BIOSAFETY
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FREQUENTLY ASKED QUESTIONS

Genome Edited Plants

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

Genome Edited Plants

Prepared by

SOUTH ASIA
BIOSAFETY PROGRAM

Bangladesh, 2024

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1 Preamble

Genome editing, also called gene editing, is one of the latest developments in crop improvement technologies. Genome editing is being applied to crops to introduce traits, such as withstanding climatic factors, resistance to pathogens, improved nutritional value, and even reduced wastage in the post-harvest stage in multiple crops. This technology is more precise and efficient than conventional breeding and, hence, can reduce the time needed to develop new plant varieties. Extensive research efforts are underway for over 70 crops in about 60 countries. Genome edited plants are already moving beyond the laboratory, and its products, such as high GABA tomato, high oleic soybean, milder flavored mustard, etc., are already on the market in Japan and the USA.

SOPs for Research and Release of SDN-1 and SDN-2 Genome Edited Plants in Bangladesh, 2023

Bangladesh Agricultural Research Council
Ministry of Agriculture
Government of the People's Republic of Bangladesh

Standard Operating Procedures for Research and Release of Genome Edited Plants of Categories SDN-1 and SDN-2 in Bangladesh

December, 2023

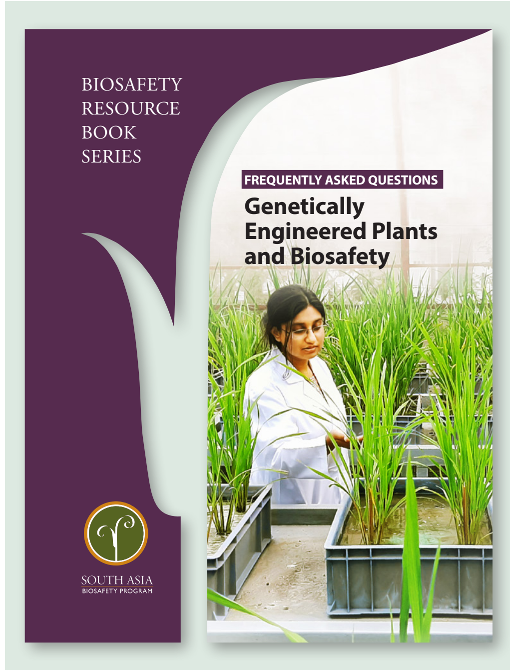
Standard Operating Procedures for Research and Release of Genome Edited Plants of Categories of SDN-1 and SDN-2 in Bangladesh, 2023 was published in December 2023.

The *National Agricultural Policy 2018* of Bangladesh supports the adoption of modern techniques, including biotechnology, for the development of traits, including biotic and abiotic stress tolerance and nutritious crop varieties, to ensure food and nutritional security. Many laboratories in Bangladesh have already initiated research to develop genome edited plants. Recognizing the potential of genome edited plants for crop improvement, the Ministry of Agriculture, Government of the People's Republic of Bangladesh, in December 2023, approved the "Standard Operating Procedures for Research and Release of Genome Edited Plants of Categories of SDN-1 and SDN-2 in Bangladesh" so that the farmers and consumers can benefit from these novel technologies.

In this context, the present booklet provides information about genome edited plants in a simple language, so readers may better understand the science, applications, and policies at the global and national levels.

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 the development of regulatory documents, manuals, and assessment guidelines. SABP is also involved in capacity building for the research community to ensure proper implementation of biosafety regulatory processes. This booklet is the third installment in the *Biosafety Resource Book Series* and has been prepared as a part of SABP's capacity development interventions.



Frequently Asked Questions: Genetically Engineered Plants and Biosafety was published on March 30, 2021.

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 genetically engineered crops. Under the current biosafety regime, it is crucial to follow these steps to take 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 genetically engineered crops (Chapter 3). The final chapter (Chapter 4) deals with the application process for the cultivation of genetically engineered crops in confined field trials, as well as release for field cultivation.

Published in 2021, the second installment in the series, *Frequently Asked Questions: Genetically Engineered Plants and Biosafety*, was written to explain information about genetically engineered plants in easy and understandable language. It aims to answer questions or concerns the general public may have, as Bangladesh is one of the countries growing genetically engineered crops, with Bt brinjal approved for cultivation in the country.

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

2 Frequently Asked Questions

1. What is genome editing?

Genome editing, also known as gene editing, is a group of technologies used to make precise and targeted changes in an organism's Deoxy-Ribonucleic Acid (DNA). Genome editing is done using site-directed nucleases (SDNs), such as Zinc Finger nucleases (ZFNs), Transcription Activator-like Effector Nucleases (TALENs), CRISPR/Cas, etc. Base editing and prime editing are advanced methods of genome editing.

