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GENETICALLY MODIFIED CROPS AND REGULATIONS IN INDIA

MYTHS VS FACTS

Prepared under

gef UNEP

Phase-II Capacity Building Project on Biosafety

Ministry of Environment
Forests and Climate Change

Ministry of Environment
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Government of India

In association with

BCIL
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Genetically Modified Crops and Regulations in India
Myths vs Facts

Prepared by

Ministry of Environment, Forest and Climate Change (MoEFCC) and
Biotech Consortium India Limited, New Delhi
under the UNEP/GEF supported Phase II Capacity Building Project on Biosafety

Key Contacts:

Dr Sujata Arora
Adviser, MoEFCC
Vice Chair, Genetic Engineering Appraisal Committee (GEAC)

Dr Murali Krishna Chimata
Joint Director, MoEFCC
Member Secretary, GEAC

Project Coordination Unit (Phase II Capacity Building Project on Biosafety)

Dr Vibha Ahuja
Chief General Manager
Biotech Consortium India Limited

For further information, please contact

Ministry of Environment, Forest and Climate Change
Indira Paryavaran Bhawan, Jor Bagh Road, Ali Ganj
New Delhi 110003
Email: biosafety-mef@nic.in

CONTENTS

Introduction

Genetically modified (GM) crops are plants used in agriculture, the DNA of which has been modified using genetic engineering techniques. In most cases, the aim is to introduce a new trait to the plant which does not occur naturally in the species like resistance to certain pests, diseases, environmental conditions, herbicides etc. Genetic modification is also done to increase nutritional value, production of pharmaceuticals, biofuels etc. GM crops are also referred as genetically engineered (GE) plants, transgenic crops, living modified organisms (LMOs) or biotech crops.

GM crops first introduced in USA in the mid-1990s, are presently widely cultivated and used globally. In 2017, GM crops were planted on 189.8 million hectares in 24 countries[1]. Additional 43 countries imported GM crops or their products for food, feed or other uses. GM crops currently grown are engineered mainly for insect resistance or herbicide tolerance. A total of 16 GM crops are cultivated in various countries out of which corn, soybean, cotton and canola are the four largest acreage.

In India, Bt cotton is the only GM crop approved for cultivation. It is grown on approx. 11 million hectares. Bt cotton, first grown in 2002 now occupies more than 90% of cotton area in the country. Several more crops such as chickpea, pigeonpea, corn, sugarcane, etc. are in various stages of research and field trials.

[1]ISAAA,2017

As with any new emerging technologies, safety concerns have been expressed with the use of genetically modified organisms (GMOs). The use of GMOs and products has been accepted more readily in healthcare, as these are directly beneficial for consumers. For example, Human insulin produced using GM bacteria was first approved in 1982. Presently, 100% of human insulin used globally is produced using GMOs. Several other therapeutics, vaccines, monoclonal antibodies are produced using GMOs. However concerns have been expressed about GM crops by some groups since their introduction, primarily because of the perception that modern biotechnology tools such as genetic engineering lead to creation of new species. Safety concerns associated with the use of GM crops broadly relate to risk to human and animal health, and environment. Safety concerns differ greatly depending on gene-crop combination.

Biosafety regulations are in place to review and approve various activities involving GMOs in all countries with active biotechnology programmes. In India, all GMOs including GM crops are regulated as per the "Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or commonly Cells" referred to as Rules, 1989 under the Environment (Protection) Act, 1986. The rules are supported by guidelines and protocols for evaluation of GM crops at various stages of development viz. contained research, confined fields trials and safety assessment. Despite continuous increase in adoption of GM crops and regulatory frameworks being strengthened, there have been polarised debates about the biosafety concerns related to GM crops.

Several opinions, discussions and statements about GM crops are regularly being published. Review of such documents indicates that there are several myths prevailing around this technology among the general public. Enhancing public awareness is one key component of UNEP/GEF supported Phase II Capacity building project on Biosafety implemented by Ministry of Environment, Forest and Climate change (MoEFCC), Government of India. Biotech Consortium India Limited (BCIL) is the Project Coordination Unit of the project. This booklet is an attempt to inform the readers with the basic scientific facts to clarify the myths surrounding the GM crops particularly about biosafety regulations, need and status, safety to health and environment and other issues.

Biosafety Regulations

1. Myth

Regulatory framework for GM crops in India is weak.

