BIOSAFETY ISSUES RELATED TO TRANSGENIC CROPS

(With Focus on Bt Cotton)

PREPARED BY

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NEW DELHI

IN ASSOCIATION WITH

MINISTRY OF ENVIRONMENT AND FORESTS
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FOREWORD

Commercial cultivation of Bt cotton as the first transgenic crop in the country was approved by Government of India in March 2002. In the same year, BCIL in association with the Ministry of Environment & Forests (MoEF) and the Department of Biotechnology (DBT) organized a series of eight workshops at selected locations in the country to create awareness about the biosafety issues related to genetically modified organisms (GMOs). These were attended by stakeholders including scientists, industry, policy makers, farmers and NGOs and helped in a close interaction and appreciation of the issues involved.

In 2004, another series of workshops on transgenic crops was organized by BCIL and MOEF in Aurangabad, Coimbatore, Hyderabad, Dharwad, Ahmedabad and Indore. The locations chosen were in the six Bt cotton growing states. The participants also visited Bt cotton fields or transgenic crops research facilities near four of the centers for interaction with the farmers and the scientists. Thus, these workshops helped in capacity building for effective monitoring.

Since 2002, through the three seasons of cultivation, the area under Bt cotton grew from 30,000 Ha to 5,30,000 Ha in 2004. *Prima facie*, the growth clearly points to a general acceptance of the crop by the farmers and the cotton processing industry.

The present series of six workshops is expected to bring much greater clarity on the value of transgenic crops through the experience of the farmers and other stakeholders. Apart from the six Bt cotton growing states of Andhra Pradesh, Gujarat, Karnataka, Madhya Pradesh, Maharashtra and Tamil Nadu, it is proposed to cover Punjab, Haryana and Rajasthan where large-scale field trials of Bt cotton are under way.

In this document, BCIL has attempted to cover briefly the science and applications of transgenic crops, biosafety issues to be addressed, the regulatory framework and the present status of commercial cultivation in India as well as globally. The compilation was done by Dr. Vibha Ahuja, Deputy General Manager assisted by Mr. Anil Kumar Bhushan, Manager and others at BCIL. We gratefully acknowledge the valuable guidance from Shri. Desh Deepak Verma, Joint Secretary and Dr. Ranjini Warrier, Additional Director, MoEF and Dr. K.K. Tripathi, Adviser and Dr. T.V. Ramanaiah, Director, DBT.

New Delhi
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Dr. S. R. Nair
Managing Director, BCIL

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CHAPTER 1
INTRODUCTION

Bt cotton was approved by Government of India in March 2002 as the first transgenic crop for commercial cultivation for a period of three years. Bt cotton incorporates a gene from a bacterium *Bacillus thuringiensis,* which is effective against the American bollworm, the major pest on cotton. Bt cotton has since been grown in six states, i.e., Madhya Pradesh, Gujarat, Maharashtra, Andhra Pradesh, Karnataka and Tamil Nadu. The area under Bt cotton from 72,000 acres in 2002 increased to 2,30,000 acres in 2003 and 13,00,000 acres in 2004. Initially, three hybrids produced by M/s Maharashtra Hybrid Seeds Company Ltd. (MAHYCO) were approved in 2002. Other seed companies such as M/s Rasi Seeds, M/s Ankur Seeds, M/s. Krishidhan Seeds and M/s Ajeet Seeds have initiated development of Bt cotton hybrids in association with MAHYCO. On April 1, 2004, one hybrid of M/s Rasi Seeds has been accorded approval for commercial cultivation and 12 more varieties are under large scale field trials. Companies such as Nath Seeds, Syngenta and J.K. Agrigenetics are developing transgenic cotton using different genes/events.

Apart from cotton, there are more than 20 crops under research and development in about 50 public and private sector organizations in India. These include rice, potato, brinjal, cabbage, cauliflower, groundnut and pigeon peas. The target traits include insect resistance, herbicide tolerance, viral and fungal disease resistance and stress tolerance. Out of these, 13 crops have been approved for contained limited field trials in India. These are mostly related to insect resistance using Cry genes.

These first generation transgenic crops afford higher crop yields, reduced farm costs, increased profit and improvement in the environment. Next generation of transgenic crops which feature increased nutritional and/or industrial traits are expected to have more direct benefits to consumers. Examples are rice enriched with iron and vitamin A, potatoes with higher starch

content, edible vaccines in maize and potatoes and healthier oils from soybean and canola.

However, as more and more transgenic 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. Questions centre around increased toxicity and allergenicity, impact of introduced traits introgressing into other related species through out crossing, the potential buildup of resistance in insect populations to engineered insecticidal traits, unintended secondary effects on non-target organisms, and potential effects on biodiversity

Biosafety legislation and regulatory institutions to implement them have been put in place by many countries including India, engaged in transgenic research and commercialization. There are elaborate steps to manage these risks and it is the responsibility of the scientists, industry, and the government to assure the public of the safety of the novel products commercialized.

India has a well-defined regulatory mechanism for development and evaluation of GMOs including transgenic crops and the products thereof. Rules notified in 1989 under Environmental Protection Act, 1986 (EPA) define the competent authorities and composition of such authorities for handling regulation of GMOs and products thereof. Presently, there are six competent authorities:

i. Recombinant DNA Advisory Committee (RDAC)
ii. Review Committee on Genetic Manipulation (RCGM)
iii. Genetic Engineering Approval Committee (GEAC)
iv. Institutional Biosafety Committees (IBSC) attached to every organization engaged in rDNA research
v. State Biosafety Coordination Committees (SBCC)
vi. District Level Committees (DLC).

Guidelines for safety in biotechnology have been issued by the Department of Biotechnology (DBT) in 1990 covering research, field trials and commercial applications. DBT also brought out separate guidelines for research in transgenic plants in 1998. The National Seed Policy, 2002 also has a separate section on transgenic plant varieties.

As the first commercial transgenic crop in the country, Bt cotton has been subject to extensive monitoring by both at the central and the state levels during the last three years of commercial cultivation. Simultaneously, there have been various initiatives towards capacity building of various stakeholders. A series of eight workshops on "Biosafety issues related to GMOs" was organized in 2002 by Biotech Consortium India Limited in association with Ministry of Environment & Forests (MoEF), Government of India and Department of Biotechnology, Govt. of India. MoEF sponsored another series of workshops on "Biosafety issues related to transgenic crops" in 2003 in the six Bt cotton growing states covering various stakeholders such as government officials, research institutions, agricultural universities, NGOs and farmers for sensitization and creation of awareness.

In the present second series of workshops being organized in the states where Bt cotton is grown during the last three years, MoEF proposes to interact with all the stakeholders to share the experience of first transgenic crop in the country. In addition, two workshops are proposed to be held in the Northern region for the states of Punjab, Haryana and Rajasthan where large scale trials of Bt cotton are underway. This background document prepared by Biotech Consortium India Limited (who are organizing these workshops) in association with MoEF aims to provide an update and overview of transgenic crops, their applications and the status of regulations and approvals.

CHAPTER 2

PRODUCTION OF TRANSGENIC CROPS

For thousands of years, farmers have relied on selective breeding and cross-fertilization to impart desirable traits in plants such as higher yields and resistance to pests. 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 have 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 a GM crop or transgenic crop.