Plants that have been modified using genome editing techniques are called genome edited plants.

2. How is genome editing possible?

All living organisms have DNA within their cells that contains all the necessary information to build and maintain it. Genes are DNA sequences that determine a particular characteristic/trait of an organism. Genome refers to the complete set of genes in an organism or, in other words, the total DNA content within a cell.

Genome editing is possible due to advances in the knowledge of plant breeders and scientists about:

1. the function and sequences of genes
2. available tools to change a particular sequence of a gene or several genes.

This is similar to editing a book with tools available to identify the exact page, the exact paragraph, and even the exact word to be changed. Just like editing a book, where the ability to read the entire text is needed before making the edits, genome editing requires precise knowledge of the plant genome and the DNA sequence of the gene targeted for editing.

3. What is CRISPR, and how does it work?

CRISPR is one of the most revolutionary genome editing tools because of its simplicity and efficiency. Its discoverers, Dr. Emmanuelle Charpentier and Dr. Jennifer Doudna (see page 6), were awarded the Nobel Prize for Chemistry in 2020.

CRISPR stands for clustered regularly interspaced short palindromic repeats. These are repeated DNA sequences that occur in the genomes of many bacteria and play an important role in bacterial defense systems. CRISPR, along with Cas9 (CRISPR associated protein 9), can be used to make edits in the genome.

CRISPR-mediated editing involves a guide RNA and a Cas protein. The guide RNA helps direct the Cas protein to a particular region of the genome, and the Cas protein then makes a cut in the DNA. After the

Portrait of Dr. Emmanuelle Charpentier by Hallbauer & Fioretti (emmanuelle-charpentier.org).

Portrait of Dr. Jennifer Doudna by Christopher Michel (Wikimedia Commons).

DNA is cut, normal cellular processes repair the break, resulting in different types of edits, depending on the presence or absence of a DNA template.

4. What are various types of genome editing?

Genome editing uses site-directed nucleases (SDNs) to make changes that may either be a small deletion, a substitution, or the addition of a number of nucleotides, as shown in Figure 1 (page 7). Such targeted edits result in a new and desired characteristic.

There are three types of genome editing involving site-directed nucleases—SDN-1, SDN-2, and SDN-3:

- **SDN-1** produces a double-stranded break in the genome of a plant without the addition of foreign DNA. The spontaneous repair of this break can lead to the addition or deletion of a few nucleotides, causing gene silencing, gene knock-out, or a change in the activity of a gene. The mutations produced in this way are of the same type that occur naturally or are induced by a chemical or radiation.
- **SDN-2** produces a double-stranded break, and while the break is repaired by the cell, a small nucleotide template complementary to the target region is supplied, which is used by the cell to repair the break. The template contains one or several small sequence changes in the genomic code that are copied into the plant's genetic material, resulting in a desired change within the target gene.
- **SDN-3** produces a double-stranded break in the DNA but is accompanied by a template containing a gene or other sequence of genetic material. The cell's natural repair process then utilizes this template to repair the break, resulting in the introduction of new genetic material in the genome.

Therefore, SDN-1 and SDN-2 genome edited plants do not contain inserted foreign DNA, while SDN-3 genome edited plants contain foreign DNA.

