix) carrying out and sponsoring investigations and research relating to problems of environmental pollution;

(x) inspection of any premises, plant, equipment, machinery, manufacturing or other processes, materials or substances and giving, by order, of such directions to such authorities, officers or persons as it may consider necessary to take steps for the prevention, control and abatement of environmental pollution;

(xi) establishment or recognition of environmental laboratories and institutes to carry out the functions entrusted to such environmental laboratories and institutes under this Act;

(xii) collection and dissemination of information in respect of matters relating to environmental pollution;

(xiii) preparation of manuals, codes or guides relating to the prevention, control and abatement of environmental pollution;

(xiv) such other matters as the Central government deems necessary or expedient for the purpose of securing the effective implementation of the provisions of this Act.

(3) The Central Government may, if it considers it necessary or expedient so to do for the purposes of this Act, by order, published in the Official Gazette, constitute an authority or authorities by such name or names as may be specified in the order for the purpose of exercising and performing such of the powers and functions (including the power to issue directions under section 5) of the Central Government under this Act and for taking measures with respect to such of the matters referred to in sub-section (2) as may be mentioned in the order and subject to the supervision and control of the Central Government and the provisions of such order, such authority or authorities may exercise the powers or perform the functions or take the measures so mentioned in the order as if such authority or authorities had been empowered by this Act to exercise those powers or perform those functions or take such measures.

4. (1) Without prejudice to the provisions of sub-section (3) of section 3, the Central Government may appoint officers with such designations as it thinks fit for the purpose of this Act and may entrust to them such of the powers and functions under this Act as it may deem fit.

(2) The officers appointed under sub-section (1) shall be subject to the general control and direction of the Central Government or, if so directed by that Government, also of the authority or authorities, if any, constituted under sub-section(3) or of any other authority or officer.

5. Notwithstanding anything contained in any other law but subject to the provisions of this Act, the Central Government may, in the exercise of its powers and performance of its functions under this Act, issue directions in writing to any person, officer or any authority and such person, officer or authority shall be bound to comply with such directions.

Explanation: For the avoidance of doubts, it is hereby declared that the power to issue directions under this section includes the power to direct:

(a) the closure, prohibition or regulation of any industry, operation or process; or

(b) stoppage or regulation of the supply of electricity or water or any other service.

6. (1) The Central Government may, by notification in the Official Gazette, make rules in respect of all or any of the matters referred to in section 3.

(2) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely:-

(a) the standards of quality or air, water or soil for various areas and purposes;

(b) the maximum allowable limits of concentration of various environmental pollutants (including noise) for different areas;

(c) the procedures and safeguards for the handling of hazardous substances;

(d) the prohibition and restrictions on the handling of hazardous substances in different areas;

(e) the prohibition and restriction on the location of industries and the carrying on of processes and operations in different areas;

(f) the procedures and safeguards for the prevention of accidents which may cause environmental pollution and for providing for remedial measures for such accidents.

CHAPTER-3. PREVENTION, CONTROL AND ABATEMENT OF ENVIRONMENTAL POLLUTION

7. No person carrying on any industry, operation or process shall discharge or emit or permit to be discharged or emitted any environmental pollutant in excess of such standards as may be prescribed.

8. No person shall handle or cause to be handled any hazardous substance except in accordance with such procedure and after complying with such safeguards as may be prescribed.

9. (1) Where the discharge of any environmental pollutant in excess of the prescribed standards occurs or is apprehended to occur due to any accident or other unforeseen act or event, the person responsible for such discharge and the person in charge of the place at which such discharge occurs or is apprehended to occur shall be bound to prevent or mitigate the environmental pollution caused as a result of such discharge and shall also forth with:-

(a) intimate the fact of such occurrence or apprehension of such occurrence; and

(b) be bound, if called upon, to render all assistance, to such authorities or agencies as may be prescribed.

(2) On receipt of information with respect to the fact or apprehension of any occurrence of the nature referred to in subsection(1), whether through intimation under that sub-section or otherwise, the authorities or agencies referred to in sub-section (1) shall, as early as practicable, cause such remedial measures to be taken as are necessary to prevent or mitigate the environmental pollution.

(3) The expenses, if any, incurred by any authority or agency with respect to the remedial measures referred to in sub-section (2), together with interest (at such reasonable rate as the Government may, by order, fix) from the date when a demand for the expenses is made until it is paid may be recovered by such authority or agency from the person concerned as arrears of land revenue or of public demand.

10. (1) Subject to the provisions of this section, any person empowered by the Central Government in this behalf shall have a right to enter, at all reasonable times with such assistance as he considers necessary, any place:-

(a) for the purpose of performing any of the functions of the Central Government entrusted to him;

(b) for the purpose of determining whether and if so in what manner, any such functions are to be performed or whether any provisions of this Act or the rules made thereunder or any notice, order, direction or authorisation served, made, given or granted under this Act is being or has been complied with;

(c) for the purpose of examining and testing any equipment, industrial plant, record, register, document or any other material object or for conducting a search of any building in which he has reason to believe that an offense under this Act or the rules made thereunder has been or is being or is about to be committed and for seizing any such equipment, industrial plant, record, register, document or other material object if he has reasons to believe that it may furnish evidence of the commission of an offense punishable under this Act or the rules made thereunder or that such seizure is necessary to prevent or mitigate environmental pollution.

(2) Every person carrying on any industry, operation or process or handling any hazardous substances shall be bound to render all assistance to the person empowered by the Central Government under sub-section (1) for carrying out the functions under that subsection and if he fails to do so without any reasonable cause or excuse, he shall be guilty of an offense under this Act.

(3) If any person willfully delays or obstructs any person empowered by the Central Government under sub-section (1) in the performance of his functions, he shall be guilty of an offense under this Act.

(4) The provisions of the Code of Criminal Procedure, 1973, or, in relation to the State of Jammu and Kashmir, or any area in which that Code is not in force, the provisions of any corresponding law in force in that State or area shall, so far as may be, apply to any search or seizure under this section as they apply to any search or seizure made under the authority of a warrant issued under section 94 of the said Code or, as the case may be, under the corresponding provision of the said law.

11. (1) The Central Government or any officer empowered by it in this behalf, shall have power to take, for the purpose of analysis, samples of air, water, soil, or other substance from any factory, premises or other place in such manner as may be prescribed.

(2) The result of any analysis of a sample taken under subsection (1) shall not be admissible in evidence in any legal proceeding unless the provisions of the sub-section (3) and (4) are complied with.

(3) Subject to the provisions of sub-section (4), the person taking the sample under sub-section(1) shall :

(a) serve on the occupier or his agent or person in charge of the place, a notice, then and there, in such form as may be prescribed, of his intention to have it so analyzed;

(b) in the presence of the occupier or his agent or person, collect a sample for analysis.

(c) cause the sample to be placed in a container or containers which shall be market and sealed and shall also be signed both by the person taking the sample and the occupier or his agent or person;

(d) send without delay, the container or the containers to the laboratory established or recognised by the Central Government under section 12.

(4) When a samples is taken for analysis under sub-section (1) and the person taking the sample serves on the occupier or his agent or person, a notice under clause (a) of sub-section (3), then :

(a) in a case where the occupier, his agent or person willfully absents himself, the person taking the sample shall collect the sample for analysis to be placed in a container or containers which shall be marked and sealed and shall also be signed by the person taking the sample, and

(b) in a case where the occupier or his agent or person present at the time of taking the samples refuses to sign the marked and sealed container or containers of the samples as required under clause (c) of sub-section(3), the marked and sealed containers or containers shall be signed by the person taking the samples, and the container or containers shall be sent without delay by the person taking the samples for analysis to the laboratory established or recognised under section 12 and such person shall inform the Government Analyst appointed or recognised under section 13 in writing, about the willful absence of the occupier or his agent or person, or, as the case may be, his refusal to sign the container or containers.

12. (1) The Central Government may, by notification in the Official Gazette:

(a) establish one or more environmental laboratories :

(b) recognise one or more laboratories or institutes as environmental laboratories to carry out the functions entrusted to an environmental laboratory under this Act.

(2) The Central Government may, by notification in the Official Gazette, make rules specifying:

(a) the functions of the environmental laboratory;

(b) the procedure for the submission to the said laboratory of samples of air, water, soil or other substance for analysis or tests, the form of the laboratory report thereon and the fees payable for such report;

(c) such other matters as may be necessary or expedient to enable that laboratory to carry out its functions.

13. The Central Government may by notification in the Official Gazette, appoint or recognise such persons as it thinks fit and having the prescribed qualifications to be Government Analysts for the purpose of analysis of samples of air, water, soil or other substance sent for analysis to any environmental laboratory established or recognised under sub-section (1) of section 12.

14. Any document purporting to be a report signed by a Government analyst may be used as evidence of the facts stated therein in any proceeding under this Act.

15. (1) Whoever fails to comply with or contravenes any of the provisions of this Act, or the rules made or orders or directors issued thereunder, shall, in respect of each such failure or contravention, be punishable with imprisonment for a term which may extend to five years or with fine which may extend to one lakhs rupees, or with both, and in case the failure or contravention continues, with additional fine which may extend to five thousand rupees for every day during which such failure or contravention continues after the conviction for the first such failure or contravention.

(2) If the failure or contravention referred to in sub-section(1) continues beyond a period of one year after the date of conviction, the offender shall be punishable with imprisonment for a term which may extend to seven years.

16. (1) Where any offense under this Act has been committed by a company, every person who, at the time the offense was committed, was directly in charge of, and was responsible to, the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the offense and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this sub-section shall render any such person liable to any punishment provided in this Act, if he proves that the offense was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offense.

(2) Notwithstanding anything container, in sub-section (1), where an offense under this Act has committed by a company and it is proved that the offense has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also deemed to be guilty of that offense and shall be liable to be proceeded against and punished accordingly.

Explanation-For the purposes of this section:

(a) "company" means body corporate and includes a firm or other association of individuals;

(b) "director" in relation to a firm, means a partner in the firm.

17. (1) Where an offense under this Act has been committed by any Department of Government, the Head of the Department shall be deemed to be guilty of the offense and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this section shall render such Head of the Department liable to any punishment if the proves that the offense was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offense.

(2) Notwithstanding anything container in sub-section (1), where an offense under this Act has been committed by a Department of Government and it is proved that the offense has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any officer, other than the Head of the Department, such officer shall also be deemed to be guilty of that offense and shall be liable to be proceeded against and punished accordingly.

CHAPTER 4. MISCELLANEOUS

18. No suit, prosecution or other legal proceeding shall lie against the Government or any officer or other employee of the Government or any authority constituted under this Act or any member, officer or other employee of such authority in respect of anything which is done or intended to be done in good faith in pursuance of this Act or the rules made or orders or directions issued thereunder.

19. No court shall take cognizance of any offense or officer authorized in this behalf made by:-

(a) the Central Government or any authority or officer authorised in this behalf by that Government; or

(b) any person who has given notice of not less than sixty days, in the manner prescribed, of the alleged offense and of his intention to make a complaint, to the Central Government or the authority or officer authorised as aforesaid.