2.1 WHAT ARE TRANSGENIC CROPS?

A transgenic plant contains a gene or genes of a different species artificially inserted in its genome. The inserted gene sequence known as 'transgene,' may come from an unrelated plant or from a completely different species. For example, Bt cotton is a transgenic cotton plant, which incorporates a gene from the bacterium *Bacillus thuringiensis*. Bt produces crystalline inclusions (parasporal body) during sporulation. The parasporal body comprises crystal proteins of various size, shape and morphology. The biological use of Bt in insect pest control is centered on the exploitation of these crystal proteins especially ∂-endotoxins. These crystalline proteins are found to be highly toxic to agriculturally important pests at very low concentrations

2.2 WHY MAKE TRANSGENIC CROP PLANTS?

Conventional plant breeding involves exchange of genes between plants of the same species or from closely related plants to produce a hybrid having desired traits. This crossbreeding

however is limited to exchange between the same or closely related species. Therefore, it requires a long time to achieve the desired results as sometimes a related species having the characteristics of interest may not be found and incorporation of undesired characters such as origin of new pest and disease incidences may occur. Genetic engineering enables transfer of genes more easily across taxonomic boundaries. The useful genes can be introduced not just from within the crop species or from closely related plants but even from a wide range of other organisms. This gives a wider range of traits to choose from with the transfer being undertaken in a more controlled and predictable way. Transgenic crop plants can therefore incorporate the desired traits more quickly and more reliably than through conventional methods.

2.3 HOW TO PRODUCE TRANSGENIC CROPS?

Transgenic crops are produced through genetic engineering in which genes that code for desirable traits are transferred from one organism to another.

The universal presence of DNA (deoxyribonucleic acid) in the cells of all living organisms is the basis for development of transgenic plants (Figure 2.1). This molecule stores the organism's genetic information which further is responsible for metabolic processes.

Phosphate **P**
Sugar (ribose) **S**
Bases

guanine **G**
cytosine **C**
adenine **A**
thymine **T**

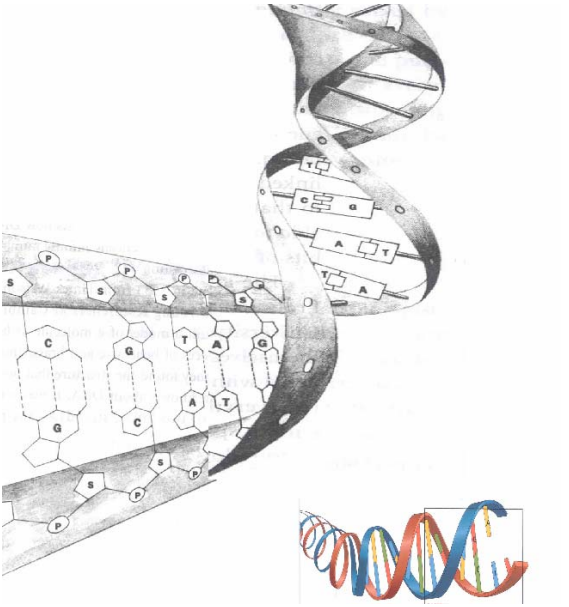


Figure 2.1: DNA double helix

Source: Eric S. Grace, "Biotechnology Unzipped", Universities Press, Hyderabad, 1997

Genetic information is specified by the sequence of four chemical bases (adenine, cytosine, guanine and thymine) along the length of the DNA molecule, joined with deoxyribose and phosphate groups. The combined unit is a nucleotide. These bases couple selectively, that is adenine with guanine (A-G) and cytosine with thymine (C-T).

Genes are a sequence of nucleotides. Once the sequence is defined, the gene has no special relationship with the organism in which it is found. The combinations of the bases form the genetic words called codons. The genetic information is expressed in the form of proteins via intermediary molecules of ribonucleic acid (RNA) and the properties of every organism are determined by the proteins it is made of. Since the genetic code is a universal code, a DNA segment from one organism (e.g. bacteria) can be interpreted and transmitted into a functional protein in another organism (e.g. plant).

Genetic engineering begins with the identification of the gene(s) responsible for a trait of interest. The most important tools for genetic engineering are enzymes that perform specific functions on DNA. Restriction enzymes recognize and cut the DNA at a specific region and the other enzymes known as ligases join the ends of two DNA fragments. The use of these enzymes enables the manipulation of DNA even in unrelated organisms (Figure 2.2).

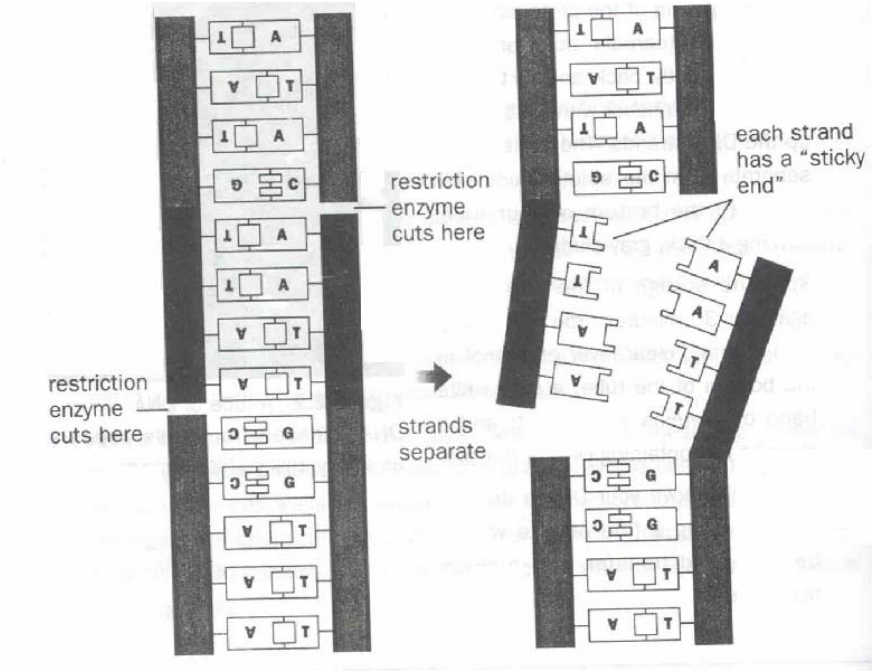


Figure 2.2: DNA fragmenting by restriction enzymes

Source: Eric S. Grace, "Biotechnology Unzipped", Universities Press, Hyderabad, 1997

Identifying and locating genes for agriculturally important traits is currently the most limiting step in the development process. Relatively little is known about the specific genes required to enhance yield potential, improve stress tolerance, modify chemical properties of the harvested product, or otherwise affect plant characters. Further, identifying a single gene related to a trait alone is not sufficient; it is also important to understand how the gene is regulated, what other effects it might have on the plant, and how it interacts with other genes active in the same biochemical pathway.

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 plant. 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. Sometimes, the gene is also modified to achieve greater expression in a plant. 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 incorporation and expression of transgenes in plant cells is a rare event, occurring in just a small portion of the targeted tissues or cells.

Two primary methods currently exist for introducing transgenes into plant genomes, a process also referred to as transformation.

The first involves a device called a ‘gene gun.’ The DNA to be introduced into the plant cells is coated onto tiny particles. 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 method uses a bacterium i.e. *Agrobacterium tumefaciens* to introduce the gene(s) of interest into the plant DNA (Figure 2.3). Whichever method is used, the success rate of the transformation is rarely more than one in ten thousand cells. Furthermore, it is difficult to determine where the new gene (or perhaps several copies of it) has been incorporated.