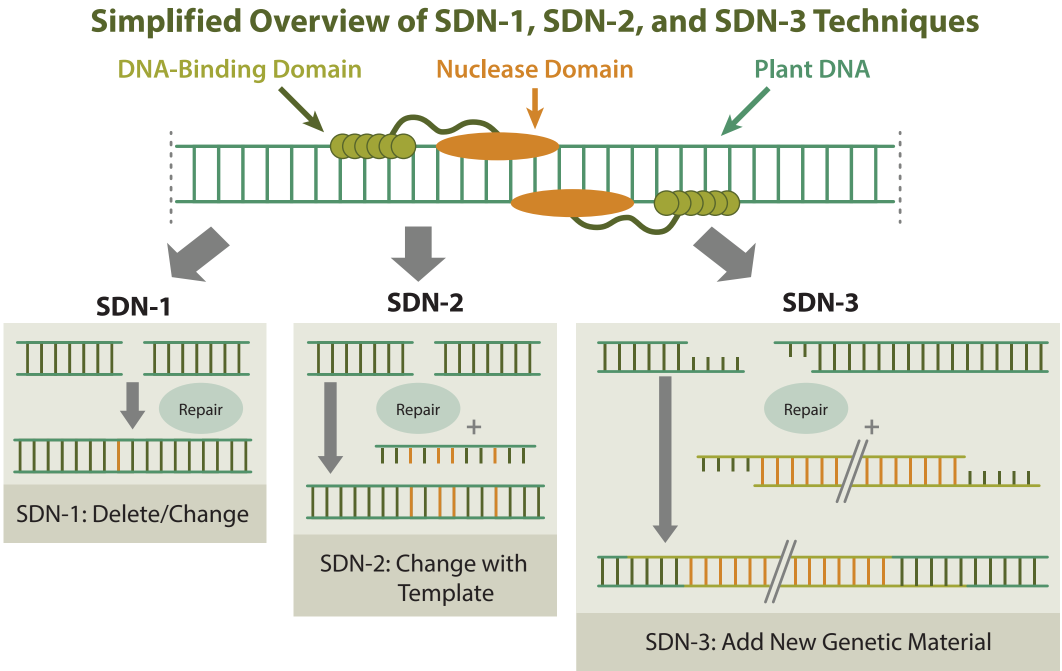


Figure 1: Simplified overview of SDN-1, SDN-2, and SDN-3 techniques.

5. How do genome edited plants compare with those developed using traditional plant breeding techniques?

Plants developed using traditional plant breeding techniques and plants that have been genome edited both aim to incorporate desirable characteristics for crop improvement. The plants altered for changes using these two techniques may be similar to each other, but the process involved is different, particularly in terms of precision and speed, to achieve the final outcome.

The traditional breeding process uses crossbreeding or mutagenesis triggered by either hybridization or mutagens like chemicals and radiation. This results in random changes of several genes without any clarity on the number(s) and location(s) of alteration(s) in the genome. The selection process takes years and multiple generations to achieve the desired outcome.

Genome editing uses genetic and molecular knowledge to introduce precise and targeted changes within the genome, and the time taken to achieve the same outcome is shorter. As an example, genome editing could take two to three years to achieve the same result in a plant as what may take conventional breeding ten to twelve years.

Using genome editing, it is also possible to introduce multiple changes at the same time in different locations. For example, if multiple copies of a gene are present in an organism, one can change all these copies at the same time, which is very difficult to achieve with conventional breeding. Different genes can also be targeted at the same time using multiplex genome editing.

6. Why do we need to use genome editing in agriculture?

Agriculture faces a variety of challenges, including changing climate patterns, drought, floods, heat, diseases, and pests. Furthermore, the world's growing population and evolving consumer choices and preferences are leading to an increase in demand for nutritious food and the need for sustainable agriculture. Genome edited plants have the potential to make a positive impact in agriculture by incorporating a wide range of traits for higher crop yields, lowering the use of chemical fertilizers and pesticides, developing plant varieties resilient to climate stress, reducing postharvest losses, and enhancing the nutritional value of foods.

The European Sustainable Agriculture through Genome Editing (EU-SAGE) Network represents plant scientists, and their online database provides current information on research activities in genome editing (https://www.eu-sage.eu/genome-search). Figures 2-6 display information from this database on genome editing studies, broken down by crop, trait category, country, technique used, and type. Figures 2 and 3 show that thus far, most studies have been dedicated to improving yield and quality in rice. As shown in Figure 5 (page 9), among the various genome editing techniques, the CRISPR-Cas system is most commonly used.

7. Have genome edited plants and their derived products been commercialized?

In 2021, the first genome edited soybean was commercialized in the USA. This was followed by high GABA tomato in October 2022 in Japan. Since then, several products in other countries have been introduced into commerce.

- **High GABA tomato**: High GABA tomato contains five to six times more gamma-aminobutyric acid (GABA) than traditional tomato. This was achieved by clipping out one of the genes that inhibits the synthesis of GABA in tomato. It helps to lower blood pressure.
- **High oleic soybean**: In this genome edited soybean, two genes involved in fatty acid synthesis have been turned off. As a result, soybean oil derived from this plant contains 80% higher oleic acid, 20% less saturated fatty acids, and 0 grams of trans-fat per serving when compared to traditional soybean oil. Additionally, it has health benefits, three times the fry life, and a longer shelf life.