20. The Central Government may, in relation to its functions under this Act, from time to time, require any person, officer, State Government or other authority to furnish to it or any prescribed other information and such person, officer, State Government or other authority shall be bound to do so.

21. All the members of the authority, constituted, if any, under section 3 and all officers and other employees of such authority when acting or purporting to act in pursuance of any provisions of this Act or the rules made or orders or directors issued there under shall be deemed to be public servants within the meaning of section 21 of the Indian Penal Code.

22. No civil court shall have jurisdiction to entertain any suit or proceeding in respect of anything done, action taken or order or direction issued by the Central Government or any other authority or officer in pursuance of any power conferred by or in relation to its or his functions under this Act.

23. Without prejudice to the provisions of sub-section (3) of section 3, the Central Government may, by notification in the Official Gazette, delegate, subject to such conditions and limitations as may be specified in the notification, such of its powers and functions under this Act, [except the power to constitute an authority under sub-section (3) of section 3 and make rules under section 25] as it may deem necessary or expedient, to any officer, State Government or other authority.

24. (1) Subject to the provisions of sub-section (2), the provisions of this Act and the rules or orders made there in shall have effect notwithstanding anything inconsistent therewith contained in any enactment other than this Act.

(2) Where any act or omission constitutes an offense punishable under this Act and also under any other Act then the offender found guilty of such offense shall be liable to be punished under the other Act and not under this Act.

25. (1) The Central Government may, by notification in Official Gazette, make rules for carrying out the purposes of this Act.

(2) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely:-

(a) the standards in excess of which environmental pollutants shall not be discharged or emitted under section 7;

(b) the procedure in accordance with and the safeguards in compliance with which hazardous substance shall be handled or cause to be handled under section 8;

(c) the authorities or agencies to which intimation of the fact of occurrence or apprehension of occurrence of the discharge of any environmental pollutant in excess of the prescribed standards shall be given and to whom all assistance shall be bound to be rendered under sub-section (1) of section 9;

(d) the manner in which samples of air, water, soil, or other substance for the purpose of analysis shall be taken under subsection (1) of section 11;

(e) the form in which notice of intention to have a sample analysed shall be served under clause (a) of sub-section (3) of section 11;

(f) the functions of the environmental laboratories, the procedure for the submission to such laboratories of samples of air, water, soil and other substance for analysis or test; the form of laboratory report; the fees payable for such report and other matters to enable such laboratories to carry out their functions under sub-section(2) of section 12;

(g) the qualifications of Government Analyst appointed or recognised for the purpose of analysis of samples of air, water, soil or other substances under section 13;

(h) the manner in which notice of the offense and of the intention to make a complaint to the Central Government shall be given under clause (b) of section 19;

(i) the authority or officer to whom any report, returns, statistics, accounts and other information shall be furnished under section 20;

(j) any other matter which is required to be, or may be, prescribed.

26. Every rule made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is insession, for a total period of thirty days which may be comprised in one session or in two more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

Ministry of Environment & Forests

Notification New Delhi, the 5th December, 1989 Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/ Genetically Engineered Organism or Cells

(To be notified under the EP Act, 1986)

G.S.R. 1037 (E).- In exercise of the powers conferred by sections 6,8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986) and with a view to protecting the environment, nature and health, in connection with the application of gene technology and micro-organisms, the Central Government hereby makes the following rules, namely:-

1. SHORT TITLE, EXTENT AND COMMENCEMENT

(1) These rules may be called the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous micro-organisms/Geneti-cally engineered organisms or cells.

(2) These rules shall come into operation on the date to be notified for this purpose in the Official Gazette.

2. APPLICATION

(1) These rules are applicable to the manufacture, import and storage of micro-organisms and Gene-Technological products.

(2) These rules shall apply to genetically engineered organisms/micro-organisms and cells and correspondingly to any substances and products and food stuffs, etc., of which such cells, organisms or tissues hereof form part.

(3) These rules shall also apply to new gene technologies apart from those referred to in clauses (ii) and (iv) of rule 3 and these rules shall apply to organisms /micro-organisms and cells generated by the utilisation of such ether gene-technologies and to substances and products of which such organism and cells form part.

(1) These rules shall be applicable in the following specific cases:

(a) sale, offers for sale, storage for the purpose of sale, offers and any kind of handling over with or without a considera-tion:

(b) exportation and importation of genetically engineered cells or organisms:

(c) production, manufacturing, processing, storage, import, drawing off, packaging and repackaging of the Genetically Engi-neered Products:

(d) production, manufacture etc. of drugs and pharmaceuticals and food stuffs distilleries and tanneries, etc. Which make use of micro-organisms/ genetically engineered microorganisms one way or the other.

(4) These rules shall be applicable to the whole of India.

3. DEFINITIONS

In these rules unless the context requires.

(i) "Biotechnology" means the application of scientific and engineering principles to the processing of materials by biologi-cal agents to produce goods and services;

(ii) "Cell hybridisation" means the formation of live cells with new combinations of genetic material through the fusion of two or more cells by means of methods which do not occur naturally;

(iii) "Gene Technology" means the application of the gene tech-nique called genetic engineering, include selfcloning and dele-tion as well as cell hybridisation;

(iv) "Genetic engineering" means the technique by which herita-ble material, which does not usually occur or will not occur naturally in the organism or cell concerned, generated outside the organism or the cell is inserted into said cell or organism. It shall also mean the formation of new combinations of genetic material by incorporation of a cell into a host cell, where they occur naturally (self cloning) as well as modification of an organism or in a cell by deletion and removal of parts of the heritable material;

(v) "microorganisms" shall include all the bacteria, viruses, fungi, mycoplasma, cell lines, algae, protodoans and nematotes indicated in the schedule and those that have not been presently know to exist in the country or not have been discovered so far.

4. COMPETENT AUTHORITIES

(1) **Recombinant DNA Advisory Committee (RDAC):** This committee shall review developments in Biotechnology at national and international levels and shall recommend suitable and appropriate safety regulations for India in recombinant research, use and applications from time to time. The Committee shall function in the Department of Biotechnology.

(2) **Review Committee on Genetic Manipulation (RCGM):** This committee shall function in the Department of Biotechnology to monitor the safety related aspects in respect of on-going research projects and activities involving genetically engineered organisms/hazardous microorganisms. The Review Committee on Genetic Manipulation shall include representatives of (a) Depart-ment of Biotechnology (b) Indian Council of Medical Research (c) Indian Council of Agricultural Research (d) Council of Scientific and Industrial Research (e) other experts in their individual capacity. Review Committee on Genetic Manipulation may appoint sub groups.

It shall bring out Manuals of guidelines specifying procedure for regulatory process with respect to activities involving geneti-cally engineered organisms in research, use and applications including industry with a view to ensure environmental safety. All ongoing projects involving high risk category and controlled field experiments shall be reviewed to ensure that adequate precautions and containment conditions are followed as per the guidelines.

The Review Committee on Genetic Manipulation shall lay down procedures restricting or prohibiting production, sale, importa-tion and use of such genetically engineered organism of cells as are mentioned in the Schedule.

(3) **Institutional Biosafety Committee (IBSC):** This committee shall be constituted by an occupier or any person including research institutions handling microorganism/genetical-ly engineered organisms. The committee shall comprise the Head of the Institution, Scientists engaged in DNA work, a medical expert and a nominee of the Department of Biotechnology. The occupier or any person including research institutions handling microorganisms/genetically engineered organisms shall prepare, with the assistance of the Institutional Biosafety Committee (IBSC) an uptodate on site emergency plan according to the manu-als/guidelines of the RCGM and make available copies to the District Level Committee/State Biotechnology Co-ordination Com-mittee and the Genetic Engineering Approval Committee.

(4) **Genetic Engineering Approval Committee (GEAC)**

This committee shall function as a body under the Department of Environment, Forest and Wildlife for approval of activities involving large scale use of hazardous microorganisms and recom-binants in research and industrial production from the environ-mental angle. The Committee shall also be responsible for ap-proval of proposals relating to release of genetically engineered organisms and products into the environment including experimen-tal field trials.

The composition of the Committee shall be

(i) Chairman-Additional Secretary, Department of Environment, Forests and Wild life Co-Chairman-Representative of Department of Bio-technology

(ii) Members: Representative of concerned Agencies and Depart-ments, namely, Ministry of Industrial Development, Department of Biotechnology and the Department of Atomic Energy:

(iii) Expert members: Director General Indian Council of Agri-cultural Research, Director General-Indian Council of Medical Research, Director General-Council of Scientific and Industrial Research, Director General-Health Services, Plant Protection Adviser, Directorate of Plant Protection, Quarantine and storage, Chairman, Central Pollution Control Board and three outside experts in individual capacity.

(iv) Member Secretary: An official of the Department or Envi-ronment, Forest and Wild life.

The committee may co-opt other members/experts as necessary.

The committee or any person/s authorised by it shall have powers to take punitive action under the Environment (Protection) Act.

(5) **State Biotechnology Co-Ordination Committee (SBCC):** There shall be a State Biotechnology Coordination Committee in the States wherever necessary. It shall have powers to inspect, investigate and take punitive action in case or violations of statutory provisions through the Nodal Department and the State Pollution Control Board/Directorate of Health/Medical Services. The Committee shall review periodically the safety and control measures in the various industries/institutions handling geneti-cally engineered Organisms/Hazardous microorganisms. The composi-tion of the Coordination Committee shall be:

(i) Chief Secretary - Chairman

(ii) Secretary, Department of Environment - Member Secretary

(iii) Secretary, Department of Health - Member

(iv) Secretary, Department of Agriculture - Member

(v) Secretary, Department of Industries and Commerce - Member

(vi) Secretary, Department of Forests - Member

(vii) Secretary, Department of Public works/Chief Engineer, Department of Public Health Engineering - Member

(viii) State microbiologists and Pathologists - Member

(ix) Chairman of State Pollution Control Board

The Committee may co-opt other members/experts as necessary.

(6) **District Level Committee (DLC):** There shall be a District Level Biotechnology Committee (DLC) in the districts wherever necessary under the District Collectors to monitor the safety regulations in installations engaged in the use of genetically modified organisms/hazardous microorganisms and its applications in the environment.

The District Level Committee/or any other person/s authorised in this behalf shall visit the installation engaged in activity involving genetically engineered organisms, hazardous microorgan-isms, formulate information chart, find out hazards and risks associated with each of these installations and coordinate activ-ities with a view to meeting any emergency. The District Level Committee shall regularly submit its report to the State Biotech-nology Co-ordination Committee/Genetic Engineering Approval Committee.

The District level Committee shall comprise of:

(i) District Collector - Chairman

(ii) Factory Inspector - Member

(iii) A representative of the Pollution Control Board - Member

(iv) Chief Medical Officer (District Health Officer) – Member (Convenor)

(v) District Agricultural Officer - Member

(vi) A representative of the Public Health Engineering Department - Member

(vii) District Microbiologists pathologist (Technical expert) - Member

(viii) Commissioner Municipal Corporation - Member

The Committee may co-opt other member/s/experts as necessary.