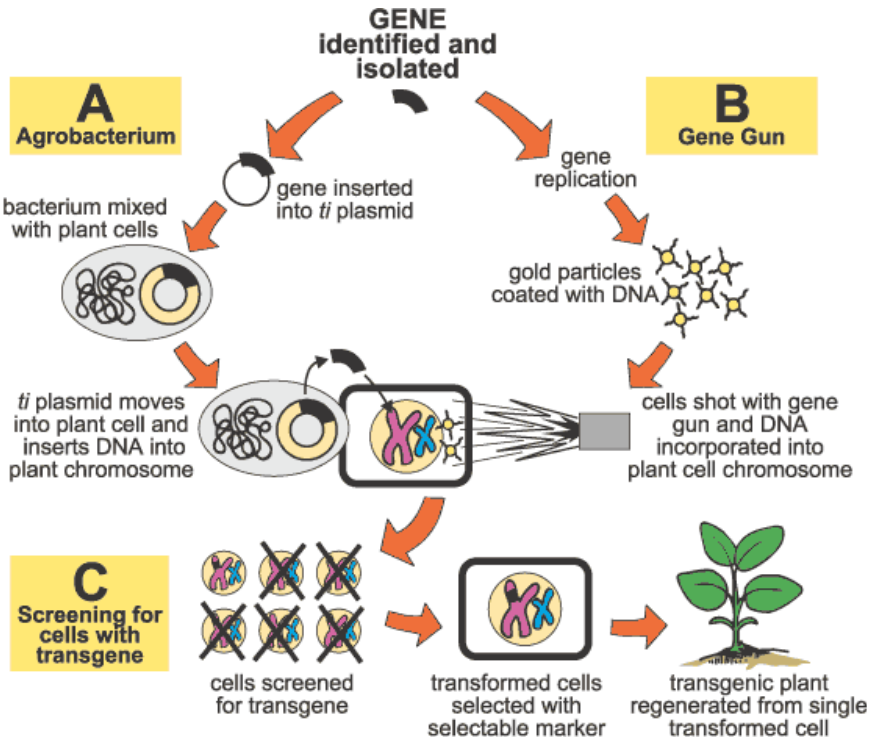


Figure 2.3: Methods of producing transgenic plant

Source: McKanzie, D (2004). Presentation by AGBIOS

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, 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, their evaluation begins.

To verify whether the inserted gene has been stably incorporated without detrimental effects to other plant functions, product quality, or the intended agroecosystem, initial evaluation includes attention to activity of the introduced gene; stable inheritance of the gene and unintended effects on plant growth, yield, and quality.

The position of the inserted gene in the genome of the plant is referred to as ‘event’ is also extremely important. While two events might be responsible for the same trait, they may act somewhat differently in the plant. For example, there are a number of Bt events that have been developed, and they may result in formation of the Bt protein but in different concentration in different plant parts, or at different times during the life of the plant. Different events for the same target gene thus represent some “genetic diversity” for the trait, and this may be useful in making the trait better adopted and in specific cases benefits such as less development of resistance to pests.

The selected 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 backcrossing. 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.

CHAPTER 3
APPLICATIONS AND BENEFITS OF TRANSGENIC CROPS

Transgenic 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 transgenic 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 transgenic crops.

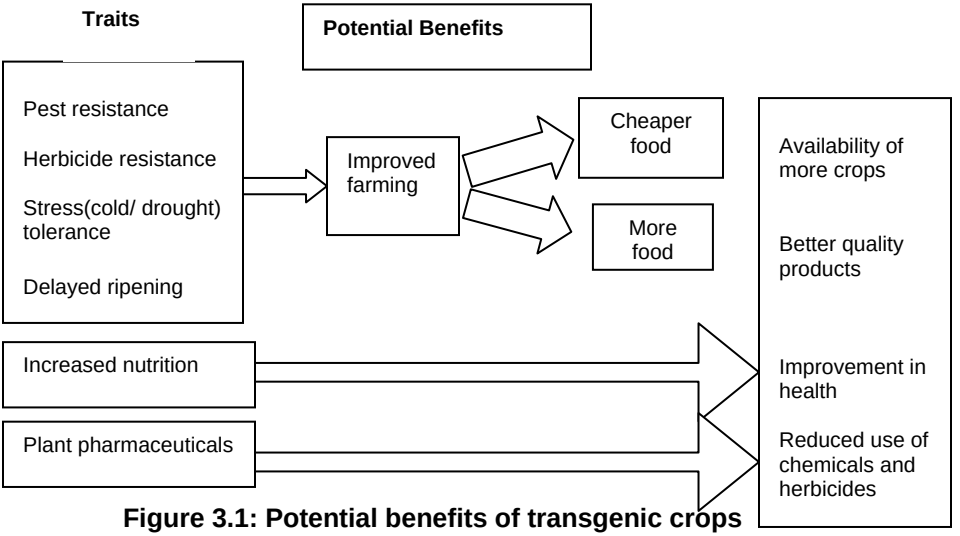


Figure 3.1: Potential benefits of transgenic crops

Source: TO BE ADDED

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

3.1 INSECT RESISTANCE:

Some organisms provide natural protection for plants, as they are toxic to target pests but do not harm humans, animals, fish, birds or beneficial insects. Using recombinant technology, the gene that makes these organisms lethal to certain insects can be transplanted into the plants on which that insect feeds. The plant that once was a food source for the insect now kills it, reducing the need for chemical pesticides to control infestation.

For example, the spores of *Bacillus thuringiensis (in short Bt)* contain a crystalline protein (Cry), which breaks down to release a toxin, known as delta-endotoxin. This toxin binds to and creates pores in the intestinal lining of lepidopteran pests such as American bollworm, resulting in paralysis of the digestive system, and consequent death. This bacterial Cry gene has now been incorporated into the plants DNA itself so that the plant's cells produce the toxin. When the insect feeds on a leaf or bores into a stem of Bt containing plant, it ingests the toxin and dies (Figure 3.2).

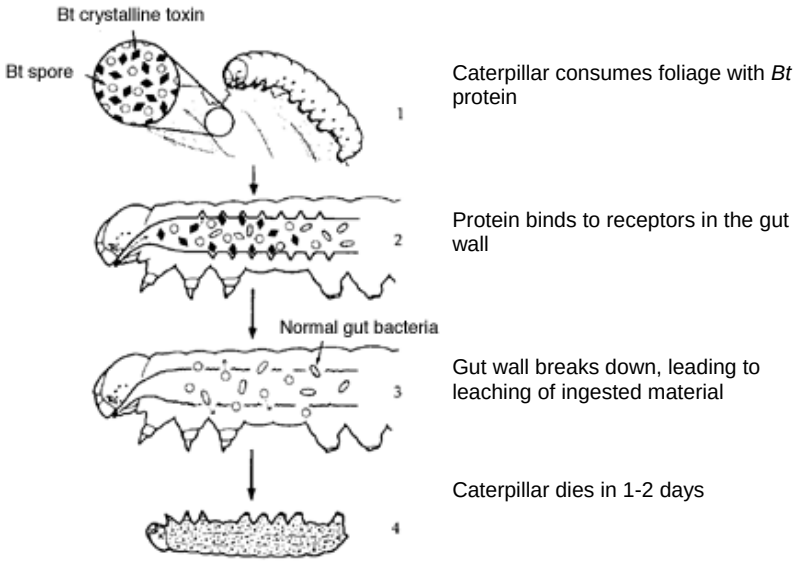


Figure 3.2: Bt toxin: Mechanism of action

Different versions of the Cry genes have been identified which are effective against different orders of insects or act on the insects in different ways.

Bt based insecticides in the form of sprays and powders have been in use for many years and are considered safe for mammals, birds, and for non-target insects.

Bt cotton and maize have been developed and cultivated since 1996. The use of Bt varieties has dramatically reduced the amount of chemical pesticides applied to these crops.

