BIOSAFETY RESOURCE BOOK SERIES

Biosafety Regulation and Processes in Bangladesh: A Guide for Researchers in Agricultural Biotechnology

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

Biosafety Regulation and Processes in Bangladesh: A Guide for Researchers in Agricultural Biotechnology

Prepared by

SOUTH ASIA
BIOSAFETY PROGRAM

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Preamble

In the 1990s, the Government of Bangladesh recognized the potentials of modern biotechnology to overcome the emerging biotic and abiotic challenges in the agricultural sector. To allow plant scientists to embrace these modern technologies, Bangladesh's first *National Agriculture Policy 1999* took up programs for the introduction, utilization, and extension of biotechnology under the Ministry of Agriculture. In 2014, the Ministry of Science and Technology gazetted the *Work Plan for the National Biotechnology Policy 2012*. One of the goals of this workplan is to improve food security through implementing the national agricultural research and development priorities. As per this workplan, the Ministry of Agriculture and other concerned ministries, research institutions, and public and private universities are going forward with their missions.

To ensure the safety of biotechnology in the environment, including safety for humans, animals, and biodiversity, Bangladesh has established a biosafety regime. The Ministry of Environment, Forest and Climate Change (MoEFCC) is the Competent National Authority and the Focal Point for implementing this biosafety regime. As per the biosafety regulations, all genetically engineered (GE) crops need to go through safety assessment before reaching farmers and consumers and are subject to oversight during the research and development stages.

The South Asia Biosafety Program (SABP) has been operating in Bangladesh since 2005 to provide support to the government to strengthen institutional governance of biotechnology, including through the 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.

The inaugural session of the 7th Annual South Asia Biosafety Conference, Dhaka, Bangladesh (September 14, 2019) (from left): Dr. Muhammad Abdur Razzaque, MP, Honorable Minister, Ministry of Agriculture, Bangladesh; Dr. Andrew Roberts, Program Lead, South Asia Biosafety Program; and Dr. Rob Bertram, Chief Scientist, Bureau for Food Security, USAID.

This booklet is part of SABP's capacity development interventions and aims to inform researchers about the prevailing regulatory administrative system of Bangladesh. It also 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 of this booklet gives an overview of the biosafety regulations in Bangladesh. The second chapter outlines different issues that need to be considered at the beginning of an agricultural biotechnology project. It is 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.

The 6th Annual South Asia Biosafety Conference, Dhaka, Bangladesh (September 15, 2018) (from left): Dr. Vibha Ahuja, Senior Advisor, SABP; Dr. Bhavneet Bajaj, Scientific Program Manager, AFSI; and Dr. Aparna Islam, Country Manager, SABP.

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 170 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.

CURRENT COLLABORATORS & PARTNERS

United States Agency for International Development · International Food Policy Research Institute · Biotech Consortium India Limited · Indian Council of Agricultural Research · Ministry of Environment, Forest and Climate Change (India) · Ministry of Environment, Forest and Climate Change, Bangladesh · Department of Environment, Bangladesh · Bangladesh Agricultural Research Council

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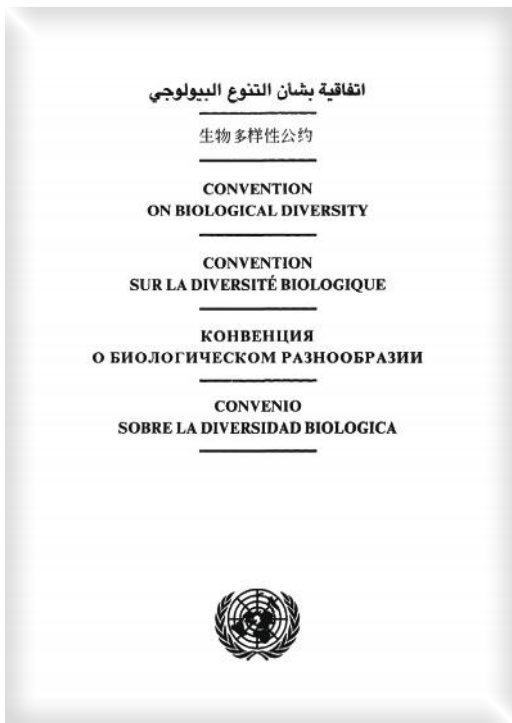
CHAPTER

1

Biosafety Regulation in Bangladesh

Bangladesh began research in biotechnology in the 1990s. Since then, the Government of Bangladesh has taken steps to ensure the safe use of this modern technology. Biosafety administration and procedures are detailed in a number of documents, including the *Biosafety Guidelines of Bangladesh 2007*, the *Bangladesh Biosafety Rules 2012*, and the *National Biosafety Framework of the People's Republic of Bangladesh 2007*, and are supported by different assessment procedures. For example, the *Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants 2012* and the *Guidelines for Environmental Risk Assessment (ERA) of Genetically Engineered Plants 2016* lay out the expected elements of food safety assessment and ERA for genetically engineered (GE) plants. This chapter provides a brief history of the development of biosafety procedures in Bangladesh. It also describes the current biosafety administrative structure for agricultural biotechnology in the country today, as per the above documents, and outlines the biosafety procedure applicable at different steps of agricultural biotechnology research and development.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生物多样性公约

