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FREQUENTLY ASKED QUESTIONS

Genetically Engineered Plants and Biosafety

SOUTH ASIA
BIOSAFETY PROGRAM

South Asia Biosafety Program

The South Asia Biosafety Program (SABP) is dedicated to assisting Bangladesh and India in further strengthening institutional governance of biotechnology. Managed by the Agriculture & Food Systems Institute (AFSI), SABP works with its in-country partners to:

- Identify and respond to technical training needs for food, feed, and environmental safety assessment.
- Develop a sustainable network of trained, authoritative local experts to communicate both the benefits and the concerns associated with new agricultural biotechnologies to farmers and other stakeholder groups.
- Facilitate systems for permitting the safe conduct of experimental field trials of new crops developed using biotechnology so that scientists and farmers can evaluate them.
- Raise the profile of biotechnology and biosafety on the policy agenda within Bangladesh and India and address the policy issues within the overall context of economic and agricultural development, international trade, and environmental sustainability.

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Biosafety Resource
Book Series

FREQUENTLY ASKED QUESTIONS

Genetically Engineered Plants and Biosafety

Prepared by

SOUTH ASIA
BIOSAFETY PROGRAM

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1 Preamble

The first Genetically Engineered (GE) plant, also called Genetically Modified (GM) crop, was approved for cultivation in 1994 in the USA. Since then, the global area under GE plants has increased to 190.4 million hectares in 2019. Bangladesh is one of the countries growing GE crops. Till date, Bt brinjal is the only GE plant approved for cultivation in Bangladesh.

As with any new technology, the general public may have questions or concerns, including those related to the safety of new plants. To answer some of those questions and shed light on the concerns, SABP designed this booklet, *Frequently Asked Questions: Genetically Engineered Plants and Biosafety,* to explain information about GE plants in easy and understandable language.

BIOSAFETY RESOURCE BOOK SERIES

The South Asia Biosafety Program (SABP) has been operating in Bangladesh since 2005 to strengthen institutional governance of biotechnology, including through development of regulatory documents, manuals, and assessment guidelines. SABP is also involved in capacity development of the research community to ensure proper implementation of biosafety regulatory processes. This booklet is the second installment in the *Biosafety Resource Book Series* and has been prepared as a part of SABP's capacity development interventions.

Facilitating the implementation of transparent, efficient, and responsive regulatory frameworks for products of modern biotechnology in South Asia

About Us

The South Asia Biosafety Program (SABP) started its mission to facilitate the implementation of transparent, efficient, and responsive regulatory frameworks for products of modern biotechnology in South Asia in 2005. Supported by the United States Agency for International Development (USAID) and managed by the Agriculture & Food Systems Institute, SABP works to assist South Asian countries to further strengthen institutional governance of biotechnology by providing technical assistance to the biosafety risk assessment and research communities.

South Asia Biosafety Conference

SABP's flagship event is the South Asia Biosafety Conference (SABC), which is now the preeminent gathering of scientists, policy makers and other biosafety practitioners in South Asia. SABC draws a diverse multi-disciplinary, multi-stakeholder audience coming from regulatory agencies, public research institutions, the private sector, and non-governmental organizations, in South Asia and around the world. Conference topics respond to regional priorities, spanning biotechnology and biosafety research, risk assessment and regulation, and science communication and stakeholder engagement.

Resources

SABP NEWSLETTER

Since the first issue in May 2005, the SABP Newsletter has been published monthly, with over 190 issues sharing information about science and activities in South Asia. The newsletter is circulated electronically and in print to over 25,000 organizations and individuals.

BANGLADESH BIOSAFETY PORTAL
bangladeshbiosafety.org

Launched in 2017 by SABP, the Bangladesh Biosafety Portal serves as the only consolidated repository of documents that inform biosafety regulation in Bangladesh. The portal provides information and links to useful national and international technical resources, including the *User's Guide to Biosafety Regulatory Process for GE Plants in Bangladesh*—the definitive informational resource for applicants and other stakeholders interested in understanding biosafety regulation in Bangladesh.

Biosafety Research in Bangladesh Grants Program

With funding from the USAID Mission in Dhaka, SABP launched the Biosafety Research in Bangladesh Grants Program (BRBGP) in 2019. This competitive grants program is designed to help support the development of a biosafety research community of practice in Bangladesh and promote inter-institutional collaboration and partnerships. Annual awards of up to **$25,000** are made available through the BRBGP for research that will expand the knowledge base for risk assessment of agricultural biotechnologies in Bangladesh.

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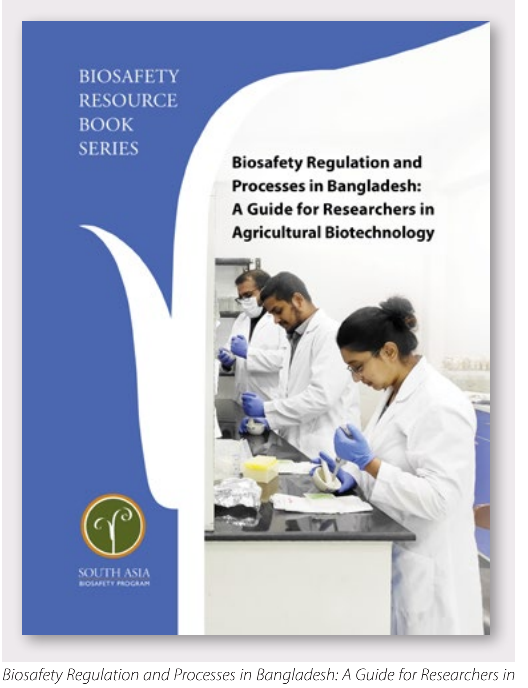
The first installment in the series, *Biosafety Regulation and Processes in Bangladesh: A Guide for Researchers in Agricultural Biotechnology*, was published on November 19, 2020. It outlines the regulatory processes functioning at different stages of research and development of GE crops. Under the present biosafety regime, it is crucial to follow these steps to take the GE research outcomes from the laboratory to the field and subsequently, to the farmers. The first chapter gives an overview of the biosafety regulations in Bangladesh, and the second chapter outlines different issues that need to be considered at the beginning of an agricultural biotechnology project. They are followed by a description of the different steps in an application to conduct laboratory work on GE crops (Chapter 3). The final chapter (Chapter 4) deals with the application process for the cultivation of GE crops in confined field trials, as well as release for field cultivation.