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 genetically engineered to be resistant to herbicides, so as to eliminate weeds more selectively. 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, Monsanto's strain of soybeans genetically modified require 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® soybeans after Roundup treatment (right).

Source: http://www.colostate.edu/programs/lifesciences/TransgenicCrops/current.html#Bt/ Monsanto

Herbicide tolerant crops have been developed by incorporating genes that provide resistance to different herbicides such as glyphosate, oxynil, phosphenothricine, sulfonyl urea etc.

3.3 DISEASE RESISTANCE:

Plants are susceptible to viral, bacterial and fungal diseases. Much progress has been made in evolving transgenic plants resistant to viruses. For example, expression of a gene that encodes the coat protein of tobacco mosaic virus (TMV) in transgenic tobacco plants has been shown to enable the plants to resist TMV infection. A number of other virus 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 shelflife
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. Transgenic 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 flavour 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 crossbreeding, 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 tolerance found naturally in some plants and bacteria and are trying to incorporate them in crops.

3.6 YIELD IMPROVEMENT:

Attempts are being made through the use of biotechnology to improve crop yields directly. Researchers in Japan added maize photosynthesis genes to rice to increase its efficiency at converting sunlight to plant starch and increased yields by 30 percent. Other scientists are altering plant metabolism by blocking gene action in order to shunt nutrients to certain plant parts. Yields increase as starch accumulates in potato tubers and not leaves, or oil-seed crops, such as canola, allocate most fatty acids to the seeds.

Crops that are better at accessing the micronutrients they need are also being developed. For example genetically modified plants have been developed to secrete citric acid, a naturally occurring compound, from their roots. In response to the slight increase in acidity, minerals bound to soil particles, such as

calcium, phosphorous and potassium, are released and made available to the plant.

Nitrogen is the critical limiting element for plant growth and, step-by-step, researchers from many scientific disciplines are working on the details of the symbiotic relationship that allows nitrogen-fixing bacteria to capture atmospheric nitrogen and provide it to the plants that harbor them in root nodules.

3.7 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 other conditions and several vaccines can potentially be grown in plants. Transgenic technology is being used to produce a plant whose seed can express a desired therapeutic protein. The desired protein can be extracted from the seed to make a biopharmaceutical. Plant based therapeutics are expected to be highly cost effective.

CHAPTER 4
CONCERNS

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

These apprehensions arise because transgenic 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 transgenic crops, because of novel combinations of genes. Transgenic crops are not toxic nor 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 risk assessment and management.

Potential risks from the use of transgenic crops broadly fall under two categories.

i. Human health
ii. Environment

4.1 RISK TO HUMAN HEALTH:

Risks to human health are related mainly to toxicity, allergenicity and antibiotic resistance.

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 transgenic 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 transgenic crops pose more risks than conventional products in triggering allergies. Further, the new transgenic crops can be tested for allergens prior to their commercial release. For example, when it was found that the consumption of transgenic soybean with a methionine-producing gene from brazil nut could trigger an allergic response in those 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.

4.2 RISK TO ENVIRONMENT:

Risks to environment due to release of TRANSGENIC crops include impact of imparted traits on 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 transgenic crops and traditional varieties through pollen transfer can contaminate the traditional local varieties with transgenes. The consequences associated with such gene transfer may 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 they were 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 transgenic crop.

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

CHAPTER 5
BIOSAFETY REGULATIONS IN INDIA

Biosafety regulations cover assessment of risks and the policies and procedures adopted to ensure environmentally safe applications of biotechnology. A national biosafety regulatory system to regulate production and release of genetically modified organisms (including transgenic crops) is considered essential in any country with a biotechnology programme. The regulatory framework for transgenic crops in India consists of the following rules and guidelines.

1. Rules and policies	• Rules 1989 under Environment Protection Act (1986) • Seed Policy 2002
2. Guidelines	• Recombinant DNA guidelines, 1990 • Guidelines for research in transgenic crops, 1998

5.1 RULES, 1989:

The Ministry of Environment & Forests, Government of India notified 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 on December 5, 1989 under the Environmental Protection Act 1986 (EPA). These rules and regulations, commonly referred as Rules 1989 cover the areas of research as well as large scale applications of GMOs and products made therefrom throughout India. A copy of the rules is placed at Annex-1.

The Rules, 1989 order 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 action provided under the EPA.

The two main agencies identified for implementation of the rules are the Ministry of Environment & Forests and the Department of Biotechnology, Government of India. The rules have also defined competent authorities and the composition of such authorities for handling of various aspects of the rules. There are six competent authorities as per the rules.

i. Recombinant DNA Advisory Committee (RDAC)
ii. Review Committee on Genetic Manipulation (RCGM)
iii. Genetic Engineering Approval Committee (GEAC)
iv. Institutional Biosafety Committees (IBSC)
v. State Biosafety Coordination Committees (SBCC)
vi. District Level Committees (DLC).

Out of these, the three agencies that are involved in approval of new transgenic crops are:

1. IBSC set-up at each institution for monitoring institute level research in genetically modified organisms.
2. RCGM set-up at DBT to monitor ongoing research activities in GMOs and small scale field trials.
3. GEAC in the Ministry of Environment and Forests set-up to authorize large-scale trials and environmental release of genetically modified organisms.

The Recombinant DNA Advisory Committee (RDAC) constituted by DBT takes note of developments in biotechnology at national and international level and prepares suitable recommendations. The State Biotechnology Coordination Committees (SBCCs) set up in each state where research and application of GMOs are contemplated, coordinate the activities related to GMOs in the state with the central ministry. SBCCs have monitoring functions and therefore have got powers to inspect, investigate and to take punitive action in case of violations. Similarly, District Level Committees (DLCs) are constituted at district level to monitor the safety regulations in installations engaged in the use of GMOs in research and application.

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.

5.2 RECOMBINANT DNA GUIDELINES, 1990:

With the advancement of research in biotechnology initiated by various Indian institutions and industry, Department of Biotechnology had formulated Recombinant DNA Guidelines in 1990. These guidelines were further revised in 1994 to cover 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.

For research, the guidelines have been classified into three categories, based on the level of the associated risk and requirement for the approval of competent authority.

- 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 employ the concept of physical and biological containment and the principle of good laboratory practices.

For containment facilities and biosafety practices, recommendations in the WHO laboratory safety manual on genetic engineering techniques involving microorganisms of different risk groups have been incorporated therein.

The guidelines categorize experiments beyond 20 liters capacity for research and industrial purposes as large-scale. In case of cultivation of plants, this limits is 20 acres area. The guideline gives principles of occupational safety and hygiene for large-scale practice and containment. Safety criteria have also been defined in the guidelines. Physical containment conditions that should be ensured for large-scale experiments and production have been specified in the guidelines.

For release to the environment the guidelines specify appropriate containment facilities depending on the type of organisms handled and potential risks involved. The guidelines require the interested party to evaluate rDNA modified organism for potential risk prior to application in agriculture and environment like 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. A copy of the guidelines can be accessed at http://www.dbtindia.nic.in.

5.3 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 purposes.

Genetic engineering experiments on plants have been grouped under three categories.

- Category I includes routine cloning of defined genes, defined non-coding stretches of DNA and open reading frames in defined genes in *E. coli* or other bacterial/fungal hosts which are generally considered as safe to human, animals and plants.

- Category II experiments include experiments carried out in lab and green house/net house using defined DNA fragments non-pathogenic to human and animals for genetic transformation of plants, both model species and crop species.

- Category III includes experiments having high risk where the escape of transgenic traits into the open environment could cause significant alterations in the biosphere, the ecosystem, plants and animals by dispersing new genetic traits the effects of which cannot be judged precisely. This also includes experiments having risks mentioned above conducted in green houses and open field conditions.