CONVENTION
ON BIOLOGICAL DIVERSITY

CONVENTION
SUR LA DIVERSITÉ BIOLOGIQUE

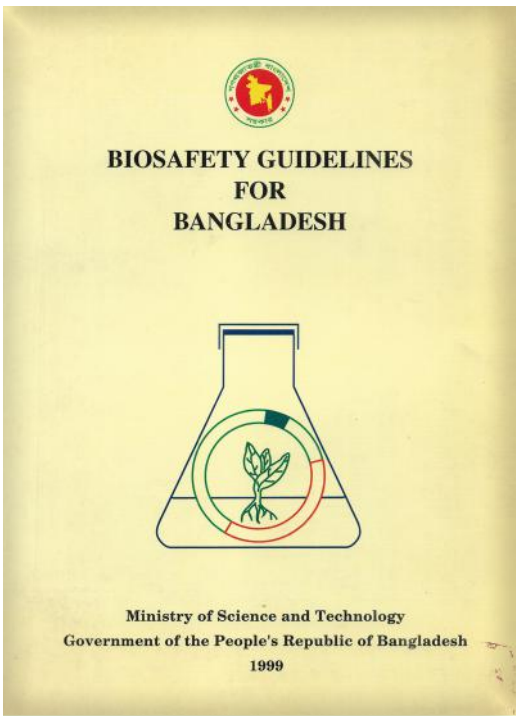
КОНВЕНЦИЯ
О БИОЛОГИЧЕСКОМ РАЗНООБРАЗИИ

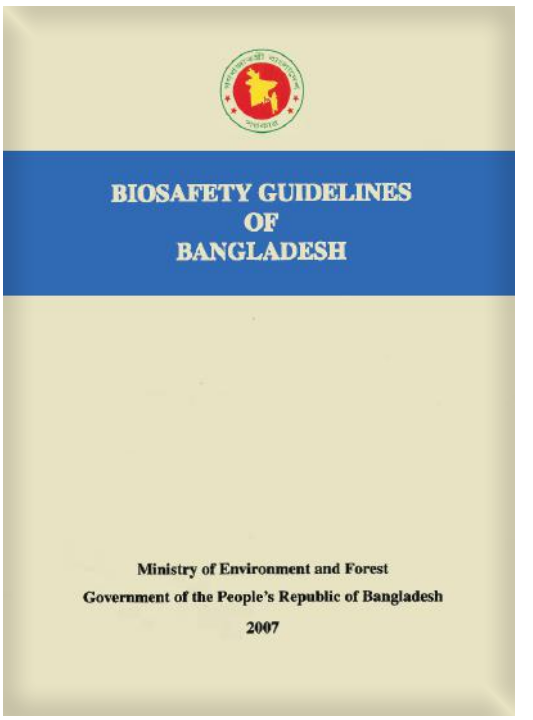
CONVENIO
SOBRE LA DIVERSIDAD BIOLOGICA

BIOSAFETY REGIME OF BANGLADESH

Bangladesh ratified the *Convention on Biological Diversity* (CBD) on 20 March 1994 in order to ensure conservation and sustainable use of the country's rich biodiversity. Research in the field of modern biotechnology also took off around the same time. To ensure safe use of biotechnology for humans, animals, and the environment, the Biosafety Guideline was first gazetted in 1999 under the Ministry of Science and Technology. Bangladesh signed the *Cartagena Protocol on Biosafety* (CPB), a subsidiary

treaty to the CBD, on 24 May 2000 and ratified four years later on 5 May 2004. Subsequently, the government assigned the Ministry of Environment, Forest and Climate Change (MoEFCC) the responsibility for the Biosafety Guideline as the Competent National Authority for implementing the obligations under the CPB. In Bangladesh, biosafety is governed by the *Biosafety Rules of Bangladesh*, promulgated under the *Environment Conservation Act* (1995) and published in the *National Gazette* in 2012. These rules codify the regulatory structures and functions mentioned in the *Biosafety Guidelines of Bangladesh 2007* and make participation in the biosafety regulatory system mandatory for all public and private sector biotechnology research. The *National Biosafety Framework of the People's Republic of Bangladesh 2007*, on the other hand, details the procedure for application approval through these committees. Therefore, as per these documents, several committees are involved in biosafety system. Moreover, these committees work under a set of procedures to evaluate the safety, compliance, and management of biotechnology.





BIOSAFETY REGULATORY STRUCTURE FOR AGRICULTURAL BIOTECHNOLOGY RESEARCH

A total of six committees composed of regulators, researchers, and experts are involved in different tiers of the biosafety system, which are described in two related documents. The specific functions of these committees are outlined in the second chapter of the *Biosafety Guidelines of Bangladesh 2007*. The administrative system of biosafety regulation, on the other hand, is elaborated in the fourth chapter of the *National Biosafety Framework of the People's Republic of Bangladesh 2007*. A brief account of the functions of these committees are given in Table 1.

From the function of the committees, it is clear that the application needs to pass through these committees sequentially. Approval from one committee leads the application to the next committee. Figure 1 is a generic flow of the application processing involving these committees.

Table 1: Functions of the committees in the biosafety system of Bangladesh, as per the Biosafety Guidelines of Bangladesh 2007 and the National Biosafety Framework of the People's Republic of Bangladesh 2007

Committees	Functions
Institutional Biosafety Committee (IBC) Chaired by a senior knowledgeable person with adequate experience in biosafety	• Review activities conducted by the institutions and recommend research proposals for consideration by the NCB. • Undertake risk assessments in cooperation with research teams, if necessary, to determine appropriate containment and biosafety conditions.
National Technical Committee on Crop Biotechnology (NTCCB) Chaired by the Secretary of the Ministry of Agriculture	• Evaluate GE crop applications and make recommendations for biosafety approval to the Ministry of Environment, Forest and Climate Change (MoEFCC).
Core Committee on Crop Biotechnology Chaired by the Executive Chairman of the Bangladesh Agricultural Research Council (BARC)	• Review technical aspects of the applications submitted to the NTCCB and make recommendations on specific biosafety approvals.
National Committee on Biosafety (NCB) Chaired by the Secretary of the MoEFCC	• Formulate, review, update, or amend national policies, acts, rules, and guidelines on biosafety. • Examine all applications submitted by any university or department or division of a research institute or a private company within a specified timeframe and approve or reject the application on a case-by-case basis. • The MoEFCC notifies the final decision of the NCB to the applicant.
Biosafety Core Committee (BCC) Chaired by the Director General of the Department of Environment (DoE)	• Provide technical comments or recommendations to the NCB or the government on policy, legal, and technical issues of biosafety as and when requested. • Examine applications for any permit/license for the import of GMOs/LMOs/GE organisms* for contained use, field trial, and field release and forward recommendations to the NCB for consideration. • Arrange annual inspections and performance evaluations of all laboratories engaged in research, development, and demonstration (R&DD) of GMOs/LMOs/GE organisms.
Field Level Biosafety Committee (FBC)	• Monitor field trial of GMOs/LMOs/GE plants.