5. CLASSIFICATION OF MICROORGANISMS OR GENETICALLY ENGINEERED PRODUCT

(i) For the purpose of these rules, microorganisms or genetically engineered organisms, products or cells shall be dealt with under two major heads; animal pathogens and plant pests and these shall be classified in the manner specified in the Schedule.

(ii) If any of the microorganism, genetically engineered organism or cell falls within the limits of more than one risk class as specified in the Schedule, it shall be deemed to belong exclu-sively to the last in number of such classes.

6. MICROORGANISMS LAID DOWN IN THE SCHEDULE ARE DIVIDED INTO THE FOLLOWING

(i) Bacterial agents:

(ii) Fungal Agents:

(iii) Parasitic Agents

(iv) Viral, Rickettsial and Chlamydial Agents:

(v) Special Category

7. APPROVAL AND PROHIBITIONS

(1) No person shall import, export, transport, manufacture, process, use or sell any hazard-ous microorganisms or genetically engineered organisms/substances or cells except with the approval of the Genetic Engineering Approval Committee.

(2) Use of pathogenic microorganism or any genetically engi-neered organisms or cell for the purpose of research shall only be allowed in laboratories or inside laboratory areas notified by the Ministry of Environment and Forests for this purpose under the Environment (Protection) Act, 1986.

(3) The Genetic Engineering Approval Committee shall give direc-tions to the occupier to determine or take measures concerning the discharge of micro-organisms/genetically engineered organisms or cells mentioned in the schedule from the laboratories, hospi-tals and other areas including prohibition of such discharges and laying down measures to be taken to prevent such discharges.

(4) Any person operating or using genetically engineered organ-ism microorganisms mentioned in the schedule for scale up or pilot operations shall have to obtain licence issued by the Genetic Engineering Approval Committee for any such activity. The possessor shall have to apply for licence in prescribed proforma.

(5) Certain experiments for the purpose of education within the field of gene technology or microorganism may be carried out outside the laboratories and laboratory areas mentioned in sub-rule (2) and will be looked after by the Institutional Biosafety Committee.

8. PRODUCTION

Production in which genetically engineered organisms or cells or micro-organism are generated or used shall not be commenced except with the consent of Genetic Engineering Approval Committee with respect of discharge of genetically engineered organisms or cells into the environment. This shall also apply to production taking place in connection with develop-ment, testing and experiments where such production, etc, is not subject to rule 7.

9. DELIBERATE OR UNINTENTIONAL RELEASE

(1) Deliberate or unintentional release of genetically engineered organisms/hazard-ous microorganisms or cells, including deliberate release for the purpose of experiment shall not be allowed.

Note: Deliberate release shall mean any intentional transfer of genetically engineered organisms/ hazardous microorganisms or cells to the environment or nature, irrespective of the way in which it is done:

(2) The Genetic Engineering Approval Committee may in special cases give approval of deliberate release.

10. PERMISSION AND APPROVAL FOR CERTAIN SUBSTANCES

Substances and products, which contain genetically engineered organisms or cells or microorganisms shall not be produced, sold, imported or used except with the approval of genetic engineering approval committee

11. PERMISSION AND APPROVAL FOR FOOD STUFFS

Food stuffs, ingredients in food stuffs and additives including processing aids containing or consisting of genetically engi-neered organisms or cells, shall not be produced, sold, imported or used except with the approval of the Genetic Engineering Approval Committee.

12. GUIDELINES

(1) Any person who applies for approval under rules 8-11 shall, as determined by the Genetic Engineering Ap-proval Committee submit information and make examinations or cause examinations to be made to elucidate the case, including examinations according to specific directions and at specific laboratories. He shall also make available an on-site emergency plan to GEAC before obtaining the approval. If the authority makes examination itself, it may order the applicant to defray the expenses incurred by it in so doing.

(2) Any person to whom an approval has been granted under rules 8-11 above shall notify the Genetic Engineering Approval Commit-tee of any change in or addition to the information already submitted.

13. GRANT OF APPROVAL

(1) In connection with the granting of approval under rules 8 to 11 above, terms and conditions shall be stipulated, including terms and conditions as to the control to be excercised by the applicant, supervision, restriction on use, the layout of the enterprise and as to the submission of information to the State Biotechnology Co-ordination Committee or to the District Level Committee

(2) All approvals of the Genetic Engineering Approval Committee shall be for a specified period not exceeding four years at the first instance renewable for 2 years at a time. The Genetic Engineering Approval Committee shall have powers to revoke such approval in the following situations:

(a) If there is any new information as to the harmful effects of the genetically engineered organisms or cells.

(b) If the genetically engineered organisms or cells cause such damage to the environment, nature or health as could not be envisaged when the approval was given, or

(c) Non compliance of any condition stipulated by Genetic Engi-neering Approval Committee.

14. SUPERVISION

(1) The Genetic Engineering Approval Committee may supervise the implementation of the terms and conditions laid down in connection with the approvals accorded by it.

(2) The Genetic Engineering Approval Committee may carryout this supervision through the State Biotechnology Coordination Commit-tee or the State Pollution Control Boards/District Level Commit-tee or through any person authorised in this behalf.

15. PENALTIES

(1) If an order is not complied with, the District Level Committee or State Biotechnology Co-ordination Committee may take measures at the expenses of the person who is responsible.

(2) In cases where immediate interventions is required in order to prevent any damage to the environment, nature or health, the District level Committee or State Biotechnology Coordination Committee may take the necessary steps without issuing any orders or notice. The expenses incurred for this purpose will be repay-able by the person responsible for such damage.

(3) The State Biotechnology Co-ordination Committee /District Level Committee may take samples for a more detailed examination of organisms and cells.

(4) The State Biotechnology Co-ordination Committee/District Level Committee shall be competent to ask for assistance from any other Government authority to carry out its instructions.

16. RESPONSIBILITY TO NOTIFY INTERRUPTIONS OR ACCIDENTS

(1) Any person who under rule 7-11 is responsible for conditions or arrangements shall immediately notify the District Level Commit-tee \State Biotechnology Co-ordination Committee and the state medical officer of any interruption of operations or accidents that may lead to discharges of genetically engineered organisms or cells which may be harmful to the environment, nature or health or involve any danger thereto.

(2) Any notice given under sub-rule (1) above shall not lessen the duty of the person who is responsible to try effectively to minimise or prevent the effects of interruptions of operations of accidents.

17. PREPARATION OF OFF-SITE EMERGENCY PLAN BY THE DLC

(1) It shall be the duty of the DLC to prepare an off-site emergency plan detailing how emergencies relating to a possible major accident at a site will be dealt with and in preparing the plan, the DLC shall consult the occupier and such other person as it may deem necessary.

(2) For the purpose of enabling the DLC to prepare the emergency plan required under sub-rule(I), the occupier shall provide the DLC with such information relating to the handling of hazardous microorganisms/genetically engineered organisms under his control as the DLC may require including the nature, extent and likely off-site affects of a possible major accident and the DLC shall provide the occupier with any information from the off-side emergency plan which relates to his duties under rule 16.

18. INSPECTIONS AND INFORMATIONS REGARDING FINANCE

(1) The State Biotechnology Co-ordination Committee or the Genetic Engi-neering Approval Committee/the DLC or any person with special knowledge duly authorised by the State Biotechnology Co-Ordina-tion Committee or the Genetic Engineering Approval Committee or the DLC where it is deemed necessary, at any time on due produc-tion if identity be admitted to public as well as to private premises and localities for the purpose of carrying out supervi-sion.

(2) Any person who is responsible for activities subject to rules 7-11 above shall at the request of District level Committee or State Biotechnology Coordination Committee or the GEAC submit all such information including information relating to financial conditions and accounts, as is essential to the authority's administration under these rules. He shall also allow supervi-sion or inspection by the Authorities or persons indicated in sub-rule(I).

(3) The Genetic Engineering Approval Committee may fix fees to cover, in whole or in part, the expenses incurred by the authorities in connection with approvals, examinations, supervi-sion and control.

19. APPEAL

(1) Any person aggrieved by a decision made by Genetic Engineering Approval Committee/State Biotechnology Co-ordination Committee in pursuance of these rules may within thirty days from the date on which the decision is communicated to him, prefer an appeal to such authority as may be appointed by Ministry of Environment and Forests provided that the appellate authority may entertain the appeal after the expiry of the said period of thirty days if such authority is satisfied that the appellant was prevented by sufficient cause from filing the appeal in time.

20. EXEMPTION

The Ministry of Environment and Forests shall, wherever necessary, exempt an occupier handling a particular microorganism/genetically engineered organism from rule 7-11.

A. ANIMAL AND HUMAN PATHOGENS

Schedule

BACTERIAL

Risk Group II

- Acinetobacter calcoacetieus
- Actinobacillus-all species except A mallei, which is in Risk Group III
- Aeromonoas hydrophila
- Arizona hinshawii-all serotypes
- Bacillus anthracis
- Bordetella all species
- Borrelia recurrentis.B.Vincenti
- Campylobacter fetus
- Camphylobacter jejuni, Chalamydia psittaci
- Cheamydia trachomatics
- Clostridium chauvoei, Cl.difficile Cl/fallax. Cl haemolyticum Q.histolyticum, CI novyi (CI,Pefringes) Cl.speticum, Cl.sordelli
- Corynebacterium diptheriae, C.equi, C. haemolyticum, C.Pseudotu-berculosis, C.pyogenes, C.renale
- Diplococcus (Streptococcus) pneumoniae
- Edwardsiila tarda
- Erysipelothix insidiosa
- Escherichia Coli-all enteropathogenic serotypes, enterotoxigenic
- Haemophilus ducrevi, H.influenzae, H. pneumoniae
- Herellea vaginicola
- Klebsiella-all species and all serotypes
- Legionlla pneumophila
- Letionella
- Leptospira interrogans-all serotypes reported in India
- Listeria, all species
- Mima polymorpha
- Moraxella-all species
- Mycobacteria-all species including Mycobacterium avium
- M.Bovis M.tuberculosis, M.Leprae
- Mycoplasma-all species except M.Mycoides and M.angalactiae
- Meosseroc gonorrhoea,N. Leprae
- Mycoplasma-all species except M.Mycoides and M.angalactiae
- Neisseric gonorrhoea,N. meningitis
- Pasteurella-all species except those listed in Risk Group III
- Salmonella-all species and all setotypes
- Shigella-all species and all serotypes
- Sphaerophorgs necrophorus

- Staphylococcus aureus
- Streptobacillus moniliformis
- Streptococcus pneumoniae
- Streptococcus pyogenes.S.equi
- Streptomyces madurae,s.pelleteri, s.somaliensis
- Treponema carateum, T.pallidam and T.pettenue
- Vibrio foetus V.comma including biotype EI Top and
- V. parahemolyticus
- Vibrio cholerae