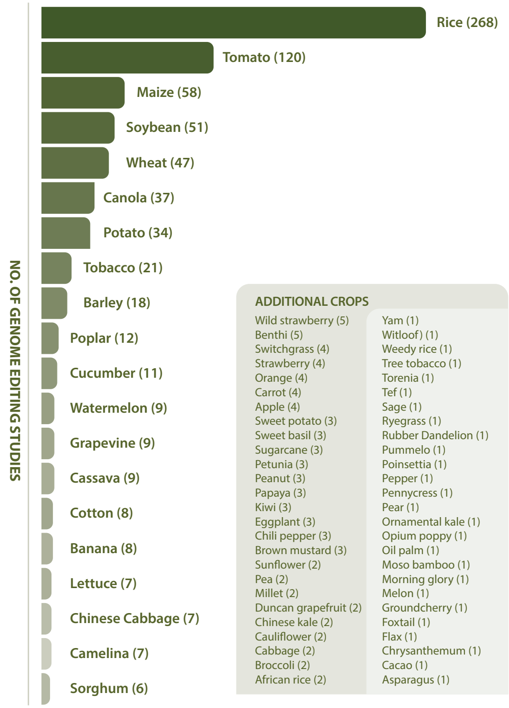


Figure 2: Bar graph showing genome editing studies by crop (data retrieved: February 5, 2024, from EU-SAGE).

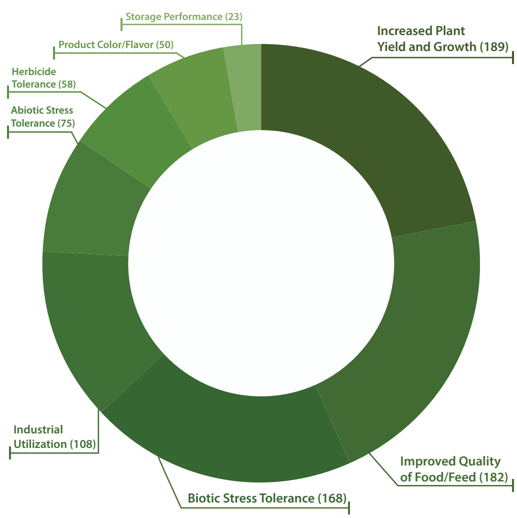


Figure 3: Pie chart showing genome editing studies by trait category (data retrieved: February 5, 2024, from EU-SAGE).

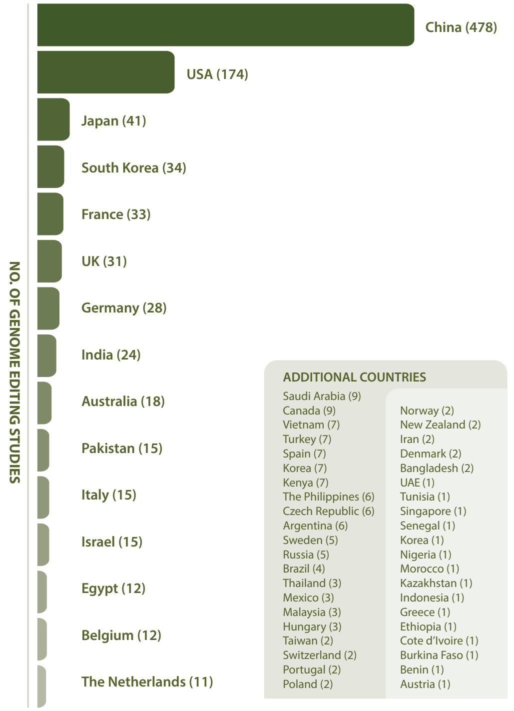


Figure 4: Bar graph showing genome editing studies by country (data retrieved: February 5, 2024, from EU-SAGE).

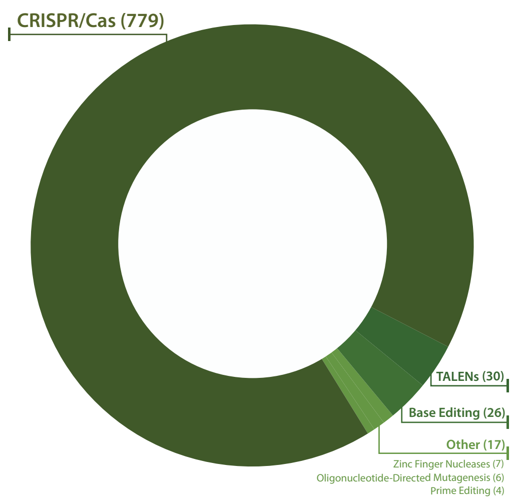


Figure 5: Pie chart showing genome editing studies by technique (data retrieved: February 5, 2024, from EU-SAGE).