**GMOs = Genetically Modified Organisms; LMOs = Living Modified Organisms; GE = Genetically Engineered*

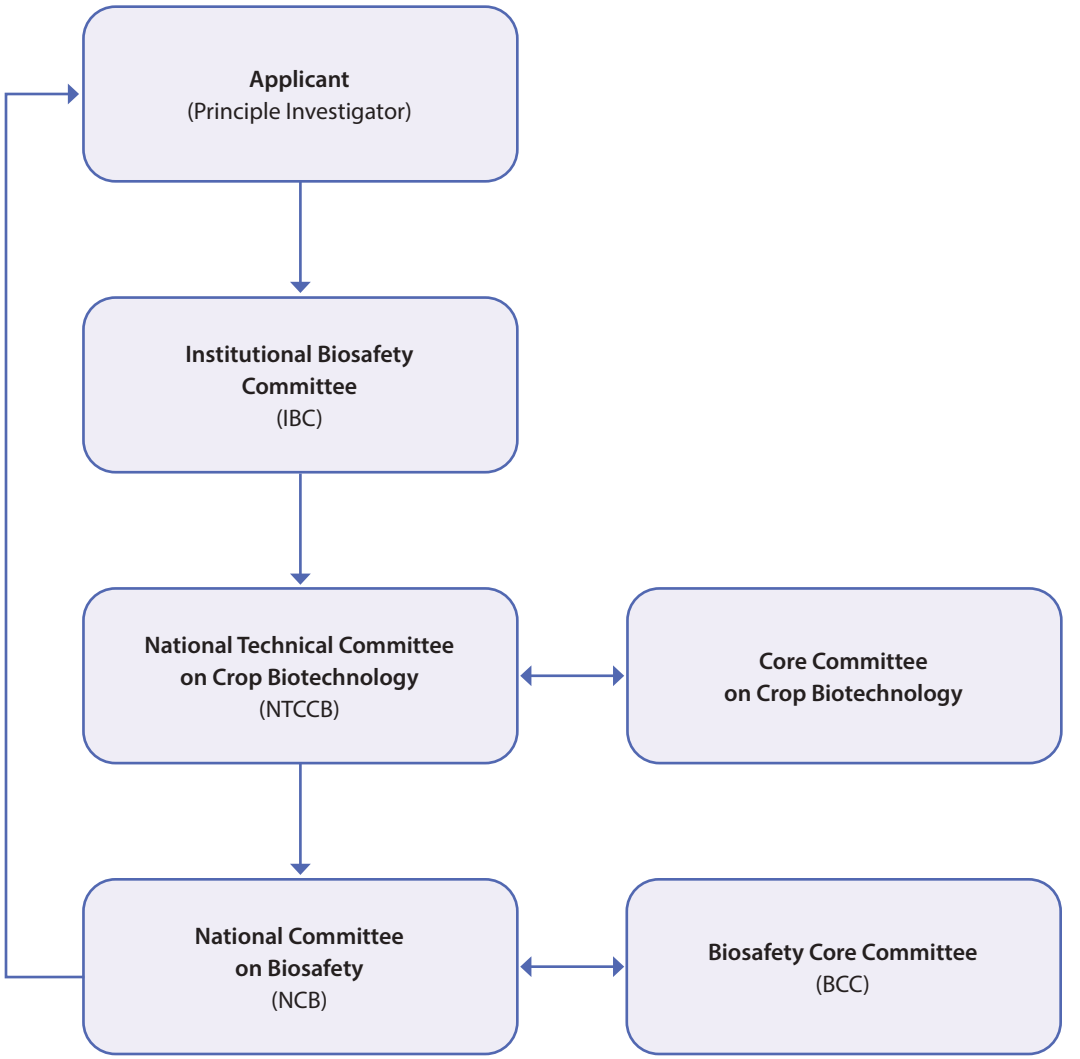


Figure 1: Flow of biosafety applications, and their review, evaluation, assessment, recommendation, and approval through different biosafety committees of Bangladesh for crop biotechnology.

BIOSAFETY PROCEDURES FOR AGRICULTURAL BIOTECHNOLOGY RESEARCH

Biosafety approval is needed at each stage of agricultural biotechnology research and development process. Approval is needed starting from the inception stage to conduct research with GMOs in the laboratory, for conducting Confined Field Trials (CFTs), and also for field release or cultivation. For each type of approval, specific pieces of information need to be included in the application. Once the application is submitted to the biosafety system, it is passed through the concerned biosafety committees sequentially. During the approval process, the potential risk of GE plants/products related to human and animal health, environment, and biodiversity is assessed on the basis of scientific data.