Electronic versions of all booklets in the *Biosafety Resource Book Series* may be downloaded at: bangladeshbiosafety.org/biosafety-books



Biosafety Regulation and Processes in Bangladesh: A Guide for Researchers in Agricultural Biotechnology was published on November 19, 2020.

2 Frequently Asked Questions

1. What are Genetically Engineered (GE) plants?

- Genetically Engineered (GE) plants are plants, where the genetic material (DNA) has been altered using modern biotechnological techniques (i.e., genetic engineering). In most cases, the aim of such activities is to introduce a new trait(s) into the plants.
- The term Living Modified Organism (LMO) is also used for GE plants and other Genetically Modified Organisms (GMOs). An LMO is defined as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. In everyday usage, LMOs are considered to be the same as GMOs and GE organisms.
- Foods produced from or using GMOs, including GE plants, are often referred to as genetically modified (GM) foods or genetically engineered (GE) foods. Examples include GE plants that are sold as food commodities (such as GM potato, GM maize, and GM papaya) and/or are further processed into food ingredients (such as GM canola for modified oil composition).

2. Why make GE plants?

- Farmers regularly need new technologies and guidance on management practices, not only to increase productivity, but also to deal with environmental stresses, such as drought, salinity, and biotic stresses, such as diseases, pests, etc.
- Because beneficial traits to address these stresses do not always exist in related species, GE plants are developed to bring together useful genes from a wide range of living sources for the development of superior plant varieties.
- Plants have been genetically engineered for benefits, such as:
  - higher crop productivity and quality by reducing loss due to pests and diseases
  - reduction in farm costs and thereby increase in farm profit
  - nutritionally enhanced food
  - reduced use of pesticides/insecticides in the environment, which would further reduce the fuel consumption, and also lead to preservation of natural resources like soil and water due to decreased tillage
  - improved weed control due to the use of herbicide resistant GE plants

3. How does genetic engineering in plants differ from traditional plant breeding?

- The objective of both genetic engineering in plants and traditional plant breeding is to produce plants with improved characteristics by changing their genetic material. In the case of plant breeding, this is achieved by crossing two plants that have relevant characteristics, and then selecting the offspring from the progeny that shows the desired combination of characteristics inherited from the two parents. On the other hand, genetic engineering achieves preferred features by introducing one or more desired genes precisely into the host.

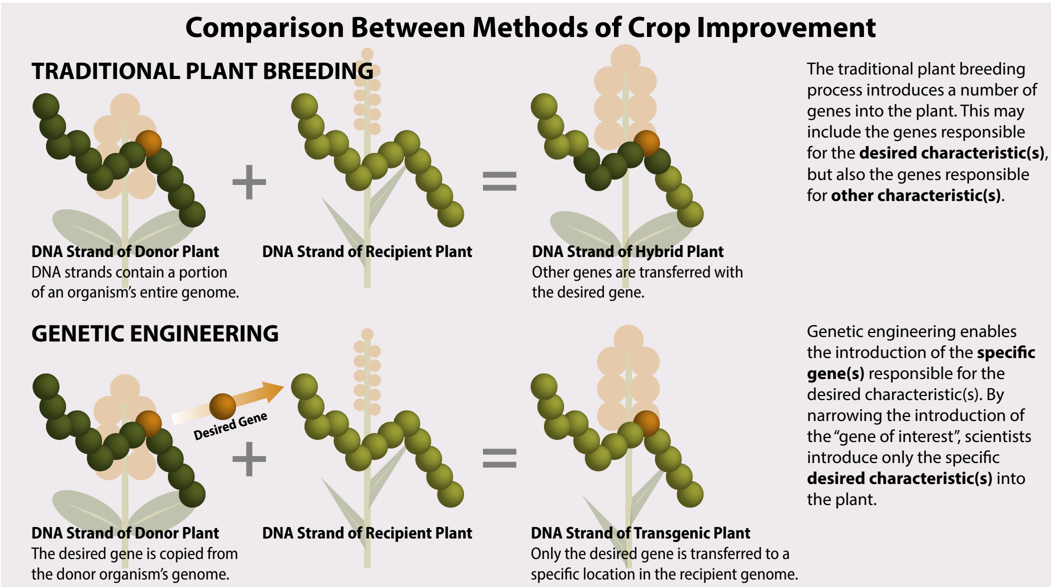


Figure 1: Graphical representation of gene introduction through traditional plant breeding and genetic engineering techniques.

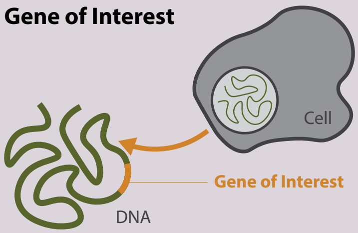
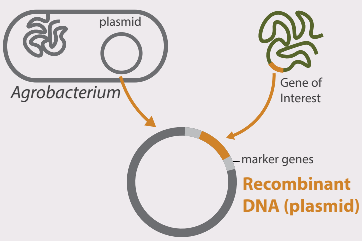
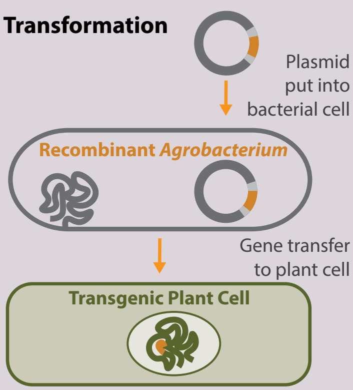
Table 1: Comparisons between traditional breeding and genetic engineering techniques in plants.