- **Non-browning banana**: Bananas start to brown when exposed to oxygen, which leads to reduced nutritional quality and market value. Bananas with a non-browning trait have been developed through genome editing, which could potentially reduce food waste and CO_2 emissions.
- **Milder flavored mustard**: Through genome editing, a family of genes responsible for the bold flavor of mustard has been altered to be milder flavored while retaining the same nutritional profile. Now, this leafy green is enjoyed by people as a nutritious leafy green.
- **Bacterial blight-resistant rice**: Genome edited rice has been developed by disrupting the function of promoters for sugar transport genes critical for the plant's susceptibility to infection by *Xanthomonas oryzae* pv. *oryzae*, resulting in resistance to bacterial blight.

In countries around the world, genome editing is being used to make healthier plant products, enhance market value, and increase the yield and shelf life of agricultural products. This suite of technologies is being used to enable the improvement of several crops in Bangladesh.

8. What is the status of genome edited plants in Bangladesh?

Recognizing the enormous potential of genome editing for plant improvement, universities and research institutions in Bangladesh, including those under the National Agricultural Research System (NARS), have initiated several research projects on various crops. Some key initiatives are briefly described below:

- The **Bangladesh Rice Research Institute (BRRI)** is using genome editing tools for the development of insect-resistant rice varieties by knocking out serotonin-producing genes. BRRI is also developing high-yielding aromatic advanced breeding lines of rice by editing the *BDH2* gene.
- In collaboration with the Global Institute for Food Security (GIFS) and the Biotechnology Division of the University of Saskatchewan in Canada, the **Bangladesh Agricultural**

Research Institute (BARI)** is working on the development of genome editing protocols for lentil, aiming at introducing biotic and abiotic stress tolerant traits. In collaboration with Cornell University in the USA, BARI is also working on developing eggplant with increased bacterial wilt resistance using genome editing.

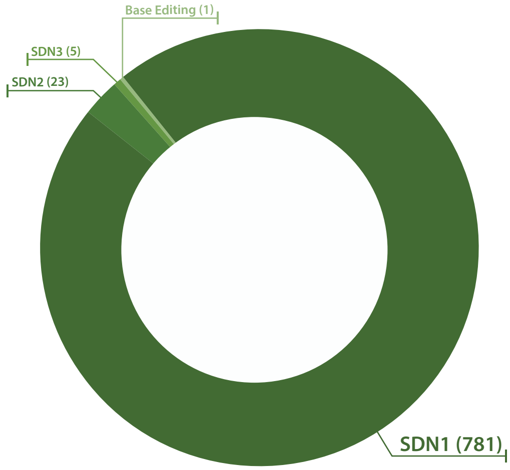


Figure 6: Pie chart showing genome editing studies by type (data retrieved: February 5, 2024, from EU-SAGE).

- The **National Institute of Biotechnology (NIB)** is working towards developing abiotic stress-tolerant eggplant and rice. The NIB is also developing diabetes-friendly high-amylose-containing rice by editing the genes coding starch branching enzymes (SBE1 and SBE3), which increases the ratio of amylose to amylopectin, resulting in a lower sugar release rate.
- The **Institute of Biotechnology and Genetic Engineering (IBGE) of Bangabandhu Sheikh Mujibur Rahman Agricultural University (BSMRAU)** is working on editing the S-genes in wheat to develop durable blast resistance. Using genome-specific primers and CRISPR technology, they have developed a rapid, precise, and convenient field-deployable method for diagnosing the wheat blast fungus.
- The **Biochemistry and Molecular Biology Department of the University of Dhaka** is working on developing salinity tolerance in rice. A specific potassium channel gene, which has been downregulated in salt-tolerant Hourkuch using the CRISPR Cas9 system, showed a loss of function. Similar research on another potassium transporter and an ABC transporter showed that downregulation caused salinity tolerance in a sensitive variety compared to the wild type. [DOI: 10.3389/fpls.2019.01420].
- The **Department of Botany at the University of Dhaka** is working on several crop-trait combinations that include low erucic acid containing mustard, drought tolerant potato, and reduced lignin jute.

9. How are genome edited plants different from genetically engineered (GE) plants?

In the case of genetically engineered (GE)/genetically modified (GM)/transgenic plants, DNA is typically inserted using recombinant DNA technology. The newly inserted gene could be from the same or a related plant species or a different organism.

In the case of SDN-1 and SDN-2 genome edited plants, recombinant DNA technology may be used in the early stages of development, but these plants do not contain any newly introduced genes. Genome edited plants contain small changes in the existing genome, like those that could occur in nature. Moreover, these changes are targeted to a precise location.