Fact

- India has been one of the early movers in the world to put in place a biosafety regulatory system way back in 1989. GMOs including GM crops are regulated as per the "Rules for the Manufacture/ Use/ Import/Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells" referred as Rules, 1989 notified under the Environment (Protection) Act, 1986. Rules, 1989 essentially cover entire spectrum of activities involving GMOs and products thereof including sale, storage, exportation, importation, production, manufacturing, packaging, etc.
- These rules are implemented by the Ministry of Environment, Forest & Climate Change (MoEFCC), the Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India and State Governments. Six competent authorities, their composition and roles have been notified under the Rules, 1989.
- While the RDAC is of advisory in function, the IBSC, RCGM, and GEAC are of regulatory function. SBCC and DLC are for monitoring purposes (Figure 1).

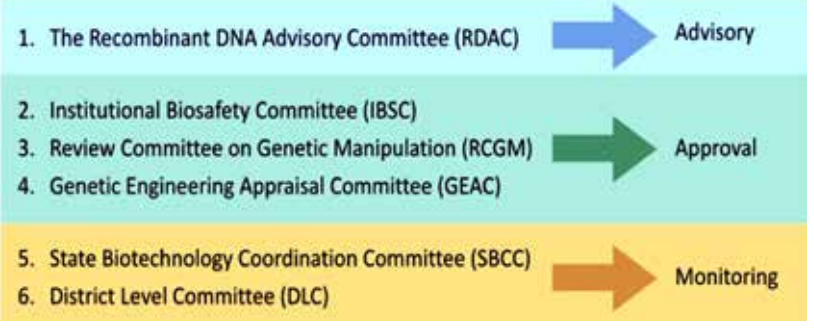


Fig 1: Competent authorities notified under Rules, 1989

- While the RDAC is advisory in function, the IBSC, RCGM and GEAC are of regulatory function. SBCC and DLC are for monitoring purpose.
- Various sub-committees and expert committees are set up by RCGM and GEAC on a case by case basis and comprise of experts from various disciplines drawn from public sector institutions to prepare and review various guidelines and biosafety data. Central Compliance Committees are also set up for monitoring of confined field trials on case by case basis. The process of seeking approval of confined field trials and environmental release of GM crops is given in Figure 2.

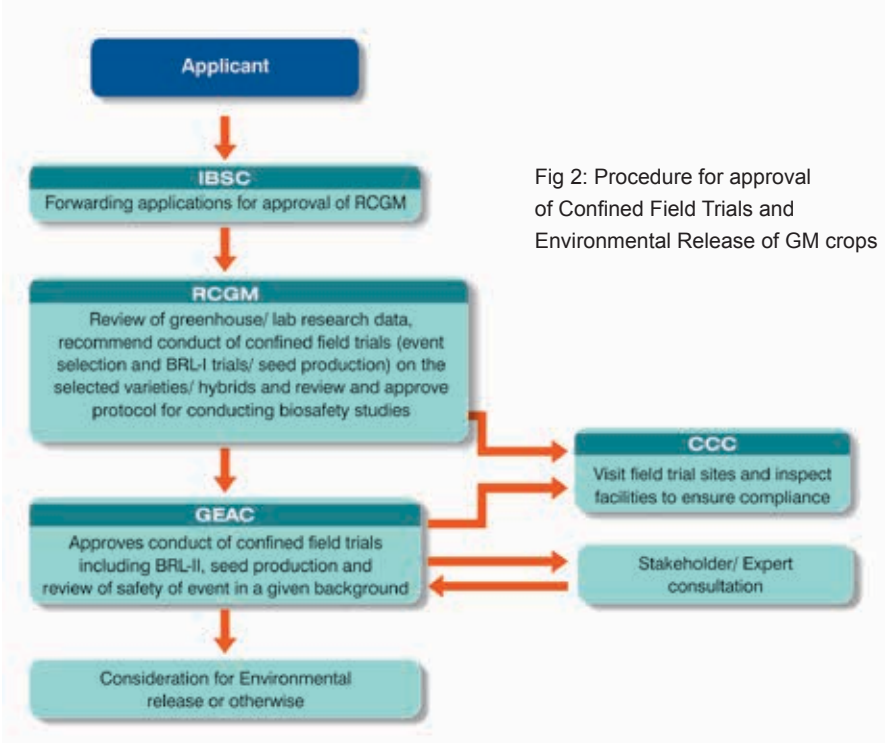


Fig 2: Procedure for approval of Confined Field Trials and Environmental Release of GM crops

- Regulation of import of germplasm/GMOs/transgenic plant material for research purpose is also covered under Plant Quarantine (Regulation for import in India) Order, 2003, Ministry of Agriculture.
- In addition, manufacture, storage, distribution, sale and import of foods which include GM food is also regulated as per the Food Safety and Standards Act, 2006, being implemented by the Food Safety and Standards Authority of India.