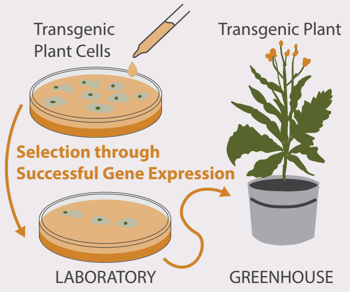
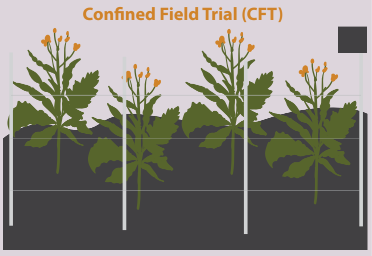
TRADITIONAL PLANT BREEDING	PLANT GENETIC ENGINEERING
Practiced for hundreds of years	Relatively new technique beginning in the 1980s
Involves random transfer of thousands of genes	Involves introduction of one or more desired genes precisely into the host organism for the development of desired features
Takes many years to produce the desired trait/ gene introduction in the progeny as gene combination is random	Faster as specific trait is introduced in a precise manner
Allows introduction of genes from within the plant species or from closely related plants	Enables introduction of useful genes, not just from within the plant species or from closely related plants, but also from a wide range of other organisms

4. What are the steps involved in the development of a GE plant?

- Genetic engineering involves identification, isolation, and transfer of genes (DNA) from one organism to another. This is possible because genetic code is universal, i.e., the DNA of all organisms is made-up of the same building blocks and is encoded in exactly the same way. Adding a specific stretch of DNA (a gene) into the plant's genome gives it a new or modified characteristic. The plant with this additional piece of DNA is called a GE plant. The seeds of this GE plant will also have this additional DNA. Thus, the progeny produced by these plants will also contain the additional DNA and the characteristics imparted by the gene.
- Transformation is a natural process, and although it is very rare, it has been known to occur without human intervention. For example, the sweet potato contains DNA sequences that were transferred thousands of years ago, from *Agrobacterium* bacteria into the sweet potato genome.

Table 2: General steps involved in the development of a GE plant.

STEP	EXPLANATION
Identification of the Gene of Interest  	The first step is the identification of a gene(s) responsible for a desired trait in an organism (plant, animal, or microorganism), followed by isolation and copying of the gene of interest by the use of molecular biology techniques.
Designing the Gene Construct for Insertion  	A gene construct consists of a gene of interest associated with the necessary regulatory sequences to ensure that the gene is turned on or off at the appropriate time and in the appropriate tissues of the plant. One or more marker genes may also be added that allow for easy identification of GE cells/tissues. Markers can include visual traits, such as color or fluorescent proteins, or may include antibiotic or herbicide resistant genes. The construct may also include sequences that help with the transformation process.
Transformation  	The gene construct is transferred to the host (target) plant by a process called transformation. For GE plants, the most frequently used method is the *Agrobacterium*-mediated transformation. In this method, the gene of interest is transferred into the *Agrobacterium tumefaciens*, which then transfers the new DNA to the genome of the plant cells. The plant cells that have successfully taken up the DNA are then grown to create a new plant.

STEP	EXPLANATION
Selection and Verification of Transformation 	Following the transformation process, plant tissues are transferred to a selective medium (such as containing an antibiotic or herbicide), depending on the type of selectable marker used. Only the plant tissues expressing the selectable marker gene will survive, indicating that they possess the gene of interest. Later, whole plants are generated using tissue culture methods for further evaluation in laboratories and green houses. The evaluation includes activity of the introduced genes, inheritance of the genes by the host plant generation after generation, and any unintended effects on plant growth, yield quality, etc.
Field Trials and Safety Assessment 	The next step in the process is multi-location and multi-year evaluation trials in the field environment to test the effectiveness of the inserted gene and the plants' overall performance. The field trials of GE plants are conducted in confined conditions under specified terms and conditions that are intended to mitigate the establishment and spread of the plant. Such trials are referred to as Confined Field Trials (CFTs). GE plants are thoroughly assessed for their safety to human health and the environment in comparison to their conventional counterpart prior to release for commercial cultivation.

5. Which traits/genes have been introduced into GE plants?

- GE plants have been developed to incorporate a variety of traits, such as insect/pest resistance, disease resistance, herbicide tolerance, altered nutritional profile, enhanced storage life, as well as others. Several commercially important plants, such as cotton, maize, soybean, tomato, potato, mustard, rice, etc., have been genetically modified. Insect resistance and herbicide tolerance are the two traits introduced most frequently and being widely cultivated, as follows:
  - **Herbicide Tolerance**
    - Many effective broad-spectrum herbicides do not distinguish between weeds and crops, but crop plants have been modified to make them resistant to these herbicides, to eliminate weeds more selectively.
    - Genes that provide resistance to commonly used herbicides have been identified and transferred to produce herbicide tolerant cotton, soybean, and corn. Resistance to these types of broad-spectrum herbicide–which would usually kill both weeds and plants–means that efficient weed control is possible because the herbicide can be applied while the plant is growing, without damage.
  - **Insect Resistance**
    - The commonly found soil bacterium *Bacillus thuringiensis* (Bt) produces a group of crystalline (*Cry*) proteins, which are toxic for certain insects, but do not harm many other insects or other animals. *Bacillus thuringiensis* is used as an insecticide spray in organic farming and in forestry. Genes for several *Cry* proteins have been introduced into many plants by genetic engineering.