10. Are genome edited plants safe to eat?

Genome edited plants are considered as safe as the ones produced using conventional plant breeding, including mutation breeding. The kinds of mutations created using SDN-1 and SDN-2 genome editing methods are the same kinds that can occur naturally, or that can be created using conventional mutation breeding techniques. There is a long history of safe consumption of plants modified using various mutation breeding techniques. The advantage of genome editing is that the location of the introduced mutation can be precisely targeted, whereas with more traditional methods, mutations are introduced randomly throughout the plant's genome. Genome editing reduces the amount of uncertainty, thereby contributing to safety.

11. Do genome edited plants affect the environment and biodiversity?

There is no evidence of any crop plants, whether produced by conventional breeding, genetic engineering, or genome editing, causing environmental damage or adversely affecting biodiversity to date. These technologies have been used to improve crop production in terms of yield and quality to ensure food and nutritional security. The greatest impacts on the environment and biodiversity are from human activities, including agricultural practices, land clearing, industrialization, and urban development. Crop improvement techniques, such as genome editing, are being used to make changes that contribute to agricultural sustainability and resilience to climate change, thus helping to protect the environment and safeguard biodiversity.

12. Is genome editing used in other organisms, medicine, etc.?

Genome editing is being successfully used to understand biological processes and for applications ranging from healthcare to industrial processes, in addition to agriculture. It is being used to breed disease-resistant animals, improve animal welfare, and achieve higher productivity for livestock. Genome editing is already employed to generate animal models for human studies, gene therapy, and xenotransplantation. In aquatic animals, it is being employed to generate higher biomass, disease resistance, and sterility. The use of genome editing extends to controlling the spread of infectious diseases, such as Zika, and developing cleaner energy sources, such as algae-based biofuels.

Genome editing has been used in developing diagnostic kits for disease screening, including diagnostic kits and vaccines for COVID-19. It is being explored in research and clinical trials for a wide variety of diseases, including single-gene disorders, such as cystic fibrosis, hemophilia, sickle cell disease, etc. It holds promise for the treatment and prevention of more complex diseases, such as cancer, heart disease, mental illness, and human immunodeficiency virus (HIV) infection. Xenotransplantation of heart and kidney from genome edited pig has been successfully demonstrated and will go a long way toward managing chronic diseases.

13. Is any genome edited organism other than plants approved?

Genome edited fish developed by Japanese researchers, *viz.* Tiger puffer and red sea bream with enhanced muscle mass and short body length, have already been approved for use in Japan.

In the USA, on March 7, 2022, the Food and Drug Administration (FDA) made a low-risk determination for genome edited beef cattle and their offspring, stating that it does not intend to object to the marketing of the cattle's associated products. The DNA of PRLR-SLICK cattle was altered so it grew shorter hairs or "slick" coats, helping the animal stay cooler in warmer temperatures.

Takifugu (or Fugu) rubripes, commonly known as the Japanese puffer, Tiger puffer, or torafugu, has the smallest genome of any vertebrate and was the first fish species selected for genome sequencing. One type of torafugu, 22-seiki fugu, has been genome edited to grow bigger than conventional counterparts.

14. Are genome edited plants regulated?

The regulations for genome edited plants are evolving globally. Several countries have decided in favor of not regulating the genome edited plants that do not contain exogenous introduced DNA under the same rules that apply to GE/GM/transgenic plants. The genome edited plants are typically exempt from biosafety assessment and are regulated in the same way as products of conventional plant breeding. Several countries have issued rules, notifications, guidelines, SOPs, etc., to provide guidance for different categories of genome edited plants, and discussions are underway in other countries. Many peer-reviewed publications have discussed the global landscape of genome editing regulations.

Table 1: Trends in approaches to handling genome edited plants.

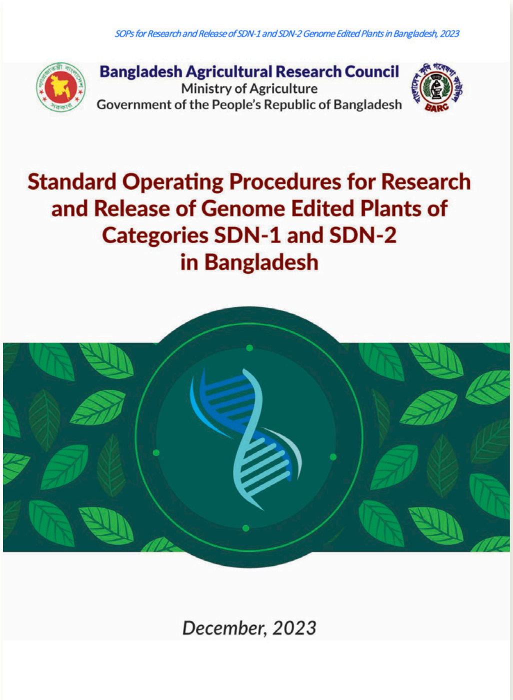
APPROACH TO THE REGULATION OF GENOME EDITED PLANTS	COUNTRY
Clear policy approach to handling plants produced by genome editing. Exemption of plants similar to those that could be produced through conventional breeding (SDN-1 or similar) from GMO regulation.	Argentina Australia (environment only) Bangladesh Brazil Canada India Japan Kenya Nigeria United Kingdom United States of America
A proposal to treat SDN-1 and SDN-2 genome edited plants through an expedited process is currently under consideration. As of now, genome edited plants are treated as GMOs.	European Union
Genome edited plants are regulated as GMOs.	New Zealand South Africa