2. Myth

There are no proper guidelines and protocols for assessing the biosafety of GM crops in India. The data requirement for biosafety evaluation is biased to the international studies and have overlooked the topography and diversity of our country.

Fact

- Guidelines and protocols prepared through consultations with stakeholders, have been put in place regularly since the notification of the Rules, 1989 to ensure safety from the use of GM crops and products thereof in research and application.
- Guidelines to followed at each step of development process for GM crops viz contained use, confined field trials, food safety assessment and environmental safety assessment are indicated in Box 1 below.

Box 1: Biosafety Guidelines for GM crops in India

Contained Use (DBT)

- Recombinant DNA Safety Guidelines, 1990
- Recombinant DNA Safety Guidelines and Regulations, 1994
- Revised Guidelines for Research in Transgenic Plants, 1998

Confined Field Trials (MoEFCC and DBT)

- Guidelines for Conduct of Confined Field Trials of Regulated GE Plants, 2008
- Standard Operating Procedures (SOPs) for CFTs of Regulated, GE Plants, 2008
- Guidelines for Monitoring of Confined Field Trials of Regulated GE Plants, 2008

Food Safety Assessment (DBT and ICMR)

- Guidelines for the Safety Assessment of Foods Derived from GE Plants, 2008 (Updated in 2012)
- Protocols for Food and Feed Safety Assessment of GE Crops, 2008

Environmental Safety Assessment (MoEFCC and DBT)

- Guidelines for Environmental Risk Assessment (ERA) of GE Plants, 2016
- Risk Analysis Framework, 2016
- ERA of GE Plants: A Guide for Stakeholders, 2016

- Extensive review of guidelines in countries with functional regulatory systems and scientific advice by international agencies is also undertaken as part of formulating new guidelines.
- The data generated in the country is essential for consideration of any GM crops by the Indian regulatory authorities. In case of Bt cotton, data from years of field trials in different agro climatic zones and lab studies conducted in India was reviewed prior to its environmental release.

3. Myth

The data requirements about GM crops are not strict in India and are not been being supervised by competent experts

Fact

- The data requirements for safety assessment are extremely rigorous for GM crops and are defined by regulatory authorities. Developers of GM crops (both public and private sector) test their products according to regulatory requirements which include detailed documentation of testing.
- The safety tests such as allergenicity, toxicity, nutritional equivalance, compostion, effect on non-target organisms, etc. are conducted in certified research institutions and the scientific data is scrutinized by the regulatory authorities at each step. Regulatory authorities undertake thorough analysis of the data and the protocols used to ensure the validity of the results.
- The major committees include eminent experts from various premier research institutions across the country.
- The safety assessments are made through experiments based on scientific principles under their expert supervision and the results are reviewed at multiple levels.

4. Myth

Biosafety data are produced by the technology developer themselves and therefore are unreliable.

Fact

- The responsibility for demonstrating the safety of any new regulated product in the market lies with the developer of that product. This is the procedure for new drugs and pharmaceuticals, pesticides and other such regulated products in India.
- GM products are no exception and the responsibility of generating the data lies with the technology developers, in accordance with the guidelines based on internationally accepted principles and protocols issued by the Government.
- The data requirements for safety assessment are extremely rigorous for GE plants.
- Developers of GE plants (both public and private sector) test their products according to regulatory requirements which include detailed documentation of testing.
- The data is analysed by regulatory authorities to ensure the validity of the results.
- Additional information and additional testing may be asked by the regulatory agencies, if the data is not sufficient.
- Such reviews are standard scientific methods of evaluation used by regulators around the world to evaluate the health and safety of a variety of products including food and drugs.
- Similar systems are in place in biosafety regulatory authorities in other countries such as USA, Canada, Europe, Australia, Brazil, South Africa etc.

5. Myth

Field trial of GM crops should be conducted in closed environment or only after complete safety assessment has been done.

Fact

- The data to be generated for safety assessment of a regulated GM crops involves research/ experiments to be undertaken both under contained facilities as well as confined field trials (CFTs) with an objective to make a comparative assessment and determine if the GM crops is as safe as its conventional non-GM counterpart.
- CFTs are small-scale field experiments to address biosafety requirements and evaluate the performance of specific trait(s) in GM crops.
- Data which fully represent the response of plants to the conditions likely to be encountered in a particular agro-ecological environment, can be collected only by growing the plants outdoors in CFTs, as it is virtually impossible to comprehensively replicate the outdoor environment in a closed environment such as greenhouse.
- The conduct of CFTs is an essential step for assessing the impact of GM crops on health and environment, and regulatory agencies have put in place elaborate guidance and mechanism to ensure that such field trials are conducted in a safe manner.
- Data regading impact on gene flow, non-target organisms, weediness potential, soil microflora etc can be collected only by field evaluation. Without the field data, developers cannot make scientifically tenable predictions about the performance of the GM crops in the field or about the environmental safety of these plants.