CHAPTER

2

Inception of an Agricultural Biotechnology Project

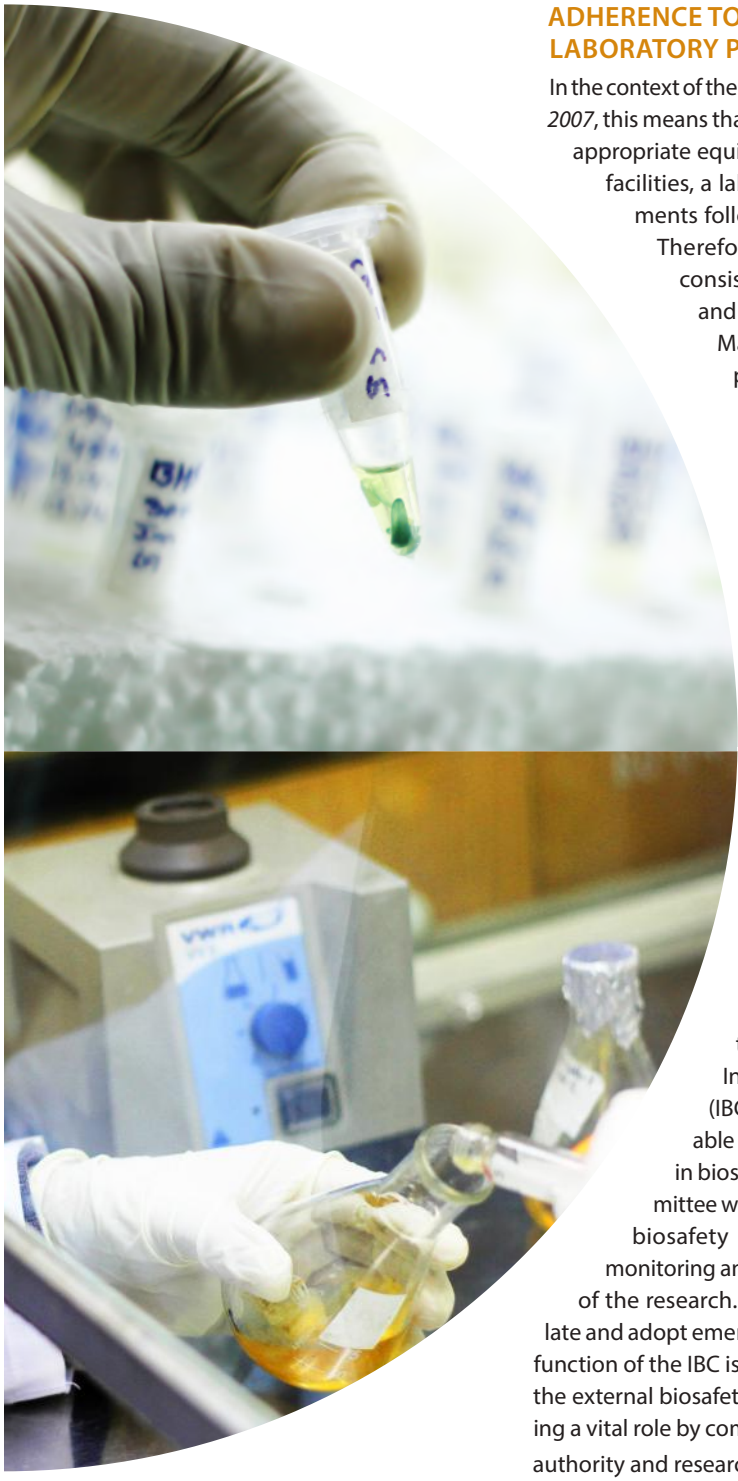
Working with Genetically Engineered (GE) organisms—also known as Genetically Modified Organisms (GMOs) and Living Modified Organisms (LMOs)—needs technical expertise. So, before starting any GE research, certain manpower and laboratory facilities need to be in place. The concerned laboratory needs to follow good and standard laboratory practices and should have an institutional body overseeing biosafety issues in the form of an Institutional Biosafety Committee (IBC).

MANPOWER

A laboratory should be staffed with a sufficient number of people to accomplish all the required tasks. These persons need to have appropriate qualifications, experience, and training in working with GE organisms and techniques.

BIOSAFETY LEVEL (BSL) LABORATORY FACILITIES

Laboratories working with organisms are categorized into four levels depending on the organism categories: Biosafety Level 1 to 4 (BSL-1 to BSL-4). For GE crop generation, the research involves working with plants and bacteria, like *Agrobacterium*. All plants that are not categorized as noxious weeds can be treated as BSL-1 organisms. *Agrobacterium* is also typically placed in Risk Group I, i.e., no risk to health and environment. Usually, laboratory precautions at BSL-1 consist of regular hand-washing, minimal protective equipment, and destruction of all materials generated from experiments through combustion or autoclaving before disposal.



ADHERENCE TO GOOD LABORATORY PRACTICES

In the context of the *Biosafety Guidelines of Bangladesh 2007*, this means that, along with qualified personnel, appropriate equipment, materials, reagents, and facilities, a laboratory will perform all experiments following standard methodologies. Therefore, the study will be uniform, consistent, reliable, and reproducible, and its reporting will be methodical. Maintenance of health and safety precautions also falls under this requirement. Therefore, good laboratory practice means controlled management of a laboratory.

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

Before inception of research activities, the institute needs to establish a four-membered Institutional Biosafety Committee (IBC) headed by a senior knowledgeable person with adequate experience in biosafety as its chairperson. This committee will look into the compliance of the biosafety requirements through regular monitoring and evaluation of biosafety aspects of the research. The committee will also formulate and adopt emergency plans. Another important function of the IBC is maintaining a close liaison with the external biosafety committees (Table 1) and playing a vital role by communicating with the regulatory authority and research team.

CHAPTER

3

Application Processing for Laboratory Work with Genetically Engineered Crops

According to the *Biosafety Guidelines of Bangladesh 2007* (Chapter 3), the Chief Investigator of a biotechnology research project needs to apply to the National Committee on Biosafety (NCB) through his/her institution's Institutional Biosafety Committee (IBC), expressing interest in working with GE crops. However, applications are not submitted directly to the NCB. For projects involving agricultural crops, the IBC will submit the application first to the National Technical Committee on Crop Biotechnology (NTCCB) at the Ministry of Agriculture. The NTCCB will evaluate the application together with the subsidiary Core Committee on Crop Biotechnology, which provides technical and scientific advice to the NTCCB. Once the NTCCB has completed the review, the application is forwarded to the NCB at the Ministry of Environment, Forest and Climate Change (MoEFCC).

Box 1 lists the information a laboratory needs to present in such an application.