To monitor the impact of transgenic plants on the environment over a period of time, 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 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 under 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.

A copy of the guidelines can be accessed at http://www.dbtindia.nic.in.

5.4 SEED POLICY 2002:

The Seed Policy 2002 contains a separate section (No. 6) on transgenic plant varieties. It has been stated that all genetically engineered crops/varieties will be tested for environment and biosafety before their commercial release as per the regulations on guidelines of the EPA, 1986. 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 in the market. 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. 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.

It has also been mentioned that transgenic varieties can be protected under the PVP legislation in the same manner as non-transgenic varieties after their release for commercial cultivation. A copy of seed policy is placed in Annex-2.

In addition the above, Ministry of Agriculture has issued a notification on November 12, 2003 nominating the Central Institute of Cotton Research (CICR) to act as a referral laboratory for Bt cotton seeds (Annex-3).

CHAPTER 6
SAFETY ASSESSMENT OF TRANSGENIC CROPS

Commercial production of a transgenic crop is the culmination of a four step process. The first step begins in government or private research laboratories and greenhouses, where scientists investigate potential beneficial traits, identify genes and carry out 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 is securing regulatory approval in the country where the plant will be grown, and/or its products consumed by humans or animals. The fourth and final step is market acceptance and large scale production.

Safety assessment of a transgenic crop is the most important step in this development process. Extensive testing and a long approval process precede every transgenic crop introduction. The approval process includes comprehensive analysis of the risks and their scientific management to ensure food, feed and environmental safety before introduction into the market.

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

Experiments are designed to systematically identify the hazards, to assess risks and to take steps to manage the risk by applying logical strategies. 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 material to other organisms.

ii. Characteristics of the vectors used such as the origin, identity and habitat, 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, humans or animals.

iv. Characteristics of the transgenic plants including methods of detection of the transgenic plant as well as the escaped transgenic traits in the environment, toxicity and pathogenicity of the transgenic plants and their seeds to other plants, human and animals, possibility of and the extent of transgenic pollen escape and pollen transfer to wild near relatives, and the impact on the environment

While information on some of these aspects may be available but many others need to be investigated using appropriately designed experiments. Toxicity and allergenicity data are generated using standard protocols devised by national and international agencies.

For minimizing the risk arising from the limited release of transgenic plants, the following may be taken into consideration:

i. Special separation for isolation, for preventing reproduction/ fertilisation and seed setting.
ii. Biological prevention of flowering by making use of sterility properties
iii. Human intervention for removal of reproductive structures of flowers.
iv. Controlling the reproductive structures of transgenic plants like the seeds and the plant propagules from unaccounted spread.
v. Controlling and destroying volunteer plants from experimental field.

vi. To take into account the proximity to human activity in case the transgenic plants have allergenic properties to human and animals.
vii. Appropriate training of field personnel handling the transgenic plants.
viii. Plans for handling unexpected events.
ix. Documentation of previous published information, if any, including any documented evidence of effects of the release to the ecosystem.

All the data generated by the developing organizations is then submitted in detailed formats to the government for seeking permission for commercial release of the transgenic crop. The initial risk assessment in India 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 assessment with respect to agronomic benefits is undertaken under the ICAR system. In fact, even after the release of the crop there is continuous monitoring by Monitoring and Evaluation Committees at the center and the state levels.

CHAPTER 7
GLOBAL STATUS OF TRANSGENIC CROPS

7.1 CROPS APPROVED FOR COMMERCIAL USE:

The first commercial transgenic crop was “Flavr Savr” tomato with delayed ripening characteristics introduced in USA in 1995. Seventeen crops have so far been approved in various countries for planting in various countries across the world incorporating one or more of the basic phenotypical characteristics such as herbicide tolerance, insect resistance, male sterility, modified colour, delayed ripening and virus resistance. Table 7.1 lists these products alongwith the genetically improved trait and countries where they have been approved.

Table 7.1: Transgenic crops approved for commercial use

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

S. No.	Crop	Uses	Countries where approved
5.	**Flax, Linseed**	Herbicide tolerance, antibiotic resistance and improved weed protection	Canada, US
6.	**Green pepper**	Virus resistance	China
7.	**Maize**	Herbicide tolerance, improved weed protection, resistance against insects and restored fertility of seeds	Canada, Japan, US, Argentina, European Union, South Africa, Philippines,
8.	**Melon**	Delayed ripening	
9.	**Polish Canola**	Herbicide tolerance and improved weed control	Canada
10.	**Potato**	Improved protection from insect and leaf roll virus	US, Canada,
11.	**Rice**	Herbicide resistance	US
12.	**Soybean**	Improved weed control and herbicide tolerance, increased cooking quality	US, Argentina, Japan, Canada, Uruguay, Mexico, Brazil and South Africa
13.	**Squash**	Resistance against watermelon mosaic virus and zucchini yellow mosaic virus	US
14.	**Sugar beet**	Herbicide tolerance	US, Canada
15.	**Sunflower**	Herbicide tolerance	Canada
16.	**Tobacco**	Herbicide tolerance	US
19.	**Tomato**	Improved shelf life, taste, color and texture, improved insect resistance, virus resistance	US, Mexico, Japan, China

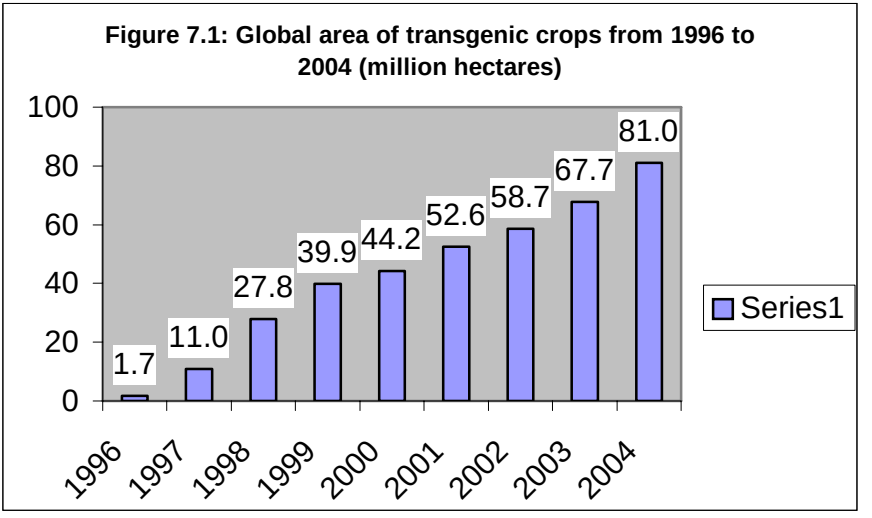
Source: http://www.agbios.com/

Out of the above, four major transgenic crops have come to market in various countries namely maize or corn, cotton, soybean and canola. Commercial production of papaya, squash and tobacco has been initiated in USA. Others such as chicory, tomatoes, rice, potatoes, flex etc. have been approved for commercial use in one or more countries, but have not yet been marketed.

7.2 AREA UNDER CULTIVATION:

In the nine-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 81.0 million hectares in 2004 (Figure 7.1). There has been a 20% increase in 2004 in the area over the same in 2003 equivalent to 13.3 million hectares. Seventeen countries have so far adopted biotech crops.