- *Cry1* proteins, the most commonly used in GE plants, break down to release a toxin, known as delta-endotoxin, which is highly toxic to lepidopteran larvae. Different Cry genes, also known as Bt genes, have been identified and characterized. Effective gene constructs have made it possible to deliver these genes into plant tissues so that they are expressed at levels high enough to kill the insects. Bt cotton and Bt maize, which have increased resistance to boll worms, have been cultivated since 1996.
- Insect resistant GE plants give several folds benefit. These GE plants are less vulnerable to pests and reduce use of pesticide; reduce yield losses and provide a better-quality yield due to reduced pest damage; increase farm income by reducing the expenses for pesticides; reduce exposure of farmers to harmful effect of pesticides. There are positive impacts on the environment due to the lower use of chemicals. The overall reduction in the number of the specific target pests can even benefit neighboring fields that are not growing insect resistant plants.

Disease Resistance

- Plants are susceptible to viral, bacterial, and fungal diseases. Much progress has been made in evolving transgenic plants resistant to various diseases, particularly viral diseases. Virus resistant papaya is one of the examples.
- These plants reduce yield loss due to disease without affecting the quality of the plant.

Environmental Stress Tolerance

- In addition to the biological challenges to plant growth and development, plants need to cope with environmental or 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 disease resistance, into many plants through crossbreeding, their success at creating plants resistant to abiotic stresses has been limited, largely because only a few plants have close relatives with genes for resistance to these stresses. To overcome this situation, genetic engineering is also being increasingly used to develop plants that can tolerate difficult growing conditions. Researchers have identified many genes involved in cold, heat, drought, and salt tolerance found naturally in some plants and bacteria and incorporated them into plants.

Nutritional Value-Added GE Crops

- Value-added GE crops have been developed using genetic engineering, such as tomato varieties exhibiting delayed ripening, transgenic potatoes with increased levels of starch, golden rice containing beta carotene (precursor of vitamin A), etc.

Confined field trial of Golden Rice, conducted by the Bangladesh Rice Research Insitute.

Box 1: Examples of GE Plants - Plants being subjected to genetic improvement for multiple traits include several commercially important plants, such as maize, soybean, tomato, cotton, potato, mustard, and rice, horticultural plants, such as papaya and plum, forage crops, such as alfalfa, and trees, such as poplar, rubber, etc. Examples of some such GE plants are given here.

EXAMPLES OF GE PLANTS

Insect resistant cotton: GE insect resistant cotton contains a built-in insecticidal protein from natural occurring soil microorganisms *Bacillus thuringiensis* (Bt) that gives protection to cotton from lepidopteron pests. The need for insecticide applications for these pests is reduced or eliminated in Bt cotton.

Insect resistant brinjal: The *Cry1Ac* gene from *B. thuringiensis* were introduced into four local brinjal varieties, namely, Uttara, Kajla, Nayantara, and ISD 006 to control the eggplant fruit and shoot borer (EFSB). The National Committee on Biosafety (NCB) of the Ministry of Environment & Forest (MoEF), People's Republic of Bangladesh officially released these four Bt Brinjal varieties: Bt Brinjal-1 (Uttara), Bt Brinjal-2 (Kajla), Bt Brinjal-3 (Nayantara), and Bt Brinjal-4 (ISD 006) on October 30, 2013. Since then, they have been grown commercially in Bangladesh.

Herbicide tolerant soybean: Herbicide tolerant soybean provides better weed control and improves farm efficiency by optimizing yield, using arable land more efficiently, saving time for the farmers, and increasing flexibility of plant protection. This flexibility in management has greatly facilitated use of low-till and no-till farming methods, which have greatly benefited soil health and erosion control.

GM corn: Corn being one of the three important grains of the world has been genetically modified, incorporating insect resistant as well as herbicide tolerant genes. These corn varieties work in a similar manner as explained above.

GM papaya: GM papaya contains a viral gene that encodes for the coat protein of papaya ringspot virus (PRSV). This gene provides the papaya plant built-in protection against PRSV.

GM potato: Fungus resistant potato contains a gene that provides built-in protection from late blight disease.

Golden rice: Incorporation of maize and bacterial genes led to the development of GE rice with an enhanced level of beta-carotene. After consumption, beta-carotene is processed in the body into Vitamin A as needed. So, the introduction of this rice could reduce Vitamin A deficiency.

6. What GE plants are currently being grown, and what is the area under cultivation?

- The first GE plant was approved in 1994 in the United States, which was followed by large scale plantings. Since 1992, a total of 4,485 approvals have been issued for environmental release and for use as food and feed. Of these, 856 are for environmental release or cultivation (ISAAA Global Status of Commercialized Biotech/GM Crops: 2019). As per the available reports, more than 16 plant species have been engineered with a variety of GE traits, and GE plants have been cultivated in 29 countries as of 2019. Some of the GE plants approved for cultivation so far are mentioned in Table 3.

Table 3: Examples of some approved GE plants cultivated in various countries.

S. NO.	GE PLANTS	TRAITS/USES	COUNTRIES WHERE APPROVED FOR CULTIVATION
1	Alfalfa	Herbicide tolerance	USA, Canada
2	Apple	Anti-bruising and anti-browning	USA
3	Canola	Herbicide tolerance and improved protection against weeds	Canada, USA, Australia, Chile
4	Carnation	Modified flower color and herbicide tolerance	Australia, Columbia
5	Cotton	Improved insect protection, herbicide tolerance, and improved protection against weeds	Australia, USA, China, Mexico, South Africa, China, Argentina, India, Columbia, Burkina Faso, Sudan, Pakistan, Brazil, Myanmar, Paraguay, Costa Rica
6	Eggplant (Brinjal)	Insect resistance	Bangladesh
7	Maize	Improved insect protection and herbicide tolerance for efficient weed management	Canada, USA, Argentina, Brazil, South Africa, Uruguay, Philippines, Chile, Columbia, Honduras, Spain, Portugal, Paraguay, Cuba, Czech Republic, Romania, Slovakia, Vietnam
8	Papaya	Virus resistance	USA, China
9	Petunia	Modified flower color	China
10	Poplar	Insect resistance	China
11	Potato	Improved quality, anti-bruising, and anti-browning	USA, Canada
12	Soybean	Improved insect protection and herbicide tolerance for efficient weed management	USA, Argentina, Canada, Paraguay, Mexico, Bolivia, Brazil, Chile, South Africa, Romania, Uruguay, Costa Rica
13	Squash	Resistance against watermelon mosaic virus and zucchini yellow mosaic virus	USA
14	Sugar Beet	Herbicide tolerance	USA, Canada
15	Tomato	Delayed ripening, virus resistance	China