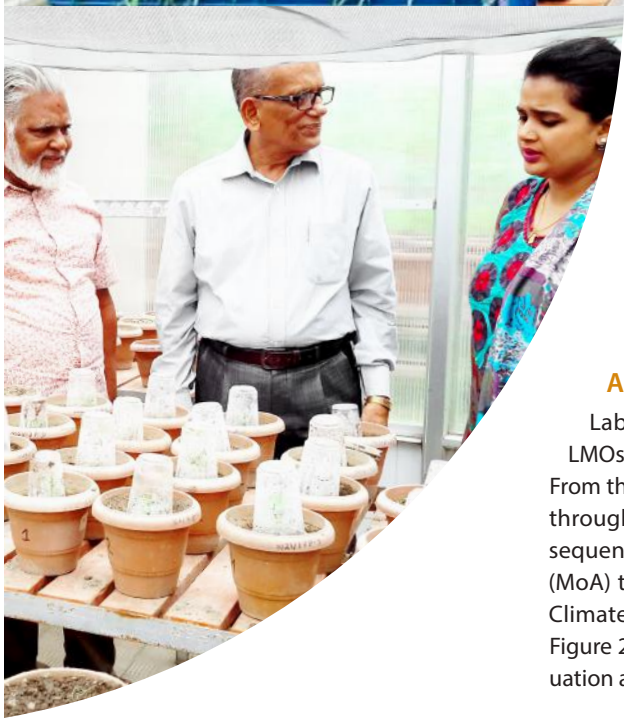
Box 1: Information needed in the project proposal (application) in favor of working with GMOs/LMOs or GE crops by a laboratory

a. Title of the project
b. Name and address of the Chief Investigator
c. Objectives of the project
   i. Overall objectives
   ii. Specific objectives
d. Intended date of commencement
e. Intended date of completion
f. Intended classification (i.e., BL1, BL2, BL3 or BL4)
g. Any special precautions to be adopted
h. Details of the biological system to be used (These will give vivid description of the donor, host characteristics, vector, viability etc.)
i. History of prior work with the system to be used
j. Personnel involved in the work and their background
k. Laboratory facilities available

In addition, the Project Proposal has to include supplementary information for work with

   i. Plants
   ii. Animals
   iii. Microorganisms

l. Additional information (if any)



IMPORTANT INFORMATION ABOUT APPLICATIONS

Once the NCB receives an application, it forwards the same to the Biosafety Core Committee (BCC) for technical advice and review. With a vetting from the BCC, the NCB gives permission according to the concerned organism's Biosafety Level mentioned in the *Biosafety Guidelines of Bangladesh 2007* (Annexes 1 and 4). Plants are typically categorized as BSL-1. In addition, upon the approval of the Member Secretary of the NCB, the NCB registers the laboratory for the given Biosafety Level.

For GE research work, a laboratory might need to import LMOs/GMOs for their research. Prior to each import, the Chief Investigator needs to inform the NCB, via the IBC. The requirements for notifying the NCB vary according to the biosafety levels of the organism. As per the *Biosafety Guidelines of Bangladesh 2007* (Chapter 3), the NCB only needs to be informed about the import of BSL-2, BSL-3, and BSL-4 organisms. BSL-1 organisms (which include most plants) are exempt from this requirement. Moreover, all laboratories need to follow the rules and regulations of the Ministry of Commerce during the import of any material related to biotechnology.

APPLICATION PROCEDURE

Laboratories intending to work with GMOs/LMOs/GE crops need to apply through their IBCs. From the applicant institutions, the applications go through all the biosafety regulatory committees sequentially, through the Ministry of Agriculture (MoA) to the Ministry of Environment, Forest and Climate Change (MoEFCC) for the final decision. Figure 2 presents the procedure of application evaluation and approval.