Risk Group III

- Actinobacillus mallei
- Bartonella-all species
- Brucella-all species
- Clostridium botulium Cl.tetani
- Francisella tularensis
- Mycobacterium avium,. M.bovis, M.tuberculosis,m.leprae
- Pasteurella multocida type B("buffalo" and other foreign viru-lent strains)
- Pseudomonas pseudomallai
- Yersinia pestis

FUNGAL

Risk Group II

- Actinomycetes (including Nocardia SP, Actinomyces species and Arachina propinica)
- Aspergillus fumigatus
- Blastomyces dermatitis
- Cryptococcus neoformans C. fersiminosos
- Epidermophyton madurella, microsporon
- Paracoccidiodes brasiliensis
- Sporothrix
- Trichoderma
- Trichophyton

Risk Group III

- Coccidioides immitis
- Histoplasma capulatum
- Histoplasma capsulatum var duboiss

PARASITIC

Risk Group II

- Entahoeba histolytica
- Leishmania species
- Naegleria gruberia
- Plasmodium theilera, *P. babesia, P. falcoparum*
- Plasmodium babesia
- Schistosoma
- Toxoplasma gondii
- Toxocana canis
- Trichinella spiralis
- Trichomanas
- Trypanosoma cruzi

Risk Group III

- Schisistosoma mansoni

VIRAL RICKETTSIAL AND CHALMYDIAL

Risk Group II

- Adenoviruses - Human all types
- Avian loukosis
- Cache Valley virus
- CELO (avian adenovirus)
- Coxsackie A and B viruses
- Corona viruses
- Cytomegalo viruses
- Dengue virus, when used for transmission experiments
- Echo viruses - all types
- Encephalomyocarditis virus (EMC)
- Flanders virus
- Hart Part virus
- Hepatitis - associated antigen material - hepatitis A and B viruses, non A and non B, HDV
- Herpes viruses - except herpesviruses simiae (monkey B virus) which is in Risk Group IV.
- Infectious Bovine Rhinotraechitis virus (IBR)
- Infectious Bursal diseases of poultry and Infectious Bronchitus
- Infectious Laryngotraechitis (ILT)
- Influenza virus - all types, except A PR 834 which is in Risk Group I
- Langat virus Leucosis Complex
- Lymphogranuloma venereum agent

- Marek's Disease virus
- Measles virus
- Mumps virus
- Newcastle disease virus (other than licenced strain for vaccine use)
- Parainfluenza viruses - all type except parainfluenza virus 3, SF4 strain, which is in Risk Group I.
- Polio viruses - all types, wild and attenuated
- Poxviruses - all types except Alastrim, monkey pox, sheep pox and white pox, which depending on experiments are in Risk Group III or IV.
- Rabies virus - all strains except rabies stret virus, which should be classified in Risk Group III when inoculated into cornivores
- Reoviruses - all types
- Respiratory syncytial virus
- Rhinoviruses - all types
- Rinderpest (other than vaccine strain in use)
- Rubella virus
- Stimian viruses - all types except herpeavirus simlae (Monkey Virus) which is in Risk Group IV.
- Simian virus 40 -
- Ad 7 SV 40 (defective)
- Sindbis virus
- Tensaw virus
- Turlock virus
- Vaccinia virus
- Varicella virus
- Vole rickettsia
- Yellow fever virus, 17D vaccine strain

Risk Group III

- African House Sickness (attenuated strain except animal passage)
- Alastrim, monkey pox and whitepox, when used in vitro
- Arboviruses - All strains except those in Risk Group II and IV.
- Blue tongue virus (only serotypes reported in India)
- Ebola fever virus
- Feline Leukemia Epstein-Barr virus
- Feline sarcoma
- Foot and Mouth Disease virus (all serotypes and sutbypes)
- Gibbon Ape Lymphosarcoma
- Herpesvirus ateles
- Herpesvirus saimiri
- Herpes simplex 2

- HIV-I & HIV-2 and strains of SIV
- Infectious Equine Anaemia
- Lymphocytic choriomeningitis virus (LCM)
- Monkey pox, when used in vitro
- Nen-defective Adeno-2 SV-40 hybrids
- Psittacosis-ornithosis-trachoma group of agents
- Pseudorabies virus
- Rabies street virus, when used inoculations of carnivores
- Rickettsia-all species except Vole rickettsia and Coxiell burnetti when used for vector transmission or animal inoculation experiments
- Sheep pox (field strain)
- Swine Fever virus
- Vesicular stomatitis virus
- Woolly monkey Fibrosarcoma
- Yaba pox virus

Risk Group IV

- Alastrim, monkeypox, whitepox, when used for transmission or animal inoculation experiments
- Hemorrhagic fever agents, including Crimean hemorrhagic fever (congo)
- Korean hemorrhagic fever and others as yet undefined
- Herpesvirus simlae (monkey B virus)
- Tick-borne encephalitis virus complex, including - Russian
- Spring Summer Encephalitis, Kyasanur Forest Diseast, omsk hemorrhagic fever and Central European encephalitis viruses.

SPECIAL CATEGORY

BACTERIAL

- Contagious Equine Metritis (H. equigenitalis)
- Pestis petit de ruminantium

VIRAL RICKETTSIAL AND CHLAMYDIAL

- African Horse Sickness virus (serotypes not reported in India and challenge strains)
- African Swine Fever
- Bat rabies virus
- Blue tongue virus (serotypes not reported in India)
- Exoitic FMD virus types and sub-types
- Junin and Machupo viruses
- Lassa virus

- Marburg virus
- Murrey valley encephalitis virus
- Rift Valley Fever virus
- Smallpox virus - Archieval storage and propagation Swine Vesicular Disease
- Veneseulan equine encephalitis virus - epidemic strains
- Western Equine encephalitis virus Yellow fever virus - Wild strain
- Other Arboviruses causing epizootics and so far not recorded in India

B. PLANT PESTS

Any living stage (including active and dormant forms) of insects, mites nematodes, slugs, snails, bacteria, fungi, proto-zoa, other parsitic plants or reproductive parts thereof: vi-ruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants are considered plant pests.

Organisms belonging to all lower Taxa contained within the group listed are also included.

1. Viruses

All viroids

All bacterial, fungal, algal, plant, insect and nematode viruses; special care should be take for:

(i) Geminiviruses,
(ii) Caulimoviruses,
(iii) Nuclear Polyhedrosis viruses,
(iv) Granulosis viruses, and
(v) Cytoplasmic polyhedrosis viruses.

2. Bacteria

Family Pseudomonadaceae

Genus Pseudomonas
Genus Xanthomonas
Genus Azotobacter

Family Rhizobiaceae

Genus Rhizobium/Azorhizobium
Genus Bradyrhizobium
Genus Agrobacterium
Genus Phyllobacterium
Genus Erwinia
Genus Enterobacter
Genus Klebzieller

Family Spirollacea

Genus Azospirillum

- Genus Acquspirillum
- Genus Oceonospirillum

Family Streptomycetaceae
- Genue Streptomyces
- Genue Nocardia

Family Actinomycetaceae
- Genue Actinomyces

Coryneform Group
- Genus Clavibacter
- Genus Arthrobacter
- Genus Curtobacterium
- Genus Bdellovibro

Family Rickettsiaceae
- Rickettsial-like organisms associated with insect diseases
- Gram-negative phloem-limited bacteria associated with plant diseases
- Gram-negative xylem-limited bacteria associated with plant diseases
- Cyanobacteria - All members of blue-green algae
- Mollicutes

Family Spiroplasmataceae
- Mycoplama-like organisma associated with plant diseases
- Mycoplasma-like organisms associated with insect diseases

Algae
- Family Chlorophyceae
- Family Euglenophyceae
- Family Pyrophyceae
- Family Chrysophyceae
- Family Phaephyceae
- Family Rhodophyceae

Fungi
- Family Plasmodiophoraceae
- Family Chytridiaceae
- Family Olpidiopsidaceae
- Family Synchytriaceae
- Family Catenariaceae
- Family Coelomomycetaceae
- Family Saprolegniaceae
- Family Zoopagaceae
- Family Albuginaceae

Family Peronosporaceae
Family Pythiaceae
Family Mucoraceae
Family Choanephoraceae
Family Mortiercllaceae
Family Endogonaceae
Family Syncephalastraceae
Family Dimargaritaceae
Family Kickxellaceae
Family Saksenaeaceae
Family Entomophthoraceae
Family Ecerinaceae
Family Taphrinaceae
Family Endomycetaceae
Family Saceharomycetaceae
Family Eurotiaceae
Family Gymnoascaceae
Family Aseophaeriaceae
Family Onygenaceae
Family Microascaceae
Family Protomycetaceae
Family Elsinoeaceae
Family Myriangiaceae
Family Dothidiaceae
Family Chaetothyriaceae
Family Parmulariaceae
Family Phillipsiellaceae
Family Hysteriaceae
Family Pleosporaceae
Family Melamomataceae
Family Ophiostomataceae
Family Aseosphaeriaceae
Family Erysiphaceae
Family Meliolaceae
Family Xylariaceae
Family Diaporthaceae
Family Hypoereaceae
Family Clavicipataceae
Family Phacidiaceae
Family Ascocorticiaceae
Family Hemiphacidiaceae

Family Dermataceae
Family Sclerotiniaceae
Family Cyttariaceae
Family Helosiaceae
Family Sarcostomataceae
Family Sarcoscyphaceae
Family Auricolariaceae
Family Ceratobasidiaceae
Family Corticiaceae
Family Hymenochaetaceae
Family Echinodintiaceae
Family Eistuliniaceae
Family Clavariaceae
Family Polyporaceae
Family Tricholomattaceae
Family Ustilaginaceae
Family Sporobolomycetaceae
Family Uredinaceae
Family Agaricaceae
Family Graphiolaceae
Family Pucciniaceae
Family Melampsoraceae
Family Gandodermataceae
Family Labonlbeniaceae
Family Sphaeropsidaceae
Family Melabconiaceae
Family Tubercularíaceae
Family Dematiaceae
Family Moniliaceae
Family Aganomucetaceae

Parasitic Weeds
Family Balanophoraceae-parasitic species
Family Cuscutaceae-parasitic species
Family Ttydonoraceae-parasitic species
Family Lauraceae-parasitic species Genus Cassytha
Family Lennoaceae-parasitic species
Family Loranthaceae-parasitic species
Family Myzodendraceae-parasitic species
Family Olacaceae-parasitic species
Family Orobanchaceae-parasitic species

Family Rafflesiaceae-parasitic species
Family Santalaceae-parasitic species
Family Scrophulariaceae-parasitic species

Protozoa
Genus Phytomonas
And all protozoa associated with insect diseases.