- While 29 countries planted commercialized biotech plants in 2019, an additional 42 countries including the EU, Japan, Korea, Russia, and others have granted regulatory approvals for GE plants for import as food and feed. From these countries, 4,485 approvals have been issued by regulatory authorities across 29 GE plants (not including those for carnation, rose, and petunia) and 403 GE events. Of these approvals, 2,115 are for food use (direct use or for processing), 1,514 are for feed use (direct use or for processing), and 856 are for environmental release or cultivation.
- In addition to the above, Bt cowpea, the world's first GM cowpea variety was approved by Nigeria for cultivation in 2019. Golden rice has been approved for use as food in Australia, New Zealand, Canada, Philippines, and the USA.
- The area under cultivation of GE plants has increased from 1.7 million hectares in 1996 to 190.4 million hectares in 2019, grown by over 18 million farmers globally. Out of these, developing countries contributed to 56% of the area under GE plants, as compared to 44% by developed countries. Several countries, including the USA, Canada, Brazil, Argentina, Australia, China, and South Africa that grow GE plants, export products derived from GE plants to countries around the world. The export of GE plants and products thereof requires approval for use in respective countries.

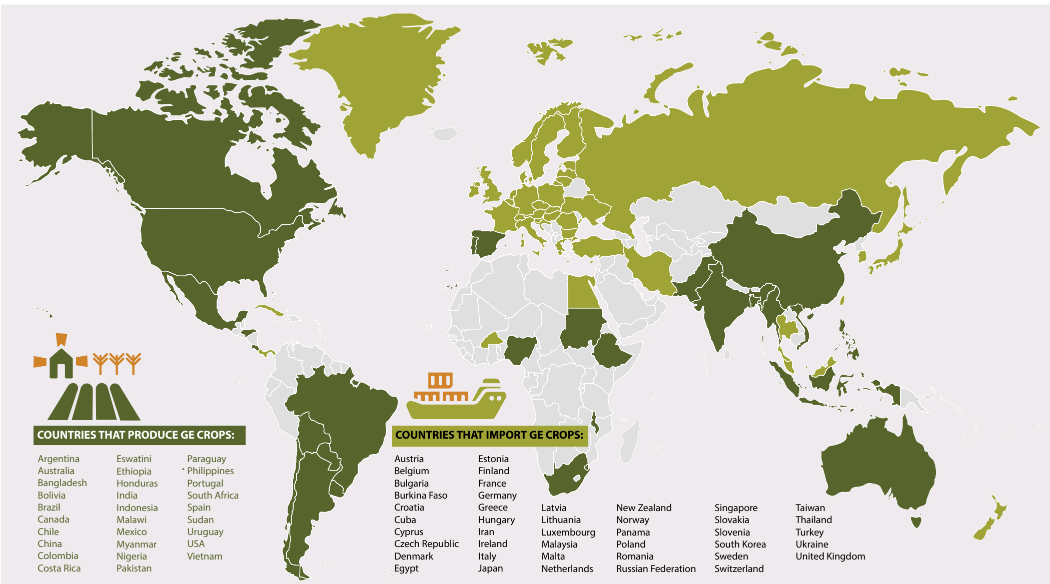
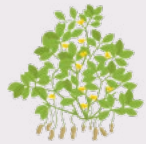


Figure 2: Countries that adopted GE plants for cultivation and importation. *(Source: ISAAA. 2019. Global Status of Commercialized Biotech/GM Crops in 2019. ISAAA Brief No. 55. ISAAA: Ithaca, NY.)*

7. How many GE plants are approved and cultivated in Bangladesh?

- Bt brinjal is the only GE plant approved for commercial cultivation in Bangladesh. On October 30, 2013, the National Committee on Biosafety (NCB) of the Ministry of Environment & Forest (MoEF) officially gave approval for limited cultivation to four Bt Brinjal varieties: Bt Brinjal-1 (Uttara), Bt Brinjal-2 (Kajla), Bt Brinjal-3 (Nayantara), and Bt Brinjal-4 (ISD 006).
- Several public and private institutions and universities are involved in the research and development of GE plants in Bangladesh.
- As per the available reports, several plants with varying traits, such as biotic and abiotic stress tolerance, are under various stages of development (Table 4).

Table 4: Plants and traits that are under research to develop GE plants in Bangladesh. *(Source: Souvenir. 9th International Plant Tissue Culture and Biotechnology Conference on Biotechnology for Food Security and Sustainable Environment, 2020)*

PLANT	TRAIT	PLANT	TRAIT
Rice 	Salinity and drought tolerance, nutritional enhancement, submergence tolerance, blight and streak resistance	**Mungbean** 	Yellow mosaic virus resistance
Wheat 	Salinity tolerance	**Peanut** 	Biotic stress tolerance
Brinjal 	Biotic stress tolerance	**Sugarcane** 	Salinity and drought tolerance
Potato 	Late blight disease resistance	**Napier Grass** 	Salinity tolerance
Tomato 	Leaf curl virus resistance, salinity tolerance	**Jute** 	Salinity tolerance, fungal and viral disease resistance, cold tolerance
Cotton 	Insect resistance	**Lentil** 	Fungal and viral disease resistance
Mustard 	Fungal and viral disease resistance	**Chickpea** 	Fungal and viral disease resistance

8. What are the concerns regarding the safety of GE plants?

- As with any technology, safety concerns have been expressed with the use of genetic engineering.
- Safety concerns associated with the use of GE plants broadly relate to the risk to human and animal health, and the environment. These differ greatly depending on gene-crop combination, and may include:
  - potential risk of introducing toxins, allergens, and other anti-nutrition factors in foods
  - potential likelihood of transgenes escaping from cultivated crops into wild relatives
  - changes in weediness potential
  - interaction with non-target organisms
  - resistance/tolerance of target organisms