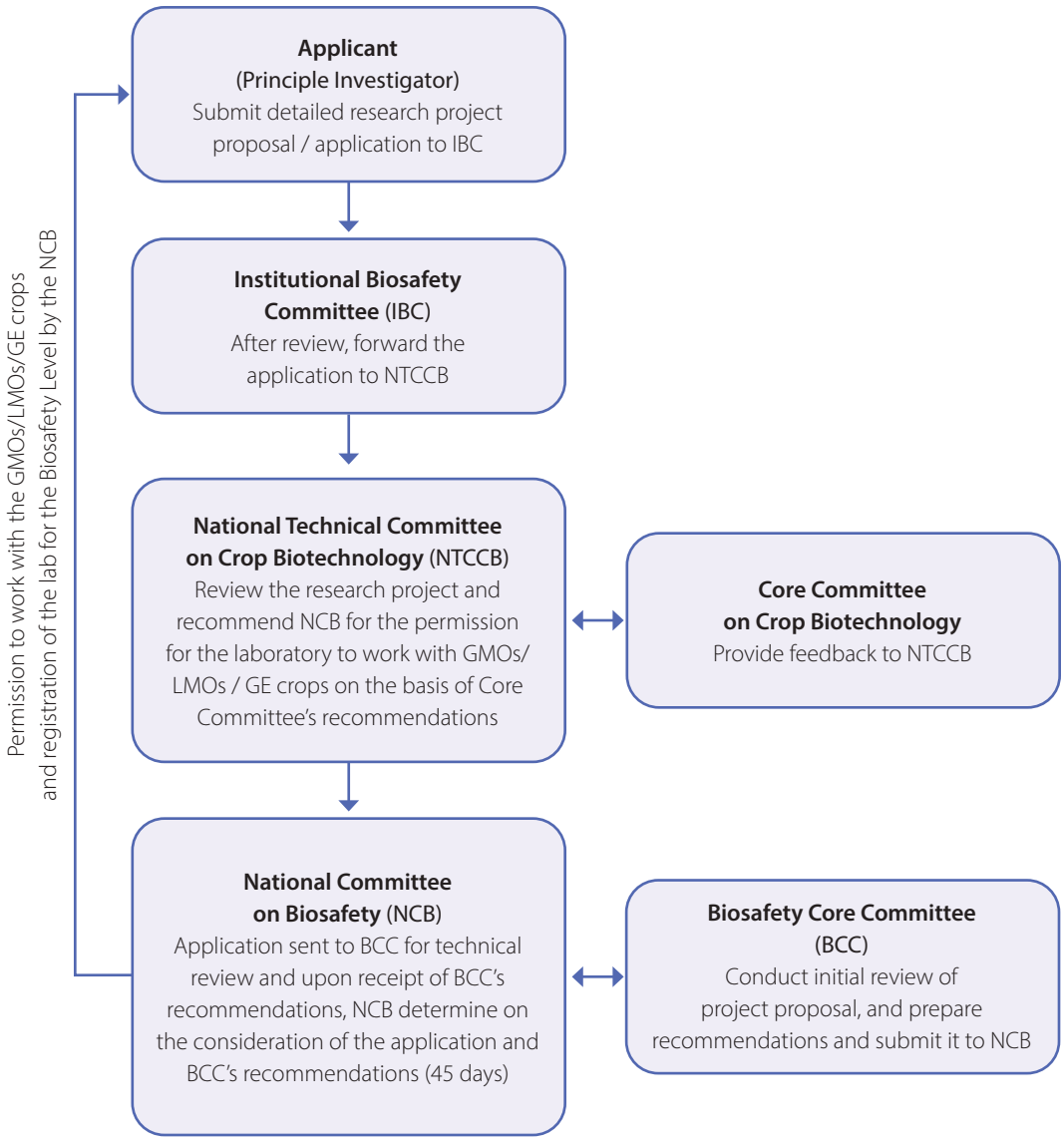


Figure 2: Procedure for approval of a research project proposal/application made by a laboratory to work with GMOs/LMOs/GE crops.

BIOSAFETY CONSIDERATIONS DURING APPLICATION EVALUATION

During the evaluation of an application, the biosafety committees consider several aspects of biosafety. These include: qualification and training of the persons involved in the project; availability of appropriate facilities, equipment, and materials in the proposed laboratory; health and safety precautions as per the national and/or international regulations; and implementation of the principles of good laboratory practice as per the *Biosafety Guidelines of Bangladesh 2007* (Annexes 1 and 2) in the applicant's laboratory.

CHAPTER

4

Application Processing of GE Plant Cultivation for Confined Field Trials & Field Release/Cultivations

Once a GE crop is successfully regenerated and grown satisfactorily in the laboratory, it is time to take the plants outside. In the environment, a GE crop is grown in two stages. First, its performance is checked and biosafety data are collected in Confined Field Trials (CFTs). Then, the best performing GE crop lines are released to the farmers for cultivation. Under the *Biosafety Guidelines of Bangladesh 2007* (Chapter 3), applications for confined field trials and field release for commercial cultivation are combined. Box 2 lists the information that needs to be presented in an application requesting permission for CFTs and field release/cultivation.

IMPORTANT INFORMATION ABOUT THE APPLICATIONS

Confined Field Trial (CFT) Application:

Confined field trials (CFTs) are small-scale field experiments that are normally conducted to address biosafety requirements and to evaluate the performance of the specific traits in GE crops. Therefore, this trial has two purposes: to generate research data and to generate data for biosafety assessments.

As part of the development of a GE crop, the performance of the transgenic trait(s) and the agronomic characters that are typical of the crop are recorded under CFT conditions. To have a clear picture of the GE crop's performance, CFTs are carried out in multiple locations and may be repeated several times.

Box 2: Information needed in the application for Confined Field Trials (CFT) and field release/ cultivation

a. Title of the project
b. Name and address of the Chief Investigator
c. Objectives of the project
   i. Overall objectives
   ii. Specific objectives
d. Intended date of commencement
e. Intended date of completion
f. Location of release with area to be covered
g. Time of release (Date)
h. Expected date of completion of release
i. Information on similar release elsewhere with adverse effect observed (if any)
j. Experimental details with quantity of materials to be released (e.g. number, weight, size etc.)
k. Is future field release of the same material expected? If yes, include amount, time location and period of release
l. What is the intended output of the field release?
m. Precautionary measures to be taken as per Biosafety Guidelines in case of adverse situation
n. Additional information (if any)

In case of commercial release application, additional information needs to be submitted:

a. Summary of the field data
   i. Duration of the field test
   ii. Location of the field test
   iii. Scale of field test
   iv. Detailed methodology of field test
   v. Result obtained
   vi. Conclusion
b. Rational for development of the organism for commercialization
c. Details of specific modifications and for what purpose it was done
d. Environmental consequences
e. Citations

After analyzing all these data, the best performing crop line(s) (event) is selected for future adaptation. During further CFTs, seeds of this selected crop line(s) is multiplied in anticipation of its commercial cultivation/field release. However, to release a GE crop, it is important to assess the biosafety issues, which is the second aspect of conducting CFTs.

Biosafety assessments are carried out using a comparative approach in order to ensure that the GE crop is "as safe as its conventional counterpart" for use in agriculture and for human health. For this reason, during CFTs, data are recorded for both the GE crop and its untransformed counterpart to do the comparative study. These data include: some core information, like, molecular changes, protein profile, and agronomic characters; environmental data, including effect of GE crop in the environment and biodiversity; and food safety data, such as compositional data, including information on toxicity and allergenicity.

Pre-requisite for CFTs:

To conduct CFTs, there are two types of information required to be prepared prior to the trials.

a. Crop-specific Biology Information:

During the CFTs, the general agronomic characteristics of the plants are evaluated. For this purpose, crop-specific biology information is used as a reference to provide pertinent biology information of the untransformed conventional counterpart. This can often be addressed through the use of a crop biology document prepared by an international organization, such as the Organization for Economic Cooperation and Development (OECD), and supplemented with needed information to understand the growing practices related to this crop in Bangladesh. Alternatively, applicants can prepare and publish a crop-specific biology document for Bangladesh, which can then serve as a resource for additional applications pertaining to this crop. SABP maintains a list of international and country-specific crop biology documents that are currently available on the Bangladesh Biosafety Portal (https://bangladeshbiosafety.org).

b. Standard Operating Procedure (SOP):

CFTs require management of i) genetic confinement (preventing gene flow by restricting cross pollination with compatible species and seed production), ii) material confinement (ensuring that GE materials do not enter the food chain), and iii) environment confinement (safeguarding the environment through complete removal of GE materials from the trial site). Therefore, a set of standard operating procedures (SOPs) are developed to

ensure management of these confinements before starting the CFTs. Many aspects of the SOPs may be standardized for a particular crop, but CFT managers should adapt SOPs for the specific requirements of their trial sites.