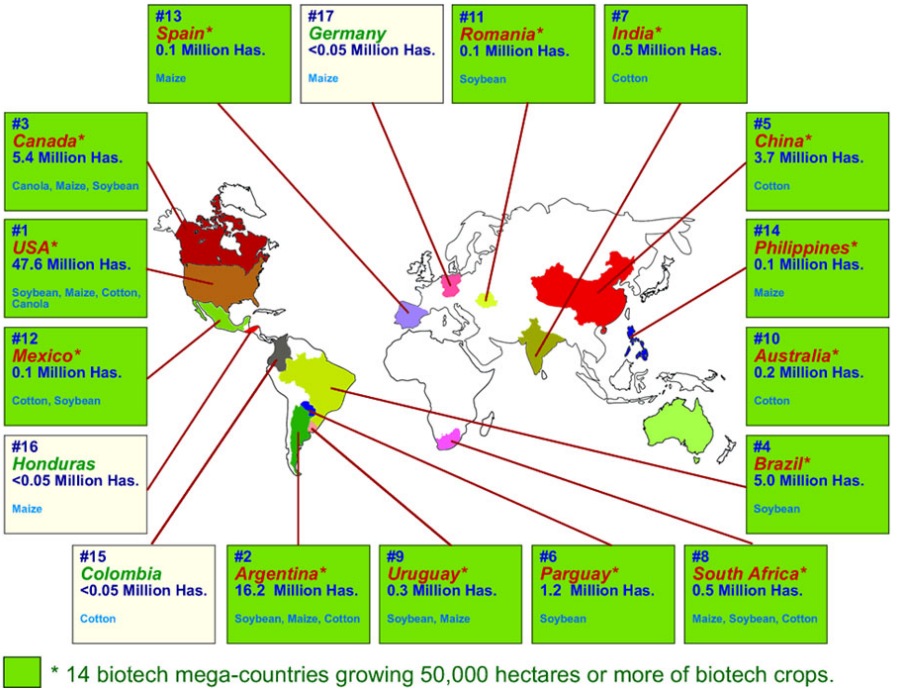
Figure 7.1: Global area of transgenic crops from 1996 to 2004 (million hectares)



Source: International Service for the Acquisition of Agri-biotech Applications (http://www.isaaa.org)

More than one third (34%) of the global biotech crop area of 81 million hectares in 2004, which is equivalent to 27.6 million hectares was grown in developing countries. In 2004, there were 14 countries referred to as biotech mega countries which have 50,000 hectares or more under transgenic. These included nine developing countries and five industrial countries. In order of hectarage, they are USA, Argentina, Canada, Brazil, China, Paraguay, India, South Africa, Uruguay, Australia, Romania, Mexico, Spain and the Philippines (Figure 7.2).

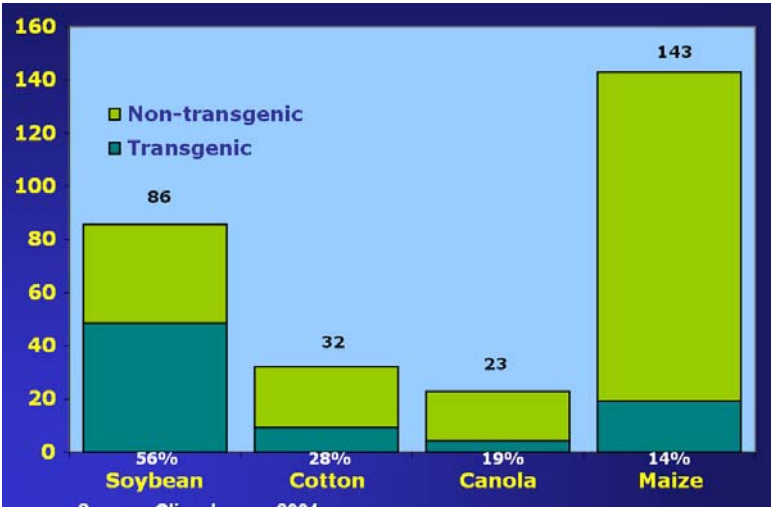
Figure 7.2: Biotech crop countries and mega countries, 2005



Source: International Service for the Acquisition of Agri-biotech Applications (http://www.isaaa.org)

Growth continued in all four commercialized biotech crops in 2004. Biotech soybean occupied 48.4 million Ha (60%), maize 19.3 million Ha (23%), cotton 9 million Ha (11%) and canola 4.3 million Ha (6%b of the global transgenics area. The proportion of transgenic crops vis-à-vis total global cultivation is also increasing rapidly. In 2004, 56% of the total soybean planted globally was transgenic (Figure 7.3).

Figure 7.3: Percentage adoption of four transgenic crops in 2004



Source: International Service for the Acquisition of Agri-biotech Applications (http://www.isaaa.org)

Herbicide tolerance has consistently been the dominant trait introduced followed by insect resistance. In 2004, herbicide tolerant soybean, maize, cotton and canola occupied 72% and Bt crops 19%. Stacked genes for herbicide tolerance and insect resistance deployed in both cotton and maize covered 9% of the global transgenic area in 2004.

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.

There is intensive research going on to develop transgenic crops with more direct benefits to consumers. It has been reported that 63 countries are in transgenic 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 7.2: Transgenic 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. The following products with direct benefits to the consumers are likely be available in the near future:

- Soybean and canola oils containing more unsaturated fatty acids
- Higher yielding peas that remain sweeter longer
- Smaller seedless melons
- Bananas and pineapples with delayed-ripening qualities

- Bananas resistant to fungi
- High protein rice
- Tomatoes with higher antioxidant content
- Fruits and vegetables with higher levels of vitamins

Further down the road the products include:

- Crops tolerant to stresses e.g. drought, floods, salts, metals, heat, and cold
- Safer foods through reduction of allergenic proteins
- Edible vaccines
- Nitrogen fixing crops
- Plants that produce latex

CHAPTER 8
STATUS OF TRANSGENIC CROPS IN INDIA

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

8.1 IN COMMERCIAL USE:

As of now, Bt cotton containing the Cry1Ac Bt gene is the only transgenic crop approved for commercial use in India. Three Bt cotton hybrids developed by Maharashtra Hybrid Seeds Company (MAHYCO) were granted approval in March 2002 for commercial cultivation for a period of three years. The approval was granted after extensive field trials. Bt cotton has since been grown in the fields of six states i.e. Andhra Pradesh, Gujarat, Madhya Pradesh, Maharashtra, Karnataka and Tamil Nadu. Starting from an area of 30,000 Ha under Bt cotton cultivation in 2002, the area under cultivation in 2004 is 5,30,000 Ha. MAHYCO has subsequently sublicensed this technology to other seed suppliers for incorporation of the gene in their own hybrids. Several Bt cotton hybrids developed by these companies are under large-scale trials and would be ready for commercial production in the near future.

Permission has also been given to MAHYCO for large scale trials of four Bt cotton hybrids containing both Cry1Ac and Cry2Ab2 at 80 locations per hybrid in southern and central India.

8.2 ONGOING FIELD TRIALS:

Thirteen crops have been approved for contained limited field trials in India (Table 8.1). The trials are being conducted by both public and private sector institutions and are mostly related to insect resistance using cry genes.