9. How is the safety of a GE plant evaluated?

- All GE plants undergo extensive evaluation to ensure safety for human health and the environment. Once they pass all these safety assessments, they are permitted to grow.
- Systematic safety assessment methodologies that are followed for GE plants have been agreed under the aegis of international organizations, such as the World Health Organization (WHO), Food and Agriculture Organization (FAO), Organization for Economic Co-operation and Development (OECD), as well as under international agreements, such as the Cartagena Protocol on Biosafety (CPB), Codex Alimentarius Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants, International Plant Protection Convention (IPPC), World Organization for Animal Health (OIE), etc.
- The evaluation is carried out through a comparative risk assessment approach where the traditionally cultivated crop serves as the comparator because of its history of safe use. At the end of the assessment, a decision is made whether the specific GE plant is as safe as its traditional crop, i.e., conventional non-GE counterpart.
- The safety assessment on both human health and the environment are carried out on a case-by-case basis through a series of tests and analysis.
- Impact on human health is studied by analyzing the modified organism for the risks of toxicity, allergenicity, nutritional analysis, etc., as relevant to the targeted genetic modification. For toxicity assessment, the chemical nature, functions, and dietary exposure of the newly expressed substance are evaluated.

Compilations of consensus documents developed by the OECD Working Group for the Safety of Novel Foods and Feeds.

In the case of allergenicity assessment, the presence of allergens is studied through bioinformatics data analysis. Finally, the nutritional equivalence is done through detailed compositional analysis of key components and then compared between GE plants with its conventional counterpart.

- Environmental risk assessment of GE plants is quite diverse, as biological properties of plants are diverse. Knowledge and experience of the unmodified plant is the basis for comparative risk assessment of a GE plant. For this purpose, the baseline information recorded in biology documents are used as basis for this comparison. Finally, potential changes are compared, which include familiarity, weediness/ invasiveness, gene flow pattern of the introduced trait, impact on non-target beneficial organisms, etc.
- Therefore, all GE plants and its products have to go through food safety assessment and environmental safety assessment along with molecular analysis. The GE plants and foods that are currently on the market have all passed these safety assessments conducted by national authorities.

10. Who performs the safety assessment?

- Developers of GE plants (both public and private sector) test their products according to the regulatory requirements, which include detailed documentation of testing.
- The data requirements for safety assessment are defined by regulatory authorities. Once submitted by the developers, regulatory authorities undertake thorough analysis of the data and the protocols used 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 to reach a conclusion of safety.
- Such reviews follow 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. Methods used are based on international expert consultations under the aegis of organizations, such as the World Health Organization (WHO), Food and Agriculture Organization (FAO), Organization for Economic Co-operation and Development (OECD), etc.

Regulators visiting GE cotton confined field trial facilities.

11. How are GE plants regulated?

- GE plants cannot be grown, either for experiments or for commercial cultivation, without approval by the appropriate regulatory authority of the country. The movement of GE plants or food between countries is also regulated. Details of this process vary from country to country, but the same objectives underlie all regulation; ensuring that the novel GE plant is safe for human or animal health and the environment before it is released into the environment or enters the food supply.
- In Bangladesh, activities involving GE plants are regulated by Biosafety Rules 2012, Biosafety Guideline of Bangladesh 2007, and other regulatory documents prepared by the Ministry of Environment, Forest and Climate Change (MoEFCC).
- Bangladesh is also a party to the Cartagena Protocol on Biosafety, since 2000.

12. What is the purpose of introducing antibiotic resistance genes in GE plants, and what is their impact on human health?

- Antibiotic resistance genes are commonly used as marker genes for the selection of transformed plant cells in which the desired gene has been successfully introduced, during the development of a GE plant. When any gene is transferred into a plant tissue, not all the cells get transformed. To identify the transformed cells and pursue only those to generate the GE plants, antibiotics are used. Once through with the selection process, antibiotics are no longer used in the growth of GE plants. Only the marker gene remains.
- Some concerns have been raised about the possibility of transferring these genes from foods derived from GE plants 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 genes moving from GE plants to any other organism is extremely remote or virtually zero.

Researchers conducting molecular anlaysis for the detection of GE plants .

13. Are there long-term health effects of foods from GE plants?

- The only difference between the GE plants and their non-GE counterparts is the proteins expressed by inserted genes.
- The safety of the consumption of these proteins is established based on biological properties and tests of digestibility, acute toxicity, and allergenicity.
- Once this is done and safety established, then the compositional equivalence confirms that the GE plant is similar to the corresponding non-GE plant, which has been used/consumed traditionally for generations and hence, no long-term effects are expected to be seen based on this history of safe human use.

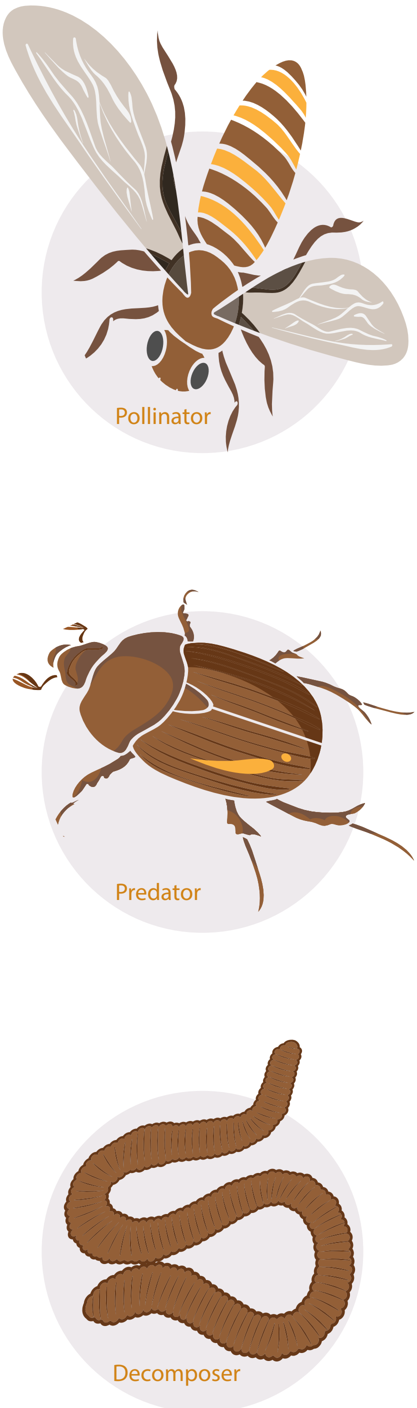
14. Do the foods from GE plants contain fewer nutrients than comparable foods?