Commercial Cultivation/Field Release Application:

During CFTs, a certain GE crop line(s) is identified as the best performing line(s). In these selected lines, the transgenic trait performs well and the GE crop is compared to the untransformed control crop line for other characteristics. At this stage, researchers consider the GE crop lines ready for large-scale cultivation. Therefore, an application is made to permit farmers and growers to cultivate the GE crop commercially. This application is also called "Application for Environmental Release."

The application will include data of CFTs, laboratory work, and prior publications. For environmental release, specific assessments are done to consider whether or not the GE crop will pose any risk to the environment, following the format of Bangladesh's *Guidelines for Environmental Risk Assessment (ERA) of Genetically Engineered Plants 2016*. Moreover, if the GE crop product aims to enter into the food chain, then assessment is done as per Bangladesh's *Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants 2012*. The totality of the assessment provides assurance of safety for food, livestock feed, and environmental release. Much of the data that are provided with this application are recorded during CFTs. A list of information required for these assessments are mentioned in Table 2.

After evaluation of the application by the relevant biosafety committees, if the decision is positive, then approval for release will be given. The approval can be with or without restrictions or risk management measures. Approved commercial cultivation is not subject to the strict confinement measures that are applied during CFTs. Nevertheless, the NCB may place some conditions or restrictions on the cultivation of the GE plant based on its risk assessment.

APPLICATION PROCEDURE

Applications for both CFTs and field release/cultivation go through all the biosafety regulatory committees sequentially—from the institute, through the Ministry of Agriculture (MoA), and to the Ministry of Environment, Forest and Climate Change (MoEFCC) for the final decision. Figure 3 presents the procedure of application evaluation and approval.

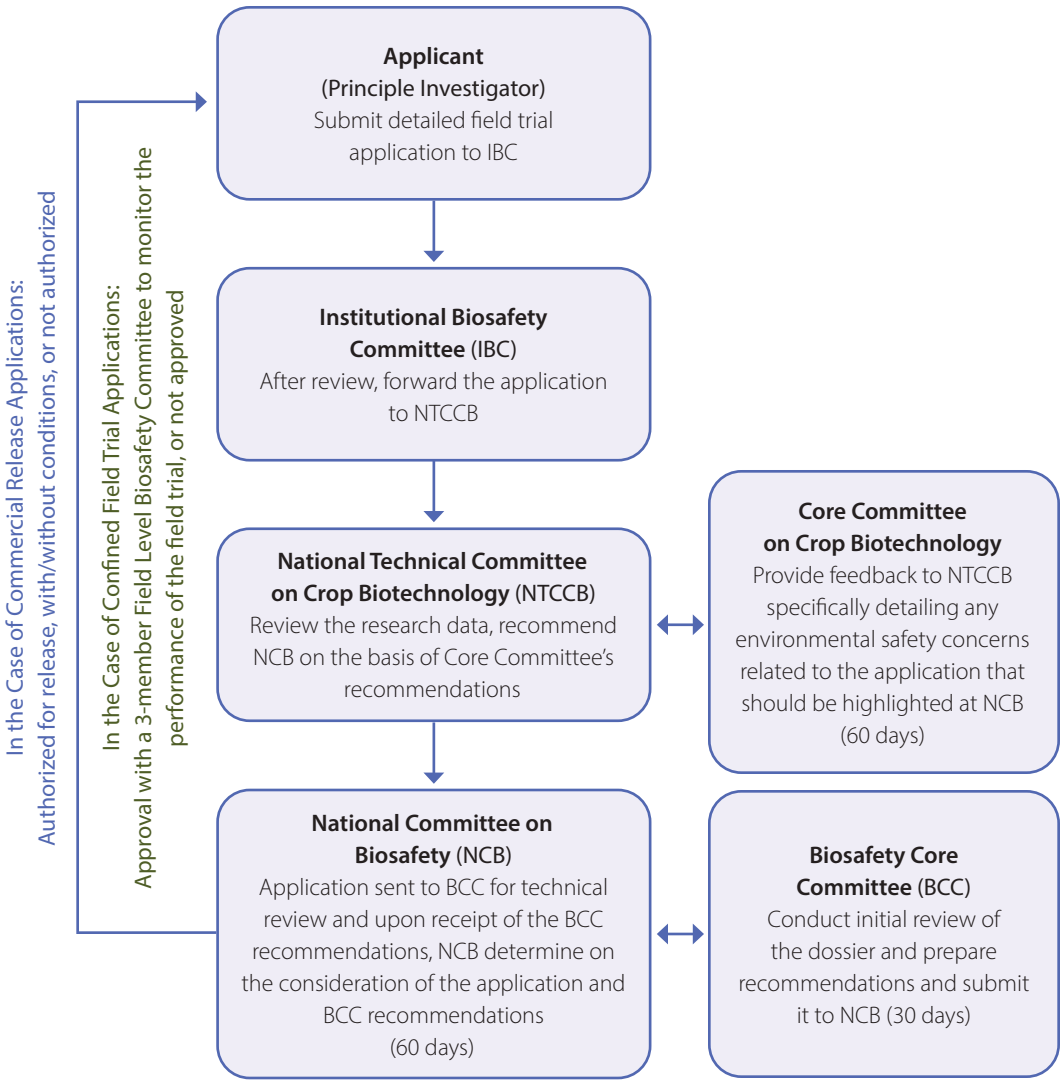


Figure 3: Procedure for approval of confined field trials (CFTs) and field release/cultivation of GE crops.

BIOSAFETY CONSIDERATIONS DURING APPLICATION EVALUATION

During the application evaluation, the biosafety committees assess several aspects of the GE plant. These assessments are carried out using a comparative approach where the GE plant is typically compared with its non-GE counterpart. The non-GE plant has a history of safe use, and thus serves as the comparator. For these assessments, information in the following categories is evaluated:

1. Genetic modification and molecular characterization of the GE plants;
2. Environmental risk assessment of GE plants; and
3. Food and feed safety assessment derived from GE plants, if the application is for commercial cultivation with an intention to include the GE product in the food chain.

Table 2: Broad information requirements for safety assessment of GE plants.