Table 8.1: Transgenic crops approved for conducting contained limited field trials (including multi-location field trials)

S. No	Crop	Trait	Organization
1.	Brinjal	Insect resistance	Indian Agricultural Research Institute (IARI), Tamil Nadu Agricultural University (TNAU), MAHYCO
2.	Cotton	Insect resistance Herbicide tolerance	UAS, Dharwad, Ankur Seeds P.Ltd., JK Agri Genetics, Krishidhan Seeds, MAHYCO, Nath Seeds, Rasi Seeds Ltd., Syngenta India Ltd., Nuziveedu Seeds, Mahendra Hybrid Seeds Ltd., Tulsi Seeds, Ganga Kaveri Pvt. Ltd., Vikki's Agrotech, Pravardhan Seeds, Prabhat Agri Biotech Ltd., Ajeet Seeds MAHYCO
3.	Cabbage	Insect resistance	IARI, MAHYCO
4.	Cauliflower	Insect resistance	MAHYCO
5.	Groundnut		International Crop Research Institute for Semi Arid Tropics (ICRISAT)
6.	Mustard	Superior hybrid cultivars, resistance to fungal attack, plants with high level of Beta carotene, abiotic stress tolerant plants	IARI, National Research Centre on Weed Sciences (NRCWS), Jabalpur, Proagro PGS (India) Ltd., The Energy and Resources Institute (TERI), University of Delhi South Campus (UDSC)
7.	Okra	Insect resistance	MAHYCO
8.	Potato	Insect resistance, nutritionally enriched with high protein content	Central Potato Research Institute (CPRI), Jawaharlal Nehru University(JNU)/National Centre for Plant Genome Research (NCPGR)

S. No	Crop	Trait	Organization
9.	Rice	Resistance to lepidopteran pests, bacterial blight and sucking pests, fungal infection, insect resistance, salt tolerance	Directorate of Rice Research, Hyderabad, Osmania University, IARI, MAHYCO, Madurai Kamaraj University, M S Swaminathan Research Foundation, TNAU
10.	Pigeonpea	Resistance to fungal pathogens	ICRISAT, MAHYCO
11.	Sorghum	Insect resistance	MAHYCO
12.	Tobacco	Insect resistance	Central Tobacco Research Institute (CTRI)
13.	Tomato	Insect resistance, resistance to fungal infection, viral resistance	IARI, JNU/NCPGR, MAHYCO

Source: Department of Biotechnology, Government of India

8.3 CROPS UNDER RESEARCH AND DEVELOPMENT:

There are more than 20 crops under research in India as listed below:

i. Bhendi
ii. Blackgram
iii. Blackgram
iv. Brassica
v. Brinjal
vi. Cabbage
vii. Cauliflower
viii. Chickpea
ix. Cotton
x. Groundnut
xi. Muskmelon
xii. Mustard/rapeseeds
xiii. Pigeonpea
xiv. Potato
xv. Rice
xvi. Sorghum
xvii. Sugarcane
xviii. Sunflower
xix. Tobacco
xx. Tomato
xxi. Watermelon
xxii. Wheat

The target traits include insect resistance, herbicide tolerance, viral and fungal disease resistance and stress tolerance.

8.4 ORGANIZATIONS IN THE AREA:

In view of the importance and potential of transgenic crop, extensive efforts have been initiated under the aegis of the Department of Biotechnology (DBT) for promoting research and development in this area. DBT supported the establishment of Centres for Plant Molecular Biology (CPMB) as early as in 1990. A total of six such centers were set up initially at various universities/institutions namely Jawaharlal Nehru University (New Delhi), Madurai Kamaraj University (Madurai), Tamil Nadu Agricultural University (Coimbatore), Osmania University (Hyderabad), National Botanical Research Institute (Lucknow) and Bose Institute (Kolkata). A seventh center was established at the University of Delhi South Campus in 1997. DBT has supported over the last 12 years a large number of research projects which deal with the development of *in vitro* regeneration and genetic transformation protocols of important crops species grown in India and the development of transgenics with genes of agronomic importance. To further strengthen research in the area of crop biotechnology, a new institute National Centre for Plant Genome Research (NCPGR) has been established in New Delhi with a mandate to strengthen plant biotechnology research in India.

More than 50 institutions in public and private sector are engaged in transgenic crops and development. This include 34 research institutions and 20 private companies.

A. RESEARCH INSTITUTIONS

1. Assam Agricultural University, Jorhat
2. Bose Institute, Kolkata
3. Central Agricultural Research Institute, Port Blair
4. Central Food Technological Research Institue, Mysore
5. Central Institute for Cotton Research, Nagpur
6. Central Potato Research Institute, Shimla
7. Central Tobacco Research Institute, Rajahmundry
8. Centre for Cellular and Molecular Biology, Hyderabad
9. Centre for Plant Molecular Biology, Osmania Univ., Hyderabad
10. Central Rice Research Institute, Cuttack
11. College of Basic Sciences and Humanities, Pantnagar
12. Delhi University South Campus, New Delhi
13. Directorate of Oil Seeds Research, Hyderabad
14. Directorate of Rice Research, Hyderabad
15. G B Pant University of Agriculture and Technology, Pantnagar

16. Indian Agricultural Research Institute, New Delhi
17. IARI sub-station, Shillong
18. International Centre for Genetic Engineering and Biotechnology, New Delhi
19. International Crop Research Institute for Semi-Arid Tropics, Hyderabad
20. Indian Institute of Chemical Biology, Kolkata
21. Indian Institute of Horticultural Research, Bangalore
22. Jawaharlal Nehru University, New Delhi
23. Madurai Kamraj University, Madurai
24. Mahatama Phule Krishi Vidyapeeth, Rahuri
25. M.S. University, Baroda
26. Narendra Dev University of Agriculture, Faizabad
27. National Botanical Research Institute, Lucknow
28. National Centre for Plant Genome Research, New Delhi
29. Punjab Agricultural University, Ludhiana
30. The Energy and Resources Institute (TERI), New Delhi
31. Tamil Nadu Agricultural University, Coimbatore
32. University of Agricultural Sciences, Bangalore
33. University of Hyderabad, Hyderabad
34. Vasantdada Sugar Institute, Pune
35. Y.S. Parmar University of Horticulture and Forestrym, Solan

B. COMPANIES

1. Ajeet Seeds Ltd., Aurangabad
2. Ankur Seeds Ltd., Nagpur
3. Bejo Shetal Seeds Pvt. Ltd., Jalna
4. De-Nocil, Mumbai
5. Hybrid Rice International Ltd., Gurgaon
6. Indo-American Hybrid Seeds, Bangalore
7. J K Seeds, Secunderabad
8. Krishidhan Seeds Ltd., Jalna
9. MAHYCO, Mumbai
10. Maharashtra State Seeds Corporation Ltd., Akola
11. Metahelix Life Sciences Pvt. Ltd., Bangalore
12. Monsanto India Ltd., Mumbai
13. Nath Seeds Ltd., Aurangabad
14. Nuziveedu Seeds Company Ltd., Hyderabad
15. Proagro PGS (India) Ltd., Gurgaon
16. Rallis India Limited, Bangalore
17. Rasi Seeds Co. Ltd., Attur
18. SPIC Foundation, Chennai
19. Syngenta India Ltd., Pune

CHAPTER 9
CASE STUDY OF Bt COTTON

9.1 BACKGROUND:

Cotton is a very important crop in India. Nearly nine million hectares of land in India is used to produce 14.2 bales of cotton lint under diverse agro climatic conditions. It contributes 29.8% of the Indian agricultural gross domestic products and provides a livelihood to more than 60 million people by way of support in agriculture, process and use of cotton in textile. 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 for this low productivity is damage caused by insect pests,, notably, *Helicoverpa armigera*, commonly referred to as American bollworm. It has been estimated nearly Rs. 12 billion worth of pesticides are used in India to control bollworms in cotton crop. Still it is a known fact that all the pesticide molecules, except the latest ones like Spinosad and Indoxacarb, failed to effectively control cotton bollworm.

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 thus over the last 40 years it has been used as an insecticide by farmers worldwide. It is applied either as spray or granules but the efficiency of both applications is quite limited as the target organism do not often come in contact with an 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 using biotechnology by introducing the insecticidal gene from the bacterium to cotton plant, commonly referred to as Bt cotton. These plants have a built in mechanism of protection against targeted pests and the protein produced by the plants does not

get washed away nor is destroyed by sunlight. 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.