- Detailed compositional analysis is an essential part of the safety evaluation process.
- Prior to approval, it is necessary to demonstrate that GE plants presently being cultivated are as nutritious as foods from comparable traditionally grown plants.
- Nutritionally enhanced GE plants are also being developed with an objective to increase levels of specific nutrients.

15. Do we eat genes when eating GE crops? What happens if the transgenic gene in a GE crop is eaten by humans or animals?

- Yes, genes or DNA are part of all living organisms, including conventionally grown plants and animals. There are varying number of genes in different organisms. Most plants cells contain about 20,000-30,000 genes and GE plants may contain an additional 1-10 genes in their cells. People eat genes whenever they eat any kind of food. Composition of DNA in GE food is the same as that in non-GE food, although in cooked or processed foods, most of the DNA is destroyed or degraded and the genes are fragmented. The digestive system breaks them down without any effect on genetic make-up. This is true of food from GE and non-GE sources. Therefore, transgenes in a GE plant are broken down in the same way as other genes.

Examples of food and feed crops with nutritionally enhanced GE varieties or hybrids *(Source: ISAAA. 2012. Pocket K: Nutritionally Enhanced GM Feed Crops. No. 41. ISAAA: Ithaca, NY.)*



Examples of non-target organisms. *(Source: Agriculture & Food Systems Institute. 2021. E-Learning Course: Environmental Risk Assessment of Non-Target Organisms for GE Crops. AFSI: Washington, DC.)*

16. Are GE plants a threat to non-target organisms like bees, butterflies, and pollinators?

- Potential risks to birds, mammals, fish, pollinators, such as bees, predators, and parasitoids, decomposers, such as earthworms, and other beneficial organisms for pest or disease resistance traits are assessed to ensure there is no unintended harm with GE plants. So far, no negative impacts of GE plants to the environment relative to the production of non-GE plants have been reported.
- Insect resistant GE plants, for example, Bt brinjal or 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 the insect gut wall of the 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 likely to be harmed by proteins produced by a particular strain of Bt.

17. Do GE plants cross-pollinate and contaminate with non-GE plants and lead to new problems, such as insect resistance in non-Bt plants?

- Gene flow between related plant species is a natural, biological process that has been integral to the domestication of plants and constant improvement through selection and breeding. GE plants are comparatively assessed with their non-GE counterparts extensively for any changes for intra- and inter- specific gene flow with compatible species. Safety assessments completed so far on plants approved for commercial release have concluded that gene flow from GE plants to wild relatives pose no risk to the environment. As new GE plants are developed, the possibility of gene flow and the consequences will continue to be evaluated on a case-by-case basis.

- Insect resistance is a natural evolutionary process enhanced by repeated exposure of the pest to insecticidal substances. It can arise due to the widespread use of GE crops or chemical pesticides on conventionally bred crops. Growing non Bt crops together with Bt crops (refugia) has been suggested as one of the measures to slow down the development of insect resistance. Other strategies that can slow down insect resistance include stacking or pyramiding genes that are distinct from each other, sterile moth releases, crop rotation, and use of trap crops.

18. Are GE seeds sterile? Why do farmers have to purchase seeds of GE plants every year?

- Seeds of GE plants are not sterile.
- Whether the farmers have to purchase seeds every year depends on whether he is growing variety or hybrids. As in the conventional seed production, farmers can save seeds in the case of varieties and in the case of hybrids, they will have to purchase it every year. The same practice has to be followed in GE plants.
- 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-GE and GE hybrids.

19. How can seeds or products of GE plants be detected?

- Generally, seeds of GE plants are indistinguishable from those of non-GE plants to the naked eye. Highly sensitive and specific testing methods are required that can look for the genes (DNA) engineered into the particular plant or the proteins produced by the introduced DNA.

Examples of GE crops that have combined traits–herbicide tolerance and insect resistance *(Source: ISAAA. 2020. Pocket K: Genetic Engineering and GM Crops. No. 17. ISAAA: Ithaca, NY.)*

GE salmon has been approved for human consumption in the USA and Canada *(Source: U.S. Food and Drug Administration. November 2015.)*

- Analytical methods to detect (qualitative or yes/no answer) and quantify (percentage content) fall into two main categories:
  - Protein analysis to detect the specific protein expressed by the transgene in the GE seed/plant parts through the use of ELISA (enzyme-linked immunosorbent assay) and lateral flow strip tests.
  - DNA analysis to detect the transgene or specific elements associated with the transgene in the GE seed/plant parts or products using polymerase chain reaction (PCR) methods.
- It is much more difficult to identify products of GE plants when they have been processed as an ingredient into a complex food.
- Considerations, such as sampling, food matrix effects on protein/DNA extraction, reference materials, method validation, harmonization of standards, and access to information databases apply to both protein and DNA based methods.

20. In addition to GE plants, which GMOs are approved for food use?

- GE Salmon has been approved for use as food in the USA (in 2015) and Canada (in 2016). This genetically engineered version of the Atlantic salmon grows roughly twice as fast as the standard variety.