15. What are the existing regulations in place for genome editing in Bangladesh?

The Seed Certification Agency under the Ministry of Agriculture, Government of the People's Republic of Bangladesh, is responsible for the certification of agricultural seeds in the country. Variety registration procedures are followed for crops developed using conventional breeding methods. The ministry approved the "Standard Operating Procedures for Research and Release of Genome Edited Plants of Categories SDN-1 and SDN-2 in Bangladesh, 2023" (page 13) in December 2023 to facilitate the research and release of genome edited crops that meet the needs of farmers and consumers in Bangladesh.

The SOPs provide guidance on initiating research and handling genome edited plants and protocols to demonstrate that a genome edited plant is free from exogenous introduced DNA.

When a genome edited plant is developed using either SDN-1 or SDN-2 methods and the final product is confirmed to be free of any exogenous introduced DNA, transgene, or foreign gene by the Institutional Oversight Body (IOB) and the Evaluation Committee for Genome Edited Plants at the Bangladesh Agricultural Research Council (BARC), the respective institute/university can proceed with the registration or release of that plant, following the same procedure as those used for conventionally bred plants in Bangladesh.


SOPs for Research and Release of SDN-1 and SDN-2 Genome Edited Plants in Bangladesh, 2023

Bangladesh Agricultural Research Council
Ministry of Agriculture
Government of the People's Republic of Bangladesh

Standard Operating Procedures for Research and Release of Genome Edited Plants of Categories SDN-1 and SDN-2 in Bangladesh

December, 2023

The Standard Operating Procedures for Research and Release of Genome Edited Plants of Categories SDN-1 and SDN-2 in Bangladesh, 2023 can be accessed on the

Bangladesh Biosafety Portal:
bangladeshbiosafety.org/bangladesh-doc/sop-genome-edited-plants-bangladesh-2023

16. Who can make genome edited plants?

Genome edited plants are developed by researchers to meet emerging needs in agriculture by making targeted changes using genome editing techniques. These may include scientists at universities (both public and private), research institutions in the public sector, and any other organization with capabilities in molecular biology and plant tissue culture.

In view of the ease of using genome editing techniques, an increasing number of universities and public sector organizations are involved in the development of genome edited plants in Bangladesh (see No. 8 on page 9).

17. Do farmers have to purchase seeds of genome edited plants every year or can these be replanted?

Whether farmers have to purchase seeds every year or if they can replant them depends on whether they are growing varieties or hybrids. In conventional seed production, farmers can save seeds in the case of varieties, and they will have to purchase them every year in the case of hybrids. The same practice has to be followed in the case of genome edited plants.

Hybrids are produced by crossing two different varieties of the same crop plant and thereby incorporating certain desirable characteristics of both plants. The reason why farmers have to purchase seeds every year in the case of hybrid cultivation is that only F1 (First Generation) seeds are recommended, as there is a possibility of segregation of the parental traits in F2 seeds, thereby reducing the optimum productivity. This is applicable to both conventional and genome edited hybrids.

18. What is the status of genome edited plants under the Cartagena Protocol on Biosafety?

The Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD) is an international treaty governing the transboundary movements of Living Modified Organisms (LMOs) resulting from modern biotechnology. It was adopted in 2000 and entered into force in 2003. To date, there are 173 Parties to the Cartagena Protocol, including Bangladesh.

Genome editing came up in discussions under the Cartagena Protocol in 2016, and Parties had different views. Many countries that regulate LMOs, as defined in the CPB, have determined that SDN-1 and SDN-2 types of genome editing do not result in the creation of a "novel combination of genetic material" and are not LMOs. SDN-3 genome editing involves targeted insertion and, thus, is regulated similar to LMOs.

19. How can genome edited plants be detected?

As SDN-1 and SDN-2 genome edited plants do not carry any foreign DNA, they are indistinguishable from naturally occurring or conventionally bred counterparts, and they are impossible to detect with established detection tools in most cases. If a genome sequence different from the two counterparts is detected, it is challenging to decide whether this difference was naturally occurring, chemically induced, or introduced using genome editing.