Nematodes
Family Anguinidae
Family Belonolaimidae
Fmaily Caloosiidae
Family Criconematidae
Family Dolichodoridae
Family Fergusobiidae
Family Hemicycliophoridae
Family Heteroderidae
Family Hoplolaimidae
Family Meloidogynidae
Family Neotylenchidac
Family Nothotylenchidae
Family Paratylenchidae
Family Pratylenchidae
Family Tylenchidae
Family Tylenchulidae
Family Aphelenchoidiae
Family Longidoridae
Family Trichodoridae

Mollusca
Superfamily Planorbacea
Superfamily Achatinacea
Superfamily Arionacea
Superfamily Limacacea
Superfamily Helicacea
Superfamily Veronicellacea

Arthropoda
Superfamily Ascoidea
Superfamily Dermanyssoidea
Superfamily Erjophyoidea
Superfamily Tetranychoidea
Superfamily Eupodoidea

Superfamily Tydeoidea
Superfamily Erythraenoidea
Superfamily Trombidioidea
Superfamily Hydryphantoidea
Superfamily Tarasonemoidea
Superfamily Pyemotoidea
Superfamily Hemisarcoptoidea
Superfamily Acaroidea
Order Polydesmida
Family Sminthoridae
Family Forfieulidae
Order Isoptera
Order Thysanoptera
Family Acrididea
Family Gryllidae
Family Gryllacrididae
Faily Gryllotalpidae
Family Phasmatidae
Family Ronaleidae
Family Tettigoniidae
Family Tetragidae
Family Thaumastocoridae
Superfamily Piesmatoidea
Superfamily Lygacoidea
Superfamily Idiostoloidea
Superfamily Careoidea
Superfamily Pentatomoidea
Superfamily Pyrrhocoroidea
Superfamily Tingoidea
Superfamily Miroidea
Order Homoptera
Family Anobiidae
Family Apionidae
Family Anthribidae
Family Bostrichidae
Family Brentidae
Family Bruchidae
Family Buprestodae
Family Byturidae
Family Cantharidae
Family Carabidae

Family Ceambycidae
Family Chrysomelidae
Family Coecinellidae
Family Curculionidae
Family Dermestidae
Family Elalteridae
Family Hydrophilidae
Family Lyctidae
Family Meloidae
Family Mordellidae
Family Platypodidae
Family Scarabaeldae
Family Scolytidae
Family Selbytidae
Order Le pidoptera
Family Agromyzidae
Family Anthomiidae
Family Cecidomiidae
Family Chioropidae
Family Ephydridae
Family Lonchaeidae
Family Muscidae
Family Otitidae
Family Syrphidae
Family Tephritidae
Family Tipulidae
Family Apidae
Family Caphidae
Family Chalcidae
Family Cynipidae
Family Eurytomidae
Family Formicidae
Family Psilidae
Family Sircidae
Family Tenthredinidae
Family Torymidae
Family Xyloiopidae and

Also unclassified organisms and/or organisms whose classification is unknown and all other organisms associated with plant and insect diseases.

National Seeds Policy, 2002

INTRODUCTION

Indian Agriculture has made enormous strides in the past 50 years, raising food grains production from 50 million tonnes to over 200 million tonnes. In the process, the country has progressed from a situation of food shortages and imports to one of surpluses and exports. Having achieved food sufficiency, the aim now is to achieve food and nutritional security at the household level.

The increase in agricultural production, however, has brought in its wake, uneven development, across regions, crops, and also across different sections of farming community. In the decade of the 'nineties', a marked slackening in the pace of growth has occurred, pointing to the need for infusing a new vitality in the agricultural sector.

Seed is the most important determinant of agricultural production potential, on which the efficacy of other agriculture inputs is dependent. Seeds of appropriate characteristics are required to meet the demand of diverse agro-climatic conditions and intensive cropping systems. Sustained increase in agriculture production and productivity is dependent, to a large extent, on development of new and improved varieties of crops and an efficient system for timely supply of quality seeds to farmers.

The seed sector has made impressive progress over the last three decades. The area under certified seeds has increased from less than 500 hectares in 1962-63 to over 5 lakh hectares in 1999-2000. The quantum of quality seeds has crossed 100 lakh quintals.

The Seeds Act, 1966 and Seeds Control Order promulgated thereunder, and the New Policy on Seeds Development, 1988, form the basis of promotion and regulation of the Seed Industry. Far-reaching changes, however, have taken place in the national economic and agricultural scenario and in the international environment since the enactment of the existing seed legislation and the announcement of the 1988 Policy.

AIMS AND OBJECTIVES

It has become evident that in order to achieve the food production targets of the future, a major effort will be required to enhance the seed replacement rates of various crops. This would require a major increase in the production of quality seeds, in which the private sector is expected to play a major role. At the same time, private and Public Sector Seed Organisations at both Central and State levels, will be expected to adopt economic pricing policies which would seek to realise the true cost of production. The creation of a facilitative climate for growth of a competitive and localised seed industry, encouragement of import of useful germplasm, and boosting of exports are core elements of the agricultural strategy of the new millennium.

Biotechnology will be a key factor in agricultural development in the coming decades. Genetic engineering/ modification techniques hold enormous promise in developing crop varieties with a higher level of tolerance to biotic and abiotic stresses. A conducive atmosphere for application of frontier sciences in varietal development and for enhanced investments in research and development is a pressing requirement. At the same time, concerns relating to

possible harm to human and animal health and bio-safety, as well as interests of farmers, must be addressed.

Globalization and economic liberalization have opened up new opportunities as well as challenges. The main objectives of the National Seeds Policy, therefore, are the provision of an appropriate climate for the seed industry to utilize available and prospective opportunities, safeguarding of the interests of Indian farmers and the conservation of agro-biodiversity. While unnecessary regulation needs to be dismantled, it must be ensured that gullible farmers are not exploited by unscrupulous elements. A regulatory system of a new genre is, therefore, needed, which will encompass quality assurance mechanisms coupled with facilitation of a vibrant and responsible seed industry.

THRUST AREAS

1. VARIETAL DEVELOPMENT AND PLANT VARIETY PROTECTION

1.1 The development of new and improved varieties of plants and availability of such varieties to Indian farmers is of crucial importance for a sustained increase in agricultural productivity.

1.1.1 Appropriate policy framework and programmatic interventions will be adopted to stimulate varietal development in tune with market trends, scientific-technological advances, suitability for biotic and abiotic stresses, locational adaptability and farmers' needs.

1.2 An effective *sui generis* system for intellectual property protection will be implemented to stimulate investment in research and development of new plant varieties and to facilitate the growth of the Seed Industry in the country.

1.2.1 A Plant Varieties & Farmers' Rights Protection (PVP) Authority will be established which will undertake registration of extant and new plant varieties through the Plant Varieties Registry on the basis of varietal characteristics.

1.2.2 The registration of new plant varieties by the PVP Authority will be based on the criteria of novelty, distinctiveness, uniformity and stability.

1.2.3 The criteria of distinctiveness, uniformity and stability could be relaxed for registration of extant varieties, which will be done within a specified period to be decided by the PVP Authority.

1.2.4 Registration of all plant genera or species as notified by the Authority will be done in a phased manner.

1.2.5 The PVP Authority will develop characterisation and documentation of plant varieties registered under the PVP Act and cataloguing facilities for all varieties of plants.

1.3 The rights of farmers to save, use, exchange, share or sell farm produce of all varieties will be protected, with the proviso that farmers shall not be entitled to sell branded seed of a protected variety under the brand name.

1.4 The rights of researchers to use the seed/planting material of protected varieties for bonafide research and breeding of new plant varieties will be ensured.

1.5 Equitable sharing of benefit arising out of the use of plant genetic resources that may accrue to a breeder from commercialisation of seeds/planting materials of a new variety, will be provided.

1.6 Farmers/groups of farmers/village communities will be rewarded suitably for their significant contribution in evolution of a plant variety subject to registration. The contribution of traditional knowledge in agriculture needs to be highlighted through suitable mechanisms and incentives.

1.7 A National Gene Fund will be established for implementation of the benefit sharing arrangement, and payment of compensation to village communities for their contribution to the development and conservation of plant genetic resources and also to promote conservation and sustainable use of genetic resources. Suitable systems will be worked out to identify the contributions from traditional knowledge and heritage.

1.8 Plant Genetic Resources for Food and Agriculture Crops will be permitted to be accessed by Research Organisations and Seed Companies from public collections as per the provisions of the 'Material Transfer Agreement' of the International Treaty on Plant Genetic Resources and the Biological Diversity Bill.

1.9 Regular interaction amongst the Private and Public Researchers, Seed Companies/Organisations and Development Agencies will be fostered to develop and promote growth of a healthy seed industry in the country.

1.10 To keep abreast of global developments in the field of Plant Variety Protection and for technical collaboration, India may consider joining Regional and International Organisations.

1.11 The PVP Authority may, if required, resort to compulsory licensing of a protected variety in public interest on the ground that requirements of the farming community for seeds and propagating material of a variety are not being met or that the production of the seeds or planting material of the protected variety is not being facilitated to the fullest possible extent.

2. SEED PRODUCTION

2.1 To meet the Nation's food security needs, it is important to make available to Indian farmers a wide range of seeds of superior quality, in adequate quantity on a timely basis. Public Sector Seed Institutions will be encouraged to enhance production of seed towards meeting the objective of food and nutritional security.

2.2 The Indian seed programme adheres to the limited three generation system of seed multiplication, namely, breeder, foundation and certified seed. Breeder seed is the progeny of nucleus seed.

2.2.1 Nucleus seed is the seed produced by the breeder to develop the particular variety and is directly used for multiplication as breeder seed.

2.2.2 Breeder seed is the seed material directly controlled by the originating or the sponsoring breeder or Institution for the initial and recurring production of foundation seed.

2.2.3 Foundation seed is the progeny of breeder seed. Foundation seed may also be produced from foundation seed. Production of foundation seed stage-I and stage-II may thus be permitted, if supervised and approved by the Certification Agency and if the production process is so handled as to maintain specific genetic purity and identity.

2.2.4 Certified seed is the progeny of foundation seed or the progeny of certified seed. If the certified seed is the progeny of certified seed, then this reproduction will not exceed three generations beyond foundation stage-I and it will be ascertained by the Certification Agency that genetic identity and genetic purity has not been significantly altered.

2.3 Public Sector Seed Production Agencies will continue to have free access to breeder seed under the National Agriculture Research System. The State Farms Corporation of India and National Seeds Corporation will be restructured to make productive use of these organisations in the planned growth of the Seed Sector.

2.4 Private Seed Production Agencies will also have access to breeder seed subject to terms and conditions to be decided by Government of India.

2.5 State Agriculture Universities/ICAR Institutes will have the primary responsibility for production of breeder seed as per the requirements of the respective States.

2.6 Special attention will be given to the need to upgrade the quality of farmers' saved seeds through interventions such as the Seed Village Scheme.

2.7 Seed replacement rates will be raised progressively with the objective of expanding the use of quality seeds.

2.8 DAC, in consultation with ICAR and States, will prepare a National Seed Map to identify potential, alternative and non-traditional areas for seed production of specific crops.

2.9 To put in place an effective seed production programme, each State will undertake advance planning and prepare a perspective plan for seed production and distribution over a rolling (five to six year) period. Seed Banks will be set up in non-traditional areas to meet demands for seeds during natural calamities.

2.10 The 'Seed Village Scheme' will be promoted to facilitate production and timely availability of seed of desired crops/varieties at the local level. Special emphasis will be given to seed multiplication for building adequate stocks of certified/quality seeds by providing foundation seed to farmers.