GM Crops: Need and Status

6. Myth

Genetic Engineering in plants is not needed; the existing farming techniques should be improved to solve various problems.

Fact

- Farmers regularly need new technologies and guidance on management practices not only to increase productivity, but also to deal with drought, salinity, diseases, weed management, nutrition enhancement, pest attacks, etc. For thousands of years, farmers have relied on selective breeding and cross-fertilization to impart desirable traits in plants using trial and error method.
- However, as characteristics of interest do not always exist in related species, GM crops are developed to bring together useful genes from a wide range of living sources for development of superior plant varieties.
- Genetic engineering unlike conventional breeding, allows scientist to move genetic material between organism that could not be bred through classical means.
- It is also to be noted that GM is not a replacement for traditional breeding, rather it compliments for crop improvement, as one of the promising tools.
- GM crops have been developed to incorporate various traits such as insect/pest resistance, herbicide tolerance, disease resistance, altered nutritional profile, enhanced storage life etc. for:
    * higher crop productivity due to reduced loss to pests and diseases.
    * reduction in farm costs and thereby increase in farm profit.
    * general improvement in health and environment due to availability of nutritionally enhanced food.

* reduced use of pesticides/ insecticides in the environment which would further reduce the fuel consumption and also led to preservation of natural resources like soil and water due to decreased tillage.
* improved weed control due to use of herbicide resistant GM crops.

Potential benefits of various traits incorporated in the GM crops are summarized in Figure 3.

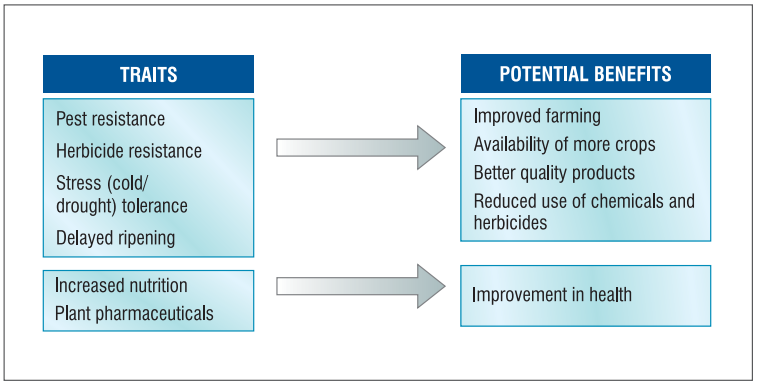


Fig 3: Potential benefits of Genetic engineering in plants

7. Myth

Genetic modification of plants is unnatural and it could turn into a menace.

Fact

- Gene exchange between organisms has been taking place in nature since millions of years along with mutations and is the basis of evolution.
- Humans have been selectively breeding plants and animals for millions of years, therefore all domesticated plant species and even animals are genetically modified. All the living organisms can be modified because of presence of a molecule called Deoxyribonucleic acid (DNA) in every cell of all the organisms. DNA is the molecule that carries the genetic blueprint for life as it stores the genetic information responsible for the inheritance of traits such as size, shape, colour, build and other physical attributes of microorganism, plants, animals and humans.
- Genetic engineering involves copying and transfer of genes from one organism to another

in a scientific and precise manner (Figure 4). GM crops are thoroughly tested for their safety to health and the environment as compared to their counterparts prior to release in the environment by regulatory authorities for large scale cultivation.

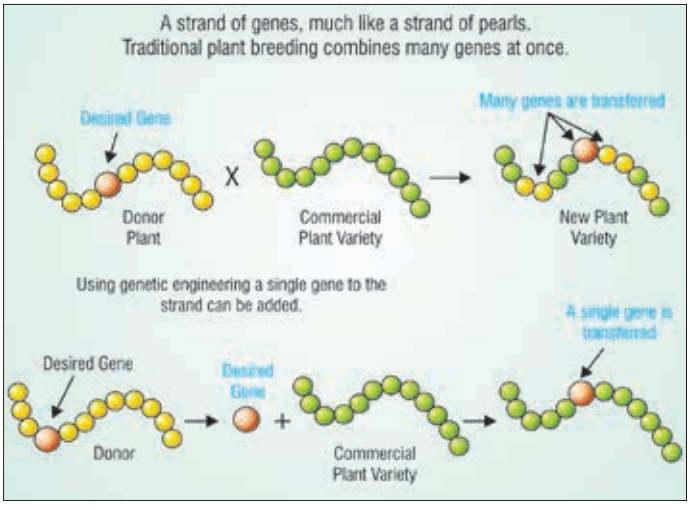


Fig 4: Traditional Plant Breeding vs Genetic Engineering

8. Myth

GM crops have not been responsible for yield increase and therefore cannot be relied for food security.