Effect of Genetic Modification and Protein Characterization	Environmental Safety	Food and Feed Safety
• Description of the GE 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	• Confirmation of expression level of new proteins: quantification of 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, such as predators and soil microflora • Changes in gene-flow pattern through pollen-flow studies and crossability studies with sexually compatible relatives	• 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

CONCLUSION

Modern biotechnology has shown its immense potential to improve agricultural crop production, especially when conventional plant breeding methods may not be productive. Nevertheless, there are concerns over potential risks of this advanced technology. It is therefore crucial to follow biosafety management protocols during research and development of GE products, including agricultural crops.

This book gives an overview of the biosafety rules and regulations to be followed in developing GE crops and releasing the same for commercial cultivation in Bangladesh. The information and biosafety provisions summarized here are essentially based upon the biosafety rules, regulations, and guidelines prevailing in Bangladesh at the time of this publication. The management of biosafety is a dynamic process, which evolves with the modern biotechnology and our improved understanding of the nature around us. So, for biotechnology researchers, it is important to stay updated with the developments of national and international biosafety regulatory regimes, while practicing biotechnology in agriculture and other fields.

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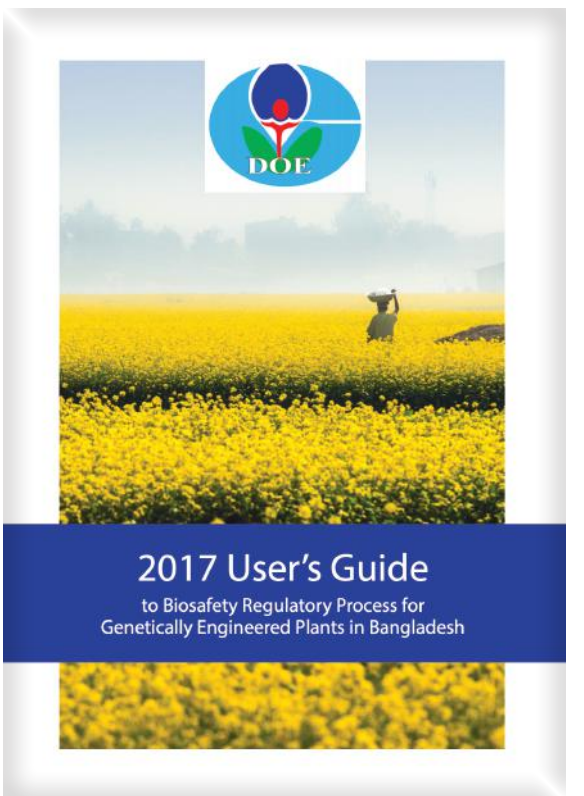
SABP Activities in Bangladesh

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 Bangladesh* 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, BCSRI 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 Ministry of Environment, Forest and Climate Change. 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

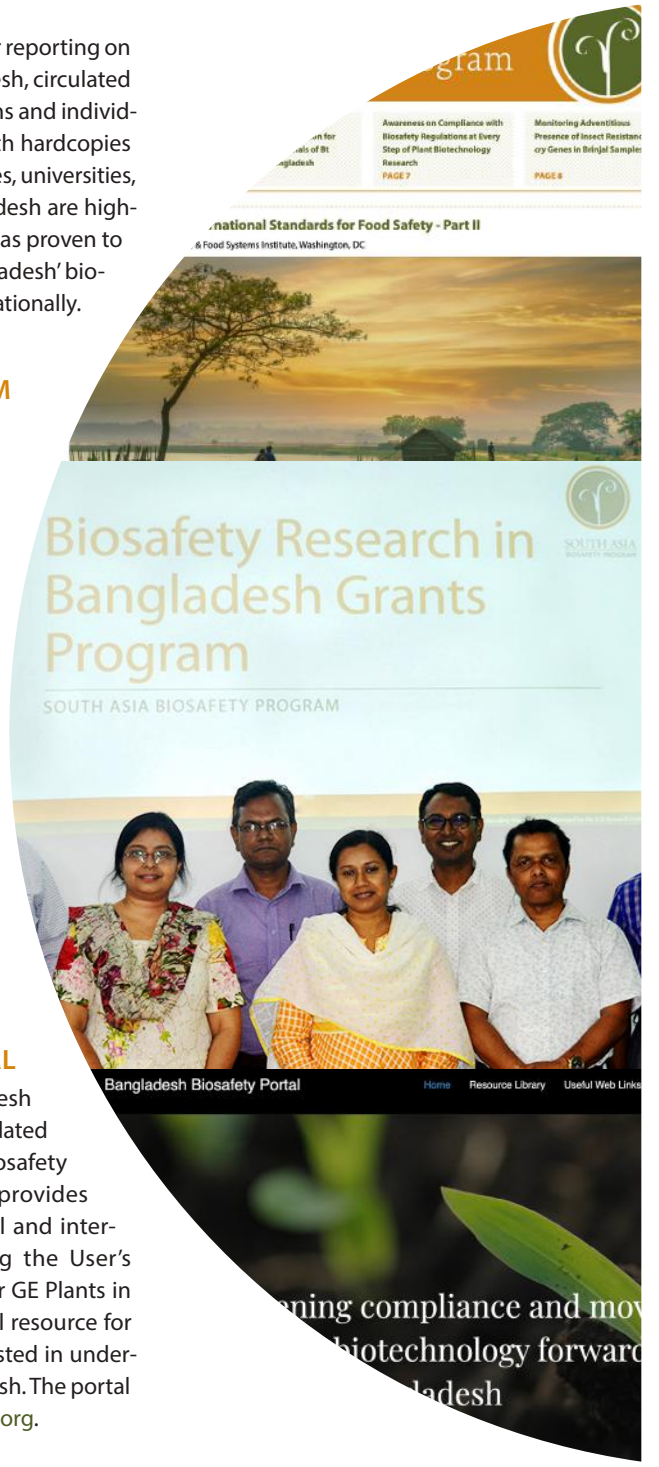
Every month, SABP publishes a newsletter reporting on activities relevant to biosafety in Bangladesh, circulated through email to over 25,000 organizations and individuals in South Asia and internationally, with hardcopies distributed to agriculture research institutes, universities, and scientists. 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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