2.11 For popularising newly developed varieties and promoting seed production of these varieties, seed minikits of pioneering seed varieties will be supplied to farmers. Seed exchange among farmers and seed producers will be encouraged to popularise new/non-traditional varieties.

2.12 Seeds of newly developed varieties must be made available to farmers with minimum time gap. Seed producing agencies will be encouraged to tie up with Research Institutions for popularization and commercialization of these varieties.

2.13 As hybrids have the potential to improve plant vigour and increase yield, support for production of hybrid seed will be provided.

2.14 Seed production will be extended to agro-climatic zones which are outside the traditional seed growing areas, in order to avoid unremunerative seed farming in unsuitable areas.

2.15 Seed Banks will be established for stocking specified quantities of seed of required crops/varieties for ensuring timely and adequate supply of seeds to farmers during adverse situations such as natural calamities, shortfalls in production, etc. Seed Banks will be suitably strengthened with cold storage and pest control facilities.

2.15.1 The storage of seed at the village level will be encouraged to facilitate immediate availability of seeds in the event of natural calamities and unforeseen situations. For the storage of seeds at farm level, scientific storage structures will be popularised and techniques of scientific storage of seeds will be promoted among farmers as an extension practice.

2.16 Seed growers will be encouraged to avail of Seed Crop Insurance to cover risk factors involved in production of seeds. The Seed Crop Insurance Scheme will be reviewed so as to provide effective risk cover to seed producers and will be extended to all traditional and non-traditional areas covered under the seed production programme.

3. QUALITY ASSURANCE

3.1 The Seeds Act will be revised to regulate the sale, import and export of seeds and planting materials of agriculture crops including fodder, green manure and horticulture and supply of quality seeds and planting materials to farmers throughout the country.

3.2 The National Seeds Board (NSB) will be established in place of existing Central Seed Committee and Central Seed Certification Board. The NSB will have permanent existence with the responsibility of executing and implementing the provisions of the Seeds Act and advising the Government on all matters relating to seed planning and development. The NSB will function as the apex body in the seed sector.

3.2.1 All varieties, both domestic and imported varieties, that are placed on the market for sale and distribution of seeds and planting materials will be registered under the Seeds Act. However, for vegetable and ornamental crops a simple system of varietal registration based on "breeders declaration" will be adopted.

3.2.2 The Board will undertake registration of kinds/varieties of seeds that are to be offered for sale in the market, on the basis of identified parameters for establishing value for cultivation and usage (VCU) through testing/trialling.

3.2.3 Registration of varieties will be granted for a fixed period on the basis of multilocational trials to determine VCU over a minimum period of three seasons, or as otherwise prescribed as in the case of long duration crops and horticultural crops. Samples of the material for registration will be sent to the NBPGR for retention in the National Gene Bank.

3.2.4 Varieties that are in the market at the time of coming into force of the revised Seeds Act, will have to be registered within a fixed time period, and subjected to such testing as will be notified.

3.2.5 The NSB will accredit ICAR, SAUs, public/private organisations to conduct VCU trials of all varieties for the purpose of registration as per prescribed standards.

3.2.6 The NSB will maintain the National Seeds Register containing details of varieties that are registered. This will help the Board to coordinate and assist activities of the States in their efforts to provide quality seeds to farmers.

3.2.7 The NSB will prescribe minimum standards (of germination, genetic characteristics, physical purity, seed health, etc.) as well as suitable guidelines for registration of seed and planting materials.

3.2.8 Provisional registration would be granted on the basis of information filed by the applicant relating to trials over one season to tide over the stipulation of testing over three seasons before the grant of registration.

3.3 Government will have the right to exclude certain kinds or varieties from registration to protect public order or human, animal and plant life and health, or to avoid serious prejudice to the environment.

3.4 The NSB will have the power to cancel the registration granted to a variety if the registration has been obtained by misrepresentation or concealment of essential data, the variety is obsolete and has outlived its utility and if the prevention of commercial exploitation of such variety is necessary in the public interest.

3.5 Registration of Seed Processing Units will be required if such Units meet the prescribed minimum standards for processing the seed.

3.6 Seed Certification will continue to be voluntary. The Certification tag/label will provide an assurance of quality to the farmer.

3.6.1 The Board will accredit individuals or organisations to carry out seed certification including self-certification on fulfillment of criteria as prescribed.

3.7 To meet quality assurance requirements for export of seeds, Seed Testing facilities will be established in conformity with ISTA and OECD seed certification programmes.

3.8 The State Government, in conformity with guidelines and standards specified by the Board, will establish one or more State Seed Testing Laboratories or declare any Seed Testing Laboratory in the Government or non-Government Sector as a State Seed Testing Laboratory where analysis of seeds will be carried out in the prescribed manner.

3.9 Farmers will be encouraged to use certified seeds to ensure improved performance and output.

3.10 Farmers will retain their right to save, use, exchange, share or sell their farm seeds and planting materials without any restriction. They will be free to sell their seed on their own premises or in the local market without any hindrance provided that the seed is not branded. Farmers' right to continue using the varieties of their choice will not be infringed by the system of compulsory registration.

3.11 Stringent measures would be taken to ensure the availability of high quality of seeds and check the sale of spurious or misbranded seeds.

4. SEED DISTRIBUTION AND MARKETING

4.1 The availability of high quality seeds to farmers through an improved distribution system and efficient marketing set-up will be ensured to facilitate greater security of seed supply.

4.2 For promoting efficient and timely distribution and marketing of seed throughout the country, a supportive environment will be provided to encourage expansion of the role of the private seed sector. Efforts will be made to achieve better coordination between State Governments to facilitate free Inter-State movement of seed and planting material through exemption of duties and taxes.

4.3 Private Seed Sector will be encouraged and motivated to restructure and reorient their activities to cater to non-traditional areas.

4.4 A mechanism will be established for collection and dissemination of market intelligence regarding preference of consumers and farmers.

4.5 A National Seed Grid will be established as a data-base for monitoring of information on requirement of seed, its production, distribution and preference of farmers on a district-wise basis.

4.6 Access to term finance from Commercial Banks will be facilitated for developing efficient seed distribution and marketing facilities for growth of the seed sector.

4.7 Distribution and marketing of seed of any variety, for the purpose of sowing and planting will be allowed only if the said variety has been registered by the National Seeds Board.

4.8 National Seeds Board can direct a dealer to sell or distribute seeds in a specified manner in a specified area if it is considered necessary to the public interest.

5. INFRASTRUCTURE FACILITIES

5.1 To meet the enhanced requirement of quality/certified seeds, creation of new infrastructure facilities along with strengthening of existing facilities, will be promoted.

5.2 National Seed Research and Training Center will be set up to impart training and build a knowledge base in various disciplines of the seed sector.

5.3 The Central Seed Testing Laboratory will be established at the National Seed Research and Training Center to perform referral and other functions as required under the Seeds Act.

5.4 Seed processing capacity will be augmented to meet the enhanced requirement of quality seed.

5.5 Modernisation of seed processing facilities will be encouraged in terms of modern equipment and latest techniques, such as seed treatment for enhancement of performance of seed, etc.

5.6 Conditioned storage for breeder and foundation seed and aerated storage for certified seed would be created in different regions.

5.7 A computerized National Seeds Grid will be established to provide information on availability of different varieties of seeds with production agencies, their location, quality etc. This network will facilitate optimum utilisation of available seeds in every region.

5.7.1 Initially, seed production agencies in the public sector would be connected with the National Seed Grid, but progressively the private sector will be encouraged to join the Grid for providing a clear assessment of demand and supply of seeds.

5.8 State Governments, or the National Seeds Board in consultation with the concerned State Government, may establish Seed Certification Agencies.

5.9 State Governments will establish appropriate systems for effective execution and implementation of the objectives and provisions of the Seeds Act.

6. TRANSGENIC PLANT VARIETIES

6.1 Biotechnology will play a vital role in the development of the agriculture sector. This technology can be used not only to develop new crops/varieties, which are tolerant to disease, pests and abiotic stresses, but also to improve productivity and nutritional quality of food.

6.2 All genetically engineered crops/varieties will be tested for environment and bio-safety before their commercial release, as per the regulations and guidelines of the Environment Protection Act (EPA), 1986.

6.3 The EPA, 1986, read with the Rules, 1989 would adequately address the safety aspects of transgenic seeds/planting materials. A list will be generated from Indian experience of transgenic cultivars that could be rated as environmentally safe.

6.4 Seeds of transgenic plant varieties for research purposes will be imported only through the National Bureau of Plant Genetic Resources (NBPGR) as per the EPA, 1986.

6.5 Transgenic crops/varieties will be tested to determine their agronomic value for at least two seasons under the All India Coordinated Project Trials of ICAR, in coordination with the tests for environment and bio-safety clearance as per the EPA before any variety is commercially released in the market.

6.6 After the transgenic plant variety is commercially released, its seed will be registered and marketed in the country as per the provisions of the Seeds Act.

6.7 After commercial release of a transgenic plant variety, its performance in the field, will be monitored for at least 3 to 5 years by the Ministry of Agriculture and State Departments of Agriculture.

6.8 Transgenic varieties can be protected under the PVP legislation in the same manner as non-transgenic varieties after their release for commercial cultivation.

6.9 All seeds imported into the country will be required to be accompanied by a certificate from the Competent Authority of the exporting country regarding their transgenic character or otherwise.

6.9.1 If the seed or planting material is a product of transgenic manipulation, it will be allowed to be imported only with the approval of the Genetic Engineering Approval Committee (GEAC), set up under the EPA, 1986.

6.10 Packages containing transgenic seeds/planting materials, if and when placed on sale, will carry a label indicating their transgenic nature. The specific characteristics including the agronomic/yield benefits, names of the transgenes and any relevant information shall also be indicated on the label.

6.11 Emphasis will be placed on the development of infrastructure for the testing, identification and evaluation of transgenic planting materials in the country.

7. IMPORT OF SEEDS AND PLANTING MATERIAL

7.1 The objective of the import policy is to provide the best planting material available anywhere in the world to Indian farmers, to increase productivity, farm income and export earnings, while ensuring that there is no deleterious effect on environment, health and bio-safety.

7.1.1 While importing seeds and planting material, care will be taken to ensure that there is absolutely no compromise on the requirements under prevailing plant quarantine procedures, so as to prevent entry into the country of exotic pests, diseases and weeds detrimental to Indian agriculture.

7.1.2 All imports of seeds will require a permit granted by the Plant Protection Advisor to the Government of India, which will be issued within the minimum possible time frame.

7.2 All import of seeds and planting materials, etc. will be allowed freely subject to EXIM Policy guidelines and the requirements of the Plants, Fruits and Seeds (Regulation of import into India) Order, 1989 as amended from time to time. Import of parental lines of newly developed varieties will also be encouraged.

7.3 Seeds and planting materials imported for sale into the country will have to meet minimum seed standards of seed health, germination, genetic and physical purity as prescribed.