Fact

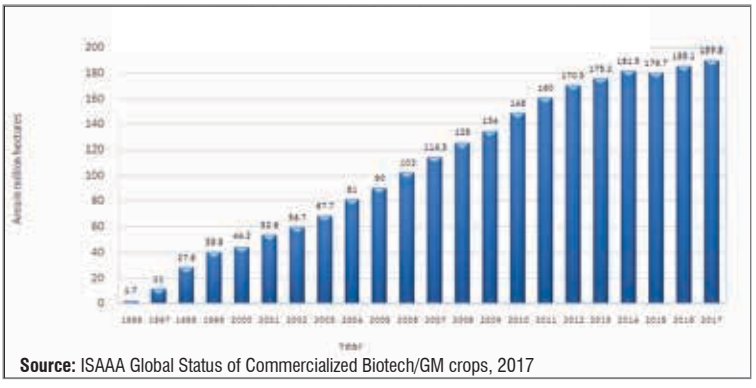
- GM crops are developed for specific traits. Most of GM crops that are cultivated globally are mainly for insect resistance, disease resistance and herbicide tolerance. These are not responsible for yield increase per se, but indirectly they do, as there is a significant reduction in losses due to pests, diseases and weeds. Savings from such losses have significantly contributed to increase in production.
- As a result there has been a continuous increase in adoption of GM crops in many countries.
- GM crops are also being developed to address challenges such as drought, salt, improved nutritional quality etc and are expected to contribute to food security.

9. Myth

GM technology is adopted by only a few countries and its non-acceptance by the most developed countries raises doubts about the efficacy of the technology.

Fact

- Beginning from the initial planting of 1.7 million hectares in 1996 when the first GM crop was commercialized, GM crops were planted on 189.8 million hectares in 2017 (Figure 5).



Source: ISAAA Global Status of Commercialized Biotech/GM crops, 2017

Fig 5: Global Area of GM Crops

- The rate of adoption of GM crops is significant, at times more than 90% in almost all countries where these crops are grown. For example, the area under Bt cotton cultivation in India has reached to 93-96% of the total cultivable cotton area since 2012-2013 to 2017-2018 (Figure

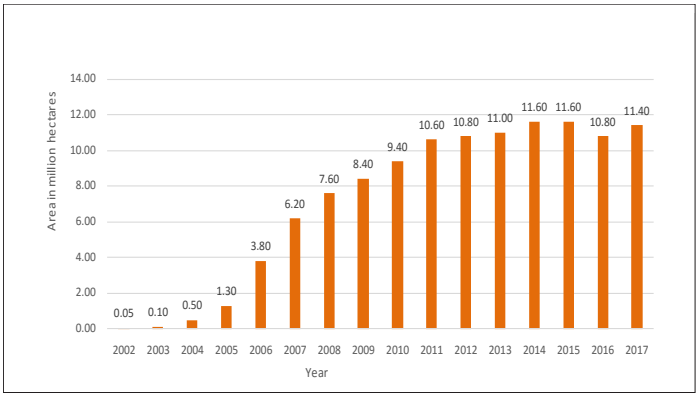


Fig 6: Area under Bt Cotton cultivation in India

- Maximum adoption of GM crops occurred in six countries (USA, Brazil, Argentina, India, Canada, China). This is because these countries have agriculture as a dominant economic activity. USA, Brazil, India and China are among the top 10 producers of various agricultural commodities in the world.
- European Union countries, Russia, Japan, Korea etc. do not cultivate GM crops and are not dependent on agriculture for their economies. These countries are mostly importers of agriculture products. Most of these countries have approved GM crops for food and feed use and are actually importing large quantities of products derived from GM crops.

Safety Concerns

10. Myth

GM crops are not adequately tested.

Fact

- Evaluating the safety of GM crops is a comprehensive process that involves several steps.
- Systematic safety assessment methodologies are in place that have been agreed on years of consultations under the aegis of international organizations and agreements viz. Food and Agriculture Organization (FAO), World Health Organization (WHO), Codex Alimentarius Commission, Organisation for Economic Co-operation and Development (OECD) and Cartagena Protocol on Biosafety.
- The potential changes introduced using genetic engineering are assessed using comparative risk assessment approach. The underline assumption of this comparative approach is that traditionally cultivated crop has a history of safe use and thus serves as the comparator. As a consequence, safety assessment process gives conclusion on whether or not the GM crop is as safe as its conventional non-GM counterpart.
- Safety assessment studies required for commercial release of GM crops comprise of food and feed safety assessment and the environmental risk assessment coupled with information through the molecular characterization of the GM crops and characterization of the expressed, transgenic proteins (Box 2).