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4 SABP Activities in Bangladesh

The South Asia Biosafety Program (SABP) started its journey in Bangladesh in 2005 with the aim to facilitate the implementation of transparent, efficient, and responsive regulatory frameworks for products of modern biotechnology in South Asia.

ASSISTANCE IN REGULATORY SYSTEM DEVELOPMENT

In collaboration with the Government of Bangladesh, SABP has produced Standard Operating Procedures (SOPs) related to transport, storage, conduct of field trials, and compliance with regulatory requirements. In 2009, SABP assisted a BARC-organized technical committee in finalizing the *Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants*. These guidelines were prepared by a committee convened by the Member Director (Crops) and have subsequently been endorsed and adopted by BSTI and MoEF. *Companion Guidelines for Environmental Risk Assessment (ERA) of Genetically Engineered Plants* were drafted and published in 2013 with the technical assistance of SABP. Most recently, the 2017 *User's Guide to Biosafety Regulatory Process for GE Plants in Banglades*h was prepared in consultation with biosafety stakeholders to reflect the practical operation of biosafety processes in Bangladesh, including those managed by BARC.

CAPACITY BUILDING

To ensure compliance with the Biosafety Rules and Biosafety Guidelines of Bangladesh, the Government of Bangladesh has highlighted the need to raise awareness and develop expertise. For this reason, annual training workshops are arranged for scientists working at various institutes like BARI, BRRI, BINA, CDB, SCRI, BFRI, BCSIR and universities like DU, BAU, BSMRAU, CU, RU, SUST, etc. A similar training program is ongoing for capacity development of the Institutional Biosafety Committee (IBC), as they play a crucial role in monitoring institutional biosafety practices and also liaising with the biosafety committees located in the Ministry of Environment, Forest and Climate Change (MoEFCC). For biotechnology research to advance toward implementation, it is crucial for current and future researchers to understand national biosafety regulatory processes at each stage of research and development. To build awareness of the country's regulatory framework among future generations, SABP organizes webinars with undergraduate and graduate biotechnology students in collaboration with leading universities in the country.

ORGANIZING CONFERENCES AND SUPPORTING PARTICIPATION

SABP has provided a continuous platform for awareness and educational workshops and conferences discussing agricultural biotechnology and biosafety. Notably, for the last seven years, SABP has hosted the

South Asia Biosafety Conference (SABC). Scientists and policymakers at BARC and various NARS institutes, ministries, and relevant departments/authorities and academia have attended and contributed to all these conferences, which were organized in various South Asian countries. SABC has taken place in Bangladesh thrice—in 2015, 2018, and 2019.

SABP NEWSLETTER

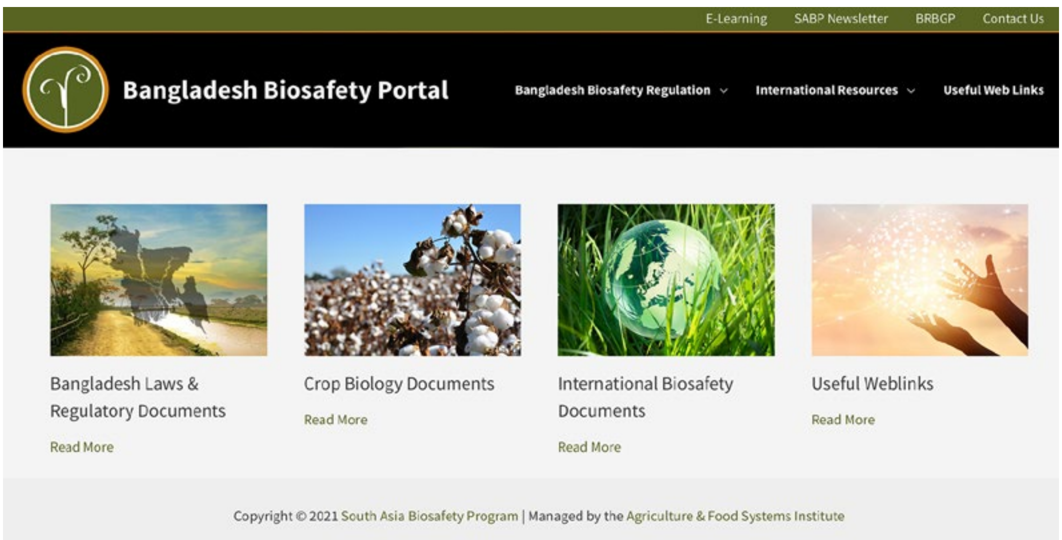
Every month, SABP publishes a newsletter reporting on activities relevant to biosafety in Bangladesh, circulated through email to over 25,000 organizations and individuals in South Asia and internationally, with hardcopies distributed to agriculture research institutes, universities, and scientists. Research efforts in Bangladesh are highlighted each month, and the newsletter has proven to be a highly effective way to profile Bangladesh' biotechnology research regionally and internationally.

BIOSAFETY RESEARCH IN BANGLADESH GRANTS PROGRAM (BRBGP)

In January 2019, SABP launched the Biosafety Research in Bangladesh Grants Program (BRBGP) with support from the USAID Mission in Dhaka. The BRBGP supports annual awards of $15,000- $25,000 for research that expands the locally produced knowledge to support risk assessment for agricultural biotechnologists in Bangladesh. As importantly, it provides a platform for SABP to further engage with motivated research scientists to build awareness and understanding around the science and practice of biosafety and to develop a community of practice in Bangladesh that can serve as a technical resource to inform the regulatory process.

BANGLADESH BIOSAFETY PORTAL

Launched in 2017 by SABP, the Bangladesh Biosafety Portal serves as the only consolidated repository of documents that inform biosafety regulation in Bangladesh. The portal provides information and links to useful national and international technical resources, including the User's Guide to Biosafety Regulatory Process for GE Plants in Bangladesh—the definitive informational resource for applicants and other stakeholders interested in understanding biosafety regulation in Bangladesh. The portal may be accessed at **bangladeshbiosafety.org**.



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