7.4 All importers will make available a small sample of the imported seed to the Gene Bank maintained by NBPGR.

7.5 The existing policy, which permits free import of seeds of vegetables, flowers and ornamental plants, cuttings, saplings of flowers, tubers and bulbs of flowers by certain specified categories of importers will continue. Tubers and bulbs of flowers will be subjected to post-entry quarantine.

7.5.1 After the arrival of consignments at the port of entry, quarantine checks would be undertaken; which may include visual inspection, laboratory inspection, fumigation and grow-out tests. For the purpose of these checks, samples will be drawn and the tests will be conducted concurrently.

8. EXPORT OF SEEDS

8.1 Given the diversity of agro-climatic conditions, strong seed production infrastructure and market opportunities, India holds significant promise for export of seeds.

8.2 Government will evolve a long term policy for export of seeds with a view to raise India's share of global seed export from the present level of less than 1% to 10% by the year 2020.

8.2.1 The export policy will specifically encourage custom production of seeds for export and will be based on long term perspective, dispensing with case to case consideration of proposals.

8.3 Establishment and strengthening of Seeds Export Promotion Zones with special incentives from the Government will be facilitated.

8.4 A data bank will be created to provide information on the International Market and on export potential of Indian varieties in different parts of the world.

8.5 A data base on availability of seeds of different crops to assess impact of exports on domestic availability of seeds will be created.

8.6 Promotional programmes to improve the quality of Indian seeds to enhance its acceptability in the International Market will be taken up.

8.6.1. Testing and certification facilities will be established in conformity with international requirements.

9. PROMOTION OF DOMESTIC SEED INDUSTRY

9.1 Incentives will be provided to the domestic seed industry to enable it to produce seeds of high yielding varieties and hybrid seeds at a faster pace to meet the challenges of domestic requirements.

9.2 Seed Industry will be provided with a congenial and liberalized climate for increasing seed production and marketing, both domestic and international.

9.3 Membership to International Organisations and Seed Associations like ISTA, OECD, UPOV, ASSINSEL, WIPO, at the National level or at the level of individual seed producing agencies, will be encouraged.

9.4 Emphasis will be given to improving the quality of seed produced and special efforts will be directed towards improving the quality of farmers' saved seeds.

9.5 Financial support for capital investment, working capital and infrastructure strengthening will be facilitated through NABARD/ Commercial Banks/Cooperative Banks.

9.6 Tax rebate/concessions will be considered on the expenditure incurred on in-house research and development of new varieties and other seed related research aspects. In order to develop a competitive seed market, the States will be encouraged to remove unnecessary local taxation on sales of seeds.

9.7 To encourage seed production in non-traditional areas including backward areas, special incentives such as transport subsidy will be provided to seed producing agencies operating in these marginalised areas.

9.8 Reduction of import duty will be considered on machines and equipment used for seed production and processing which are otherwise not manufactured in the country.

10. STRENGTHENING OF MONITORING SYSTEM

10.1 The Department of Agriculture & Cooperation (DAC) will supervise the overall implementation and monitoring of the National Seeds Policy.

10.2 The physical infrastructure in terms of office automation, communication facilities, etc., in DAC will be augmented in a time bound manner.

10.3 The technical capacity of DAC need to be augmented and strengthened to undertake the additional work relating to implementation of National Seeds Policy, implementation of PVP&FR Bill, Seeds Act, Import and Export of Seeds, etc.

10.4 Capacity building, including National and International training and participation in Seminars/ Workshops will be organized for concerned officials.

11. CONCLUSION

The Government of India trusts that the National Seeds Policy will receive the fullest support of State Governments/Union Territory Administrations, State Agricultural Universities, plant breeders, seed producers, the seed industry and all other stakeholders, so that it may serve as a catalyst to meet the objectives of sustainable development of agriculture, food and nutritional security for the population, and improved standards of living for farming communities.

The National Seeds Policy will be a vital instrument in attaining the objectives of doubling food production and making India hunger free. It is expected to provide the impetus for a new revolution in Indian agriculture, based on an efficient system for supply of seeds of the best quality to the cultivator.

The National Seeds Policy will lay the foundation for comprehensive reforms in the seed sector. Significant changes in the existing legislative framework will be effected accompanied by programmatic interventions. The Policy will also provide the parameters for the development of the seed sector in the Tenth and subsequent Plans. The progress of implementation of the Policy will be monitored by a High Level Review Committee.

Ministry of Agriculture

(Department of Agriculture and Co-operation)

NOTIFICATION

New Delhi, the 12th November, 2003

S.O. 1300(E). – In exercise of the powers conferred by Sub-section (1) of Section 4 of the Seeds Act, 1966 (54 of 1966), the Central Government hereby declares the laboratory of Central Institute of Cotton Research (CICR), Indian Council of Agricultural Research (ICAR), Nagpur as the Central Seed Laboratory to carry out the functions of ascertaining the presence or absence of Cry1AC gene in Cotton seeds under the said Act with effect from the date of publication for the whole of India.

2. In pursuance of clause (c) of rule 5 of the Seeds Rules, 1968, the Central Government also entrusts the Central Institute of Cotton Research, Indian Council of Agricultural Research, Nagpur to act as a referral laboratory for *Bacillus thuringiensis* Cotton seeds (Bt. Cotton seeds).

[F.No. 2-7/2003-SD.IV]

ASHISH BAHUGUNA, Jt. Secy. (Seeds)

Published in the Gazette of India, Part II, Section 3 sub-section (ii) Extra ordinary dated 21st September, 2006

Government of India
Ministry of Environment and Forests
NOTIFICATION

New Delhi, 1st September, 2006

G.S.R. 584(E)— In exercise of the powers conferred by Sub-section (1) of section 10 of the Environment (Protection) Act, 1986 (29 of 1986), the Central Government hereby makes the following amendments in the notification of Government of India in the Ministry of Environment and Forests number S.O. 83 (E), dated the 16th February, 1987, published in the Gazette of India (Extraordinary) Part II, Section 3, Sub – section (ii) dated 16th February, 1987 namely:-

In the said notification, in the Table, after serial number 63 and entries relating thereto, the following serial number and entries shall be *inserted*, namely:-

Serial No.	Officer/ Agency	Appointed under
1	2	3
"64	Seed Inspector (s)	Section 13 of the Seeds Act, 1966 and Section 12 of the Seeds (Control) Order, 1983"

[F.NO 10/40/2003-CS]

DESH DEEPAK VERMA
JOINT SECRETAY

Foot note: The principal rules published in the Gazette of India *vide* S.O.84(E), dated 16-2-1987 and subsequently amended vide S.O.62(E) dated 18-01-1988, S.O.623 (E) dated 8-9-1996, S.O.728 (E) dated 10-7-2002

Published in the Gazette of India, Part II, Section 3 sub-section (ii) Extra ordinary dated 21st September, 2006

Government of India
Ministry of Environment and Forests
NOTIFICATION

New Delhi, 1st September, 2006

G.S.R. 585(E)— In exercise of the powers conferred by sub section (1) of section 10 of the Environment (Protection) Act, 1986 (29 of 1986), the Central Government hereby makes the following amendments in the notification of Government of India in the Ministry of Environment and Forests No. S.O. 83 (E), dated 16th February, 1987, published in the Gazette of India (Extraordinary) Part II, Section 3, sub – section (ii) dated 16th February, 1987 namely:-

In the said notification, in the Table, after serial number 63 and entries relating thereto, the following serial number and entries shall be *inserted*, namely:-

Serial No.	Officer/ Agency	Appointed under
1	2	3
"64	Seed Inspector (s)	Section 13 of the Seeds Act, 1966 and Section 12 of the Seeds (Control) Order, 1983".

F.NO 10/40/2003-CS

DESH DEEPAK VERMA

JOINT SECRETAY

Footnote : — The principal rules were published in the gazette of India *vide* S.O.84(E), dated 16-2-1987 and subsequently amended *vide* S.O.62(E) dated 18-01-1988, S.O.623 (E) dated 8.9.1996, S.O.728 (E) dated 10.7.2002

Published in the Gazette of India, Part II, Section 3 sub-section (ii) Extra ordinary dated 21st September, 2006

Government of India
Ministry of Environment and Forests
NOTIFICATION

New Delhi, 1st September, 2006

G.S.R. 586(E) — In exercise of the powers conferred by clause (b) of Sub-section (1) of Section 12 and Section 13 of the Environment (Protection) Act, 1986 (29 of 1986), the Central Government hereby recognizes, the laboratories specified in column (2) of the Table below as environmental laboratories under the said Act and the rules made thereunder, and the persons specified in column (3) of the said Table to be the Government Analysts for the purposes of analysis of the seed samples of genetically modified crop varieties sent for analysis by the Central Government or the officer empowered under section 11 of the said Act, and for that purpose makes the following amendments in the notification of the Government of India in the Ministry of Environment and Forests number S. O. 728(E) dated the 21st July, 1987, namely:-

In the Table appended to the said notification, after serial number 137 and the entries relating thereto, the following serial number 138 and entries shall be inserted namely:–

(1)	(2)	(3)
133	Laboratories notified under Section 4 of the Seeds Act, 1966.	Persons notified under Section 12 of the Seeds Act, 1966.

[F.NO 10/40/2003-CS]

DESH DEEPAK VERMA
JOINT SECRETAY

Note: The principal notification was published in the Gazette of India *vide* number S.O. 728 (E) dated 21st July, 1987 and subsequently amended vide:-

S.O 838(E) dated 23rd September, 1987, S.O. 989(E) dated 17th November, 1987, SO 156(E) dated 24th February, 1989, SO 489(E) dated 17th May, 1989, SO 846(E) dated 24th October, 1989, SO 375(E) dated 26th April, 1990, SO 633(E) dated 31st August, 1994, SO 54 (E) dated 15th January, 1997, SO 305(E) dated 7th April, 1997, SO 173 (E) dated 9th March, 1998, SO 1508 dated 27th July, 1998, SO 454 dated 11th February, 2000, SO 683, dated 23rd March, 2001 & SO 820 (E) dated 2nd August, 2002, SO 1257(E) dated the 2nd December, 2002, SO 462 (E) dated the 23rd April, 2003, SO 598 (E) dated the 26th April, 2004, SO 1139(E) dated the 15th October, 2004 and SO 774(E) dated 7th June, 2005, SO 834 (E) dated 31.05.2006

Published in the Gazette of India, Part II, Section 3 sub-section (ii) Extra ordinary dated 21st September, 2006

Government of India
Ministry of Environment and Forests
NOTIFICATION

New Delhi, 1st September, 2006

G.S.R. 587(E) — In exercise of the powers conferred by clause (a) of section 19 of the Environment (Protection) Act, 1986 (29 of 1986), the Central Government hereby amends the notification of the Government of India in the Ministry of Environment and Forests number S.O. 394 (E), dated the 16th April, 1987, published in the Gazette of India (Extraordinary) Part II, Section 3, sub – section (ii) dated 16th April, 1987 namely:-

In the said notification, in the Table, after serial number 12 and entries relating thereto, the following serial number and entry shall be *inserted*, namely:-

Serial No.	Officer	Jurisdiction
1	2	3
"13	Seed Inspector (s)	Area (s) as laid down by the Respective State Governments in the notification issued under clause 12 the Seeds Control Order, 1983".