Box 2: Broad Information Requirements for Safety Assessment of GM crops

Effect of Genetic Modification and Protein Characterization

- Description of the GM crops
- Description of the biology of the non-modified host plant
- Description of the donor organism
- Description of the genetic modification
- Inheritance and stability of inserted gene(s)
- Molecular characterization
- Function/ specificity/ mode-of-action of expressed protein
- Protein expression levels
- History of safe use and consumption

Food and Feed Safety

- Toxicity assessment by animal toxicity studies such as acute and sub-chronic studies
- Assessment of allergenicity by comparing amino acid sequence homology of the newly expressed protein.
- Heat stability and susceptibility of the expressed protein to pepsin digestion
- Compositional analysis by comparing changes in the level of key nutrients, natural toxicants or anti- nutrients, secondary metabolites, physiologically active (bioactive) substance etc
- Livestock feeding studies
- Effect of processing

Environmental Safety

- Confirmation of expression level of new proteins: Quantify the expression level of the gene product associated with each introduced trait
- Field trial locations and experimental designs
- Description of the phenotype of the transformed plant
- Plant growth and specific observations recorded during the field trials
- Changes in weediness and aggressiveness potential
- Susceptibility to diseases and pests.
- Impact on non-target and beneficial organisms like predators, soil micro flora etc
- Changes in gene flow pattern through pollen flow studies and crossability studies with sexually compatible relatives

- Govt of India is following a case by case safety assessment of GM crops. The information requirement and analysis by regulatory authorities depends on the development stage of a particular product. Data requirement may also vary depending on the crop specific trait and intended use.

11. Myth

GM crops and the food derived from them are not safe.

Fact

- Different GM crops include different genes inserted in different ways. Accordingly, GM crops containing specific genes and their safety is assessed on a case-by-case basis.
- It is not possible to make general statements on the safety of all GM crops being developed.
- GM crops are permitted to be grown only after they have passed safety assessments and are not likely to pose risks for human health and environment.
- Food, feed and environmental safety data produced during such studies are carefully examined at all stages by regulatory authorities and several technical committees constituted by them. Only after being satisfied with the scientific data, approvals are given for their commercialization.
- Major scientific bodies and regulatory agencies in the world have reviewed such research data and rendered GM crops and the food derived from them as safe. These include the National Academy of Sciences (USA), World Health Organization, Food and Agriculture Organisation, the American Medical Association and the Royal Society of Medicine (UK) along with major science academies in India.

12. Myth

If livestock consume GM crops, there are chances of presence of transgenes in food product (meat, milk and eggs) derived from them.

Fact

- Genes are part of all living organisms including conventionally bred plants and animals. Human or animals eat genes whenever they eat any kind of food.
- Transgenic genes or expressed novel proteins present in GM crops are broken down during the digestion process in the same way as other genes or proteins.

13. Myth

GM crops contain antibiotic resistance genes that can affect human health.

Fact

- In the process of genetic modification, antibiotic resistance genes are used as markers for identification of cells into which the desired gene has been successfully introduced.
- Concerns have been expressed about the possibility of transferring these genes from GM crops/foods to bacteria that is normally present in the human gut and resulting in the development of antibiotic resistance in these bacteria.
- There have been numerous scientific studies on this issue and it has been concluded that the likelihood of antibiotic resistance gene moving from GM crops to any other organism is extremely remote ($< 10^{-14}$ to 10^{-27}) or virtually zero.

14. Myth

Food with GM crops contain fewer nutrients.

Fact

- Detailed compositional analysis is an essential part of the safety evaluation process.
- Prior to approval, it is necessary to demonstrate that GM crops being cultivated are as nutritious as food from comparable traditionally bred plants.
- Nutritionally enhanced GM crops are also being developed with an objective to increase levels of specific nutrients for e.g. Golden Rice with increased Vitamin A, biofortified Maize, etc.



15. Myth

There are long-term health effects of food from GM crops.

Fact

- The only difference between a GM crop as compared to its non-GM counterpart is the inserted gene and its expressed protein.
- The safety of the consumption of this protein is established based on its biological properties and tests of digestibility, acute toxicity, allergenicity.
- Once this is done and safety established then the compositional equivalence confirms that the GM crop/food is similar to corresponding non-GM which has been used/consumed traditionally for generations and hence no long-term effects are expected to be seen based on the history of safe human use.