9.2 GLOBAL SCENARIO:

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, Australia, South Africa, Argentina, Mexico, Indonesia and India. 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 9.0 million Ha in 2004 and which is approximately 28% of the global area under cotton.

The Bt genes that have been commercialized world over are mainly from two sources. The first is Monsanto company which 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 and the second

source is the Bt fused gene that was developed by the public sector Chinese Academy of Agricultural Sciences (CAAS) in Beijing, China. Subsequently, Monsanto has developed second generation of Bt cotton technology, which contains two different genes that encode proteins from *B. thuringiensis* i.e. Cry2Ab and Cry1Ac. This dual gene cultivars are expected to provide growers with a broader control over a wider variety of insects than achieved with the first generation Bt cotton products. In addition, it can serve as a new tool to combat the potential development of insect resistance in cotton fields by providing a second mode of action to control these pests. Research is also underway on various other genes to impart insect resistance properties in cotton such as vegetative insecticidal proteins (vip) genes by Syngenta. Combination of genes have also being developed such as Bollgard II by Monsanto which has a combination of Cry1Ac and Cry2Ab2 genes.

9.3 INDIAN SCENARIO:

In India, Maharashtra Hybrids Seed Company (MAHYCO) first imported the parental cotton cultivar Coker 312 from Monsanto and then carried out contained breeding programme to incorporate the Bt gene into their elite cotton in bred lines. The Bt trait was successfully transferred into more than 60 cotton lines by traditional backcrossing method. The biosafety of the Cry1Ac Bt gene in these hybrids was assessed and then field testing was permitted by DBT.

MAHYCO have 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 approval conditions.

- Valid for three years: April 02 to March 05

- Three hybrids namely MECH12Bt, MECH162Bt and MECH184Bt
- Provide same non Bt seed to meet refuge requirements
- Conduct studies to monitor resistance development
- Provide information to government on distribution of the seed through its dealers and agents
- Labeling requirements such as GEAC number, etc.
- Develop Bt based IPM program
- Conduct educational and awareness programs
- Meet other requirements as stipulated

The Bt transgene in the converted Indian inbred lines behaves as a single dominant -Mendelian factor and is a 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 helps in a better boll size and quality as well as reduction in picking costs. The comparative growth of a Bt cotton plant versus the non Bt hybrid is depicted in Figure 9.1

Figure 9.1: Comparison of Bt versus non Bt hybrids

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 containing Bt cotton hybrids and its non Bt cotton hybrid counterparts for covering one acre each 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 are to the tune of 13 lakhs packets, an increase of six times over the previous year. The state wise sale of Bt cotton hybrids is given in Table 9.1.

Table 9.1: State wise sale of approved Bt cotton hybrids in last three years

(in numbers)

State	Sales quantity in packs			No. of Farmers			Avg. purchase/farmer		
	2002	2003	2004	2002	2003	2004	2002	2003	2004
Andhra Pradesh	12,894	13,000	1,80,000	12,000	13,000	1,65,000	1	1	1.1
Madhya Pradesh	3,676	33,000	2,20,000	2,016	17,000	70,000	1.82	1.94	3.1
Gujarat	22,577	103,000	3,30,000	13,269	60,000	1,07.000	1.70	1.72	3
Maharashtra	30,699	54,000	5,10,000	15,935	36,000	2,30,000	1.88	1.91	2.2
Karnataka	5,401	7,500	45,000	2,960	4,000	28,000	1.82	1.88	1.6
Tamil Nadu	925	19,000	25,000	295	4,000	18,000	3.14	4.75	1.5
Total	**72,682**	**2,30,000**	**13,10,000**	**41,328**	**1,25,000**	**6,18,000**	**1.76**	**1.84**	**2.2**

The performance of Bt cotton vis-à-vis non Bt cotton can be viewed from the following picture:

Other seed firms viz., M/s Rasi Seeds, Ankur Seeds, Krishidhan and Ajeet seeds have come forward to develop Bt cotton hybrids as a sub-license of M/s Mahyco-Monsanto. In addition, M/s Nath Seeds, Syngenta and other seed firms are seeking technologies for imparting insecticidal resistance to cotton. Seven Indian companies namely Nuziveedu Seeds, Ganga Kaveri Seeds, Pravardhan Seeds, Prabhat Agri Biotech, Kaveri Seeds, Nandi Seeds, and Vikki's Agro Tech have formed a consortium by the name Swarna Bharat Biotechnics Private Ltd (SBBPL) and has entered into an agreement with the Lucknow-based, National Botanical Research Institute (NBRI) for development of Bt cotton technology.

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 environmentally favorable manner. This will positively affect the livelihood of millions of farmers by improving their net incomes.

The safety aspects of Bt cotton has 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. This 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 to plant hybrids according to the requirements of quality and needs of the market.

There is a misconception among the farmers that Bt cotton does not need any plant protection and also apprehensions that terminator Genes associated with Bt cotton. 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 total pest control 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.

ANNEX-1

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 ORGANISMS 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/Genetically 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 consideration:

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

(c) production, manufacturing, processing, storage, import, drawing off, packaging and repackaging of the Genetically Engineered 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 biological 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 technique called genetic engineering, include selfcloning and deletion as well as cell hybridisation;

(iv) "Genetic engineering" means the technique by which heritable 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) Department 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 genetically 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,

importation 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/genetically 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 manuals/guidelines of the RCGM and make available copies to the District Level Committee/State Biotechnology Co-ordination Committee and the Genetic Engineering Approval Committee.

(1) 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 recombinants in research and industrial production from the environmental angle. The Committee shall also be responsible for approval of proposals relating to release of genetically engineered organisms and products into the environment including experimental 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 Biotechnology

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

(iii) Expert members: Director General Indian Council of Agricultural 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 Environment, 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.

(4) **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 genetically engineered Organisms/Hazardous microorganisms. The composition 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.

(5) **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 microorganisms, formulate information chart, find out hazards and risks associated with each of these installations and coordinate activities with a view to meeting any emergency. The District Level Committee shall regularly submit its report to the State Biotechnology 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 exclusively 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 hazardous 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 engineered 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 directions 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, hospitals 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 organism 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 development, 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/hazardous 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 engineered 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 Approval 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 Committee 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 Engineering 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 Committee or the State Pollution Control Boards/District Level Committee 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 repayable 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 Committee \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 Engineering Approval Committee/the DLC or any person with special knowledge duly authorised by the State Biotechnology Co-Ordination Committee or the Genetic Engineering Approval Committee or the DLC where it is deemed necessary, at any time on due production if identity

be admitted to public as well as to private premises and localities for the purpose of carrying out supervision.

(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 supervision 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, supervision 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

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*
- *Borrelia recurrentis.B.Vincenti*
- *Campylobacter fetus*
- *Camphylobacter jejuni, Chalamydia psittaci*
- *Cheamydia trachomatics*
- Clostridium chauvoei, Cl.difficile Cl/fallax. Cl haemolyticum Q.histolyticum, Cl novyi (Cl,Pefringes) Cl.speticum, Cl.sordelli
- Corynebacterium diptheriae, C.equi, C. haemolyticum, C.Pseudotuberculosis, 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 El 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 virulent 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

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, protozoa, other parsitic plants or reproductive parts thereof: viruses; 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 Tuberculariaceae
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 Lepidoptera
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.

ANNEX – 2

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 requirement**s** of the respective State**s**.

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.

ANNEX – 3

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)

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