SDN-3 genome edited plants can be detected using protein or DNA based detection methods in the same way as genetically engineered plants.

20. How does genome editing help deal with challenges from climate change and contribute to sustainable agriculture?

The United Nations estimates that food production will need to increase by 60% by 2050 to feed a predicted world population of 9.3 billion.

The use of genome editing and other modern biotechnologies is crucial for dealing with climate change and other challenges to food and nutrition security. Increasing crop yields is expected to improve the livelihoods of farmers, deliver huge environmental benefits, and provide healthier and more nutritious foods to consumers in both developed and developing economies, thereby contributing to achieving Sustainable Development Goals (SDGs), particularly the first three:

1. End poverty in all its forms, everywhere
2. End hunger, achieve food security and improved nutrition, and promote sustainable agriculture
3. Ensure healthy lives and promote well-being for all at all ages.

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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. 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.

SABP has supported the Bangladesh Academy of Sciences (BAS) in convening the Technical Committee for Gene Edited Plants. This committee, upon invitation by the Secretary of the Ministry of Agriculture, was convened multiple times since July 2022 and proposed an appropriate mechanism to allow the use and introduction of gene edited plants in Bangladesh. Discussions led to the drafting of "Standard Operating Procedures for Research and Release of Genome Edited Plants of Categories SDN-1 and SDN-2 in Bangladesh, 2023," which BARC published in December 2023.

Conference on Genome Editing for Agriculture in Bangladesh (February 11, 2024).

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, SABP has arraged workshops for scientists working at various institutes, such as BARI, BRRI, BINA, CDB, SCRI, BFRI, BCSIR, NIB, BJRI, etc., and universities, such as DU, BAU, BSMRAU, CU, RU, SUST, JNU, JnU, IUB, BracU, etc. A training program was organized for the 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). SABP has also conducted a series of capacity building workshops for regulators at the Department of Environment (DoE) and MoEFCC, focusing on the implementation of a sound regulatory system and the execution of assessment systems for various types of applications.

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 has organized webinars and in-person training activities with undergraduate and graduate biotechnology students in collaboration with leading universities in the country.

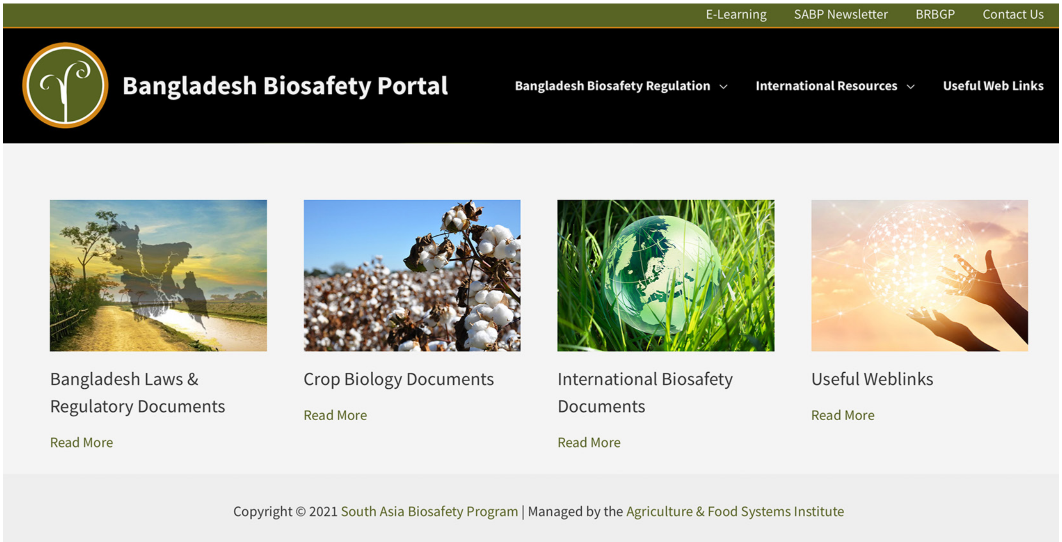
Workshop on Standard Operating Procedures for Research and Release of Genome Edited Plants in Bangladesh (February 13, 2024).

SABP NEWSLETTER

Every month since 2005, SABP has published a newsletter reporting on activities relevant to biosafety in Bangladesh. It is currently circulated through email to over 21,000 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's biotechnology research regionally and internationally. The newsletter can be subscribed to at: **foodsystems.org/resources/sabp-newsletter**.

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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