16. Myth

GM crops can contaminate and cross pollinate with non-GM crops and could lead to the creation of superweeds and insecticide resistance in plants.

Fact

- Gene flow between related plant species is a natural, biological process that has been integral to the domestication of crops and constant improvement through selection and breeding.
- The GM crops are comparatively assessed with its non-GM counterparts extensively for any changes in for intra- and inter- specific gene flow with compatible species.
- Safety assessments completed so far on crops approved for commercial release have concluded that gene flow for GM crops to wild relatives pose no risk to the environment.

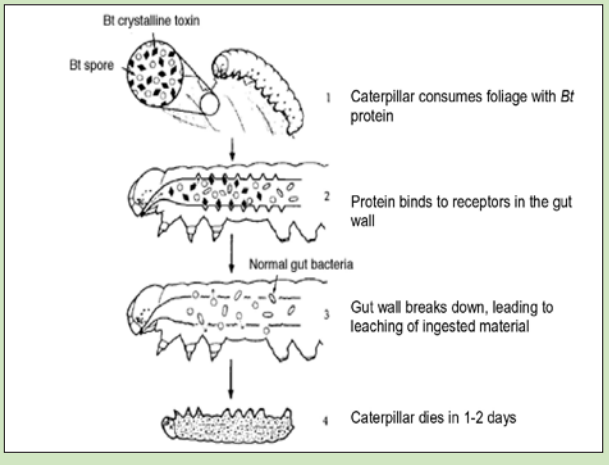
17. Myth

GM crops are a threat to non-target organism like bees, butterflies and other pollinators.

Fact

- Potential risks to birds, mammals, fish, pollinators such as bees, predators, parasitoids, decomposers such as earthworms and other beneficial organisms are assessed to ensure there is no unintended harm with GM crops having pest or disease resistance traits. So far, no negative impact of GM crops to the environment relative to the production of non-GM crops have been reported.
- Insect resistant GM crops for example, Bt cotton have a built-in mechanism of protection against targeted pests. Bt protein (insecticidal protein) expressed by the inserted gene is highly specific to receptors in insect gut wall of target insect.
- Bt toxicity depends on recognizing these receptors and damage to the gut by the protein occurs upon binding to that receptor. Each species possesses different types of receptors that will match only to certain insecticidal proteins, like a lock to a key. In view of this specificity, beneficial insects or any other organisms are not harmed by proteins produced by a particular strain of Bt.

Mechanism of action of Bt protein



The spores of *Bacillus thuringiensis* (Bt) contain a insecticidal crystalline protein (*cry*), which breaks down to release a protein, known as delta-endotoxin, which is highly toxic to lepidopteran larvae. Different *cry* genes, also known as Bt genes have been identified, cloned and characterized. Effective gene constructs have made it possible to deliver these genes into plant tissues so that they are expressed at levels high enough to kill the target insects.

18. Myth

Insect resistant GM crops such as Bt cotton is responsible for emergence of new pest or dominance of secondary pests. It has not reduced the use of insecticides nor brought profits to our farmers as claimed.

Fact

- Secondary pests used to occur even before the advent of Bt cotton, but were controlled due to repeated spraying mainly against bollworms.
- After the introduction of Bt cotton, the insecticide usage has been drastically reduced. Bt gene is only effective against bollworm complex and therefore appropriate control measures needs to be taken against minor pests in time to prevent damage.
- Such crop management lapses are not attributed to Bt cotton. To get the complete benefit of this technology, the perfect approach is integrated pest management (IPM) where Bt cotton is relied upon to control bollworms while it is necessary to be vigilant and take suitable control measures against those pests not controlled by Bt cotton.
- Various studies and surveys carried out in India by both the national and international agricultural scientists and economists have clearly demonstrated effective control of bollworms due to introduction of Bt cotton. As a result of this, production and average yield in case of Bt cotton has increased.
- The use of improved hybrids specific to agro-climatic zones further assisted to upsurge the production. Also, the insecticide sprays for bollworm control have been drastically reduced. This led to a more farmers adopting this technology, as it helped them to increase their income.
- Cotton production in India tripled from 13 million bales in 2003 to 35 million bales in 2016.
- India ranked first in the global cotton production in 2016. The production of cotton seed, and its byproducts as oil and meal, has also increased manifold. The increase in production of Bt cotton based oil is from 0.46 million tons in 2002-03 to 1.50 million tons in 2016-17.

Other Issues

19. Myth

Farmers have to purchase GM seeds from the seed companies every time thus rendering them ever dependent on seed companies for supply of seeds. GM crops increase the price of food.