[F.NO 10/40/2003-CS]

DESH DEEPAK VERMA
JOINT SECRETAY

Note: Principal Notification was published in the Gazette of India vide number S.O. 394 (E) dated 16-04-1987 and subsequently amended *vide* S.O.237(E) dated 29-03-1989 , S.O.656(E) dated 21-08-1989 and S.O. 624 (E) dated 3rd September, 1996).

Published in the Gazette of India, Part II, Section 3 sub-section (ii) Extra ordinary dated 21st September, 2006

Government of India
Ministry of Environment and Forests
NOTIFICATION

New Delhi, 1st September, 2006

G.S.R. 588(E)— In exercise of the powers conferred by Section 23 of the Environmental (Protection) Act, 1986 (29 of 1989), the Central Government hereby delegates the power vested in it under Section 14 of the said Act to the Seed Inspectors, notified under section 13 of the Seeds Act, 1966 (54 of 1966) and Section 12 of the Seeds (Control) Order 1983 to take samples of genetically modified crops for analysis and to regulate the quality thereon as conferred under sections 10 and 11 of the Environmental (Protection) Act, 1986 subject to the condition that the Central Government may revoke such delegation of powers if in the opinion of the Central Government such a course of action is necessary in public interest.

[F.NO 10/40/2003-CS]

DESH DEEPAK VERMA
JOINT SECRETAY

Note: Principal Notification published in the Gazette of India *vide* Notification No. GSR 1198 (E) dated 12-11-1986 and subsequently amended *vide* S.O. 152 (E) dated 10-2-1988, S.O. 289 (E) dated 14-4-1988, S.O. 488 (E) dated 17-5-1988, S.O. 881 (E) dated 22-9-1988, S.O. 408 (E) dated 6-6-1989, S.O. 479 (E) dated 25-7-1999, S.O. 157 (E) dated 27-2-1996, S.O. 730 (E) dated 10-7-2002

Published in the Gazette of India, Part II, Section 3 sub-section (ii) Extra ordinary dated 21st September, 2006

Government of India
Ministry of Environment and Forests
NOTIFICATION

New Delhi, 1st September, 2006

G.S.R. 589 (E)— In exercise of the powers conferred by Section 23 of the Environmental (Protection) Act, 1986 (29 of 1989), the Central Government hereby delegates the power vested in it under section 14 of the said Act to the Seed Analysts so notified under Section 12 of the Seeds Act, 1966 (54 of 1966) to use the signed document purporting to be reported of genetically modified crops as evidence of the facts stated therein in any proceedings conferred under the Environmental (Protection) Act, 1986 subject to the condition the Central Government may revoke such delegation of powers if in the opinion of the Central Government such a course of action is necessary in public interest.

[F.NO 10/40/2003-CS]

DESH DEEPAK VERMA

JOINT SECRETAY

Note: Principal Notification published in the Gazette of India *vide* Notification No. GSR 1198 (E) dated 12-11-1986 and subsequently amended vide S.O. 152 (E) dated 10-2-1988, S.O. 289 (E) dated 14-4-1988, S.O. 488 (E) dated 17-5-1988, S.O. 881 (E) dated 22-9-1988, S.O. 408 (E) dated 6-6-1989, S.O. 479 (E) dated 25-7-1999, S.O. 157 (E) dated 27-2-1996, S.O. 730 (E) dated 10-7-2002.

Ministry of Agriculture

(Department of Agriculture and Co-operation)

NOTIFICATION

New Delhi, the 5th November, 2005

S.O. 1567(E). – In exercise of the powers conferred by Section 6 of the Seeds Act, 1966 (Act 54 of 1966), the Central Government, after consultation with the Central Seed Committee hereby specifies the purity in terms of quantum of gene express of *Bacillus thuringiensis* (Bt) Protein (toxin) as 90 per cent in *Bacillus thuringiensis* cotton seed lot for labeling of *Bacillus thuringiensis* Cotton Seed.

2. This notification shall come into force on the date of its publication in the Official Gazette.

[F.No. 17-8/2005-SDIV]

S. L. BHAT, Jt. Secy.

Ministry of Agriculture

(Department of Agriculture and Co-operation)

ORDER

New Delhi, the 26th July, 2006

G.S.R. 444(E). – In exercise of the powers conferred by Section 3 of the Essential Commodities Act, 1955 (10 of 1955), the Central Government hereby makes the following Order to amend the Seeds (Control) Order, 1983, namely : –

1. (1) This Order may be called the Seeds (Control) Amendment Order, 2006.

   (2) It shall come into force on the date of its publication in the Official Gazette.

2. In the Seeds (Control) Order, 1983, after clause 8, the following clause shall be inserted, namely : –

"8A. Dealers to ensure certain standards in respect of seeds

Every dealer of seeds in notified kind or variety or other than notified kind or variety of seeds shall ensure that the standards of quality of seeds claimed by him shall conform to the standards prescribed for the notified kind or variety of seeds under Section 6 of the Seeds, Act, 1966 (54 of 1966) and any other additional standards relating to size, colour and content of the label as may be specified."

[F.No. 2-7/2003-SD.IV]
S.L. BHAT, Jt. Secy.

Note: The Seeds (Control) Order, 1983 was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) *vide* number G.S.R. 932(E), dated the 30th December, 1983.

Conditions for Approval of Bt Cotton by GEAC

1. COMMERCIAL RELEASE

The commercial release of Bt Cotton is subject to the following conditions:

- The period of validity of approval is for three years i.e. from April 2006 – March 2009.
- The applicant should look for the incidence of sucking pests on these hybrids and carry out artificial screening for CLCV resistance and submit its report to the GEAC (only for north zone).
- 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.
- 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.
- Each packet should be appropriately labeled indicating the contents and the description of the Bt hybrid including the name of the transgenes, the GEAC approval reference, physical and genetic purity of the seeds. The packet should also contain the package of agricultural practice with detailed directions for use including sowing pattern, pest management, suitability of the hybrids specifically for irrigated conditions etc., in vernacular language.
- The Applicant shall 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.
- The Applicant shall 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.
- The Applicant shall develop plans for Bt based 'Integrated Pest Management' and include this information in the seed packet.
- The Applicant shall 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 the GEAC.
- Monitoring of susceptibility of bollworms to the Bt gene shall also be undertaken by an agency identified by the Ministry of Environment and Forests at the applicant's cost.

- The Applicant shall undertake an awareness and education program, interalia through development and distribution of educational material on Bt cotton, for farmers, dealers and others.
- The Applicant shall also continue to undertake studies on possible impacts on non-target insects and crops, and report back to the GEAC annually.
- The label on each packet of seeds, and the instruction manual inside the packet should contain all relevant information.
- The Applicant shall deposit 100 g seed each of approved hybrids as well as their parental lines with the National Bureau of Plant Genetic Resources (NBPGR) and communicate the same to the Ministry of Environment & Forests within 30 days of issue of this clearance letter.
- The Applicant shall develop and deposit with the NBPGR, the DNA fingerprints of the approved varieties within 30 days of issue of this clearance letter.
- The Applicant shall also provide to the NBPGR, the testing procedures for identifying transgenic traits in the approved varieties by DNA and protein methods.
- The Ministry may stipulate additional conditions if so necessitated on the basis of feedback received from the Monitoring cum Evaluation Committee / State Department of Agriculture/ District Collector / other field functionaries under the Seed Act and other sources.

2. LARGE SCALE TRIALS

- The large scale trials (LST) in the North zone (Punjab Rajasthan and Haryana), Central (Maharashtra, Gujarat and Madhya Pradesh) and South (Andhra Pradesh, Karnataka and Tamil Nadu) during Kharif 2006 shall be subject to the following conditions:-
- All new hybrids shall undergo a minimum of 2 years of LST and 2 years of ICAR trials (Kharif 2006 and Kharif 2007) prior to its consideration for commercial release.
- The large-scale trials shall be carried out at 40 locations as per the standard Protocol.
- The Agricultural Universities would be involved in the monitoring of large-scale trials with specific reference to incidence of cotton leaf curl virus disease (CLCV).
- The applicant should look for the incidence of sucking pests on these hybrids during large-scale trials and also artificial screening for CLCV resistance.
- The firm shall provide to the GEAC/MEC/ State Department of Agriculture/ District Collector and other field functionaries under the Seed Act, the State/District wise details of locations (area, village, name of the farmer) where it intends to undertake large-scale field trials within 30 days of issue of this clearance letter. The location of large-scale trials should be carefully chosen so as to represent adequately the various agro-climatic zones and agricultural practices in the region. Detailed justification for selection of the LST locations shall also be furnished.

- The firm shall make available socio-economic data like cost of Bt cotton seed/projected demand of Bt cotton seeds/cost of Bt cotton production vs. non-Bt cotton production under various agro-climatic conditions and agricultural practices/cost benefit analysis etc.
- The Monitoring cum Evaluation Committee (MEC) set up by the RCGM would evaluate the performance of Bt cotton hybrid in the North Zone during the large-scale trials in Kharif 2006 and Kharif 2007 on a random and representative sampling basis. The MEC would submit its two year combined report on performance of the Bt cotton hybrid for consideration of the GEAC. The MEC may seek additional information / stipulate additional conditions if so necessitated based on the observations made during the monitoring of large-scale field trials.
- The firm shall be completely liable to pay compensation for damages to the environment caused by them while conducting the field trials.
- The permission letter for first year large-scale trials is valid only for the period Kharif 2006 and second year LST is valid only for the period Kharif 2007 from the date of issue and would lapse automatically after the season.

3. SEED PRODUCTION

- The Bt cotton hybrid selected for entry into LST and ICAR trials during Kharif 2006 may undertake seed production in an area of 10 ha during first year LST and 100 ha during second year LST subject to the following conditions:
- The firm shall provide to the GEAC/MEC / State Department of Agriculture/ District Collector and other field functionaries under the Seed Act, the State wise details of location (area, village, name of the farmer) where it intends to undertake seed production within 30 days of issue of the clearance letter.
- Bt cotton seeds produced by the company shall be regulated as per the provisions of the Seeds Act, 1966 and subsequent Rules/amendments. The firm shall maintain records of the seed production and shall make them available for inspection if it so desired by the GEAC/MEC/State Department of Agriculture/ District Collector and other field functionaries under the Seed Act.
- Seed generated shall not be sold or diverted for commercial purpose without the approval of GEAC.
- The lint produced and Bt cotton plant residue after harvesting should be destroyed by burning and records to this effect needs to be maintained and submitted to the GEAC/ State Department of Agriculture/ District Collector and other field functionaries under the Seed Act.
- The ministry may stipulate additional conditions if so necessitated on the basis of feedback received from the MEC, State Department of Agriculture, District Collector or the other field functionaries under the Seed Act and other sources.
- The ministry may revoke the clearance if implementation of stipulated conditions is not satisfactory.