Fact

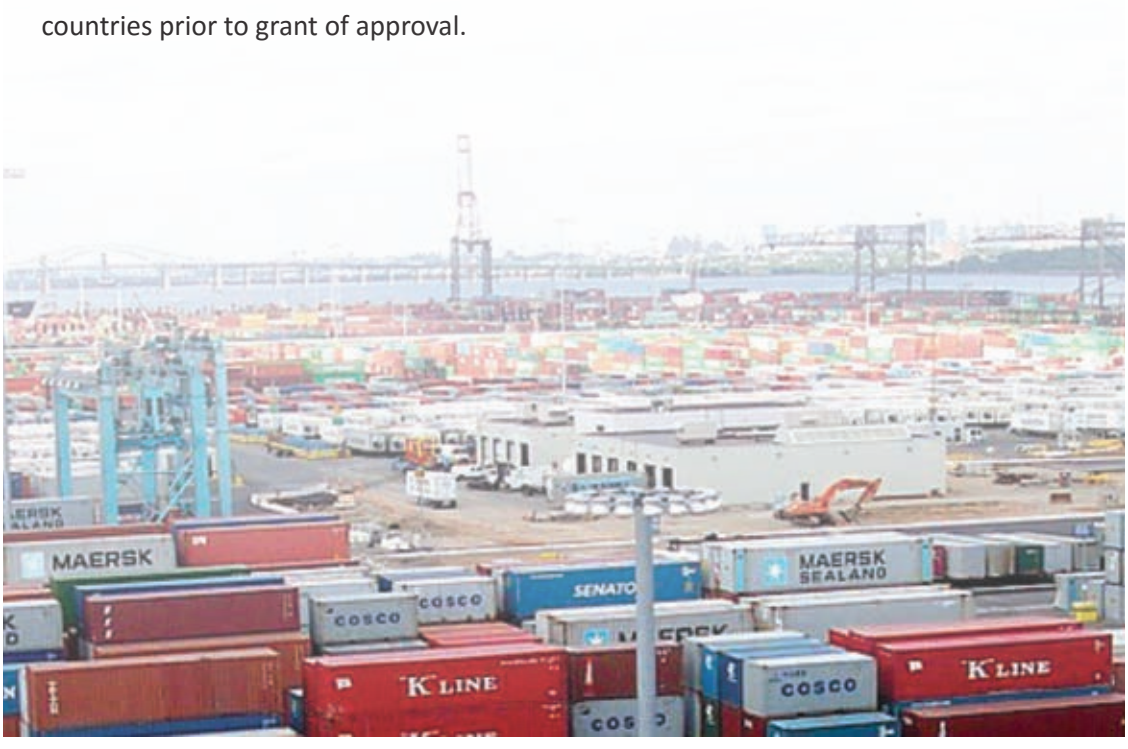
- The hybrids are produced by crossing two different varieties of the same crop plant and thereby incorporate certain desirable characteristics of both plants. The reason why farmers have to purchase seeds in case of hybrid cultivation, is because only F1 (First Generation) seeds are recommended as there is a possibility of segregation of the parental traits during the F2 seeds thereby reducing the optimum productivity. This is applicable for both non-GM and GM hybrids.
- Regarding the concern relating to purchase of GM seeds every year by the farmers, it depends on whether he is growing a variety or a hybrid.
- As in the conventional seed production, farmers can save seeds in case of varieties, but in case of hybrids they will have to purchase it every year. The same practice has to be followed in GM crops.
- The price of the GM crops and food derived from them is determined on case by case basis. Factors such as source of technology, licencing conditions, demand and supply etc. play an important role in the price for farmers and consumers, as with any other consumer products.

20. Myth

Growing GM crops prevent exports.

Fact

- Growing GM crops does not stop a country from exporting agricultural products to other countries. Several countries including U.S, Canada, Brazil, Argentina, Australia, China and South Africa that grow GM crops continue to export products derived from GM crops to countries around the world.
- The export of GM crops and products thereof requires approval for use in importing countries. From the scientific perspective, food safety data is assessed by the importing countries prior to grant of approval.



KEY CONTACTS

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Adviser, MoEFCC, Vice Chair, GEAC

Dr. Murali Krishna Chimata
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Ministry of Environment Forest and Climate Change

Ministry of Environment, Forest and Climate Change
Government of India
Indira Paryavaran Bhawan, Ali Ganj, Jor Bagh Road, New Delhi- 110003

Project Coordination Unit

BCIL
Biotech Consortium India Limited
Anuvrat Bhawan, 5th Floor, 210, Deen Dayal Upadhyaya Marg, New Delhi- 110 002

For further information, please contact: E-mail: biosafety-mef@nic.in