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## South Asia Biosafety Program

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#### **BIOSAFETY RESOURCE BOOK SERIES**

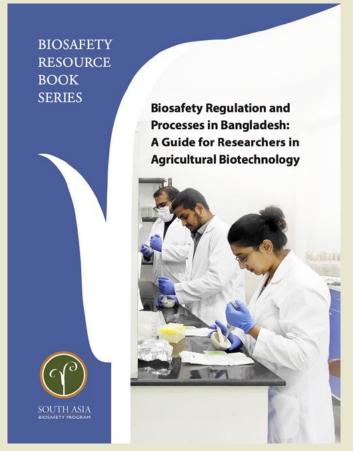
### Biosafety Regulation and Processes in Bangladesh: A Guide for Researchers in Agricultural Biotechnology

In the mid-1990s, plant scientists of Bangladesh began research in the field of genetic engineering (GE), thus modern biotechnology. Recognizing the potentials of this technology, Bangladesh's first *National Agriculture Policy 1999* included this technology in the program. Over the past three decades, biotechnology is now well adopted by various organizations. Thus, to improve country's food security and other priority areas, various ministries, research institutions, and public and private universities are now utilizing modern biotechnology to attain their missions. To date, considerable achievements have been accomplished in the field of GE crop research and development.

Further, to ensure the safety of biotechnology in the environment, including safety for humans, animals, and biodiversity, Bangladesh has established a biosafety regime. Biosafety Guidelines of Bangladesh 2007, the Bangladesh Biosafety Rules 2012, and the National Biosafety Framework of the People's Republic of Bangladesh 2007, and several assessment guidelines, manuals, and regulatory documents define the biosafety regulatory system. As per the biosafety regulations, all GE crops need to go through safety assessment before reaching farmers and consumers and are subject to oversight during the research and development stages.

In 2005, South Asia Biosafety Program (SABP) started operating in Bangladesh to provide support to the government to strengthen institutional governance of biotechnology, including through the development of regulatory documents, manuals, and assessment guidelines for biosafety. SABP is also involved in capacity development of the research community to ensure proper implementation of biosafety regulatory processes. During these activities, SABP felt the need for presenting these guidelines and regulatory documents in an easily understandable manner to the stakeholders for better implementation

In light of this, SABP has taken the initiative to publish the **Biosafety Resource Book Series**. *Biosafety Regulation and Processes in Bangladesh: A Guide for Researchers in Agricultural Biotechnology* marks the launch of this series as part of SABP's capacity development interventions in Bangladesh. This book is aimed at researchers, as it is crucial to follow biosafety steps throughout the whole process of research and development, to take the GE research outcomes from the laboratory to the field and subsequently, to the farmers. The first chapter of this book 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 different steps an application has to go through before conducting 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.

Additional installments in the series are planned for release in 2021.

**Preferred Citation**: Islam, A. and Roberts, A.F. (2020) Biosafety Regulation and Processes in Bangladesh: A Guide for Researchers in Agricultural Biotechnology. South Asia Biosafety Program, Agriculture & Food Systems Institute (AFSI), Washington, DC.

### **Download the Biosafety Resource Book:**

http://bit.ly/afsi-sabp-biosafetybook1

### Overcoming the Pandemic in 2020: Digital Dialogues on Biosafety in Bangladesh

Dr. Aparna Islam, South Asia Biosafety Program

Over the final seven months of 2020, the eight webinars organized as part of the SABP Webinar Series in Bangladesh are a milestone for several reasons. These webinars were organized in collaboration with seven universities and one research institute, mostly located outside the capital, Dhaka. Female attendees made up almost half of the 355 academics, scientists, research fellows, and students who participated in the sessions. Since universities and halls were closed, almost all participants joined the webinars from their hometown. Overall, the SABP Webinar Series resulted in a countrywide expansion of SABP's network with institutions and individuals, despite limited physical movement due to the pandemic.

In addition to the SABP Webinar Series, the SABP team in Dhaka also conducted a virtual Training on Biotech and Biosafety Policy in Bangladesh as part of the Agri Science Leadership Skill Development Training Program, which was organized by Farming Future Bangladesh and Sher-e-Bangla Agricultural University Youth Alliance, as well as a webinar on agricultural biotechnology that was organized jointly with the US Agency for International Development, US Department of Agriculture, and US Department of State. Combined, SABP's virtual outreach programs in Bangladesh reached a total of over 450 participants.

Like many countries, genetic engineering (GE) and biotechnology is in the curriculum of Bangladesh's universities that are active in research as well. But, to harness the benefit of this science, the researchers also need to incorporate biosafety practices in their research projects.

One of the main objectives of SABP is capacity development in biosafety among various stakeholders for better compliance of biosafety regulations. Therefore, SABP took an initiative to reach out to these students, early-career researchers,

SABP took an initiative to reach out to students, early-career researchers, and faculty members from various universities.

and faculty members from various universities along with the scientists from research institutes for a better understanding of the regulatory system and to improve their effectiveness at implementing biosafety in their academic and professional careers.

During the webinars organized in 2020, audiences were informed about the prevailing biosafety regulatory administrative system in Bangladesh. The sessions outlined the regulatory processes functioning at different stages of research and development of GE crops. Specific emphasis was given to exciting events, such as biosafety of GE animals and gene edited crops. Those virtual sessions also discussed new ideas on updating biosafety syllabi.

Challenges open up opportunities. But, the year 2020 can't be defined by the simple word "challenge." The pandemic has changed our perception, attitude, and relationship with life, reflected in our lifestyles, including the way we deal with our profession and education system. We have adapted to our new lifestyle by embracing the advantages of medical science and developing our resilience by pursuing modern biotechnology R&D. SABP in Bangladesh is no exception. It has also adapted to the changed situation, adopted digital innovations, and brought the audience from their confinement to interact and build a conscious generation on Bangladesh's biosafety regime.

VIDEO

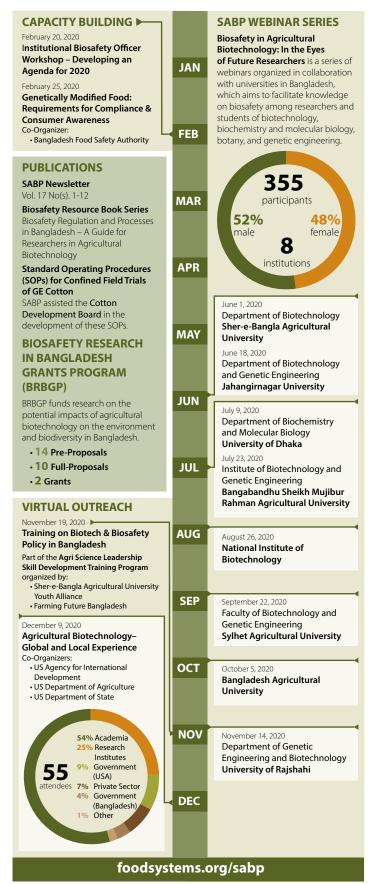
Watch All Eight Installments of the 2020 SABP Webinar Series:

http://bit.ly/sabpwebinarseries2020



### **Bangladesh**

### 2020 HIGHLIGHTS



### Agricultural Biotechnology: Global and Local Experience

Mr. Sium Ahmed, Biosafety Support Office, South Asia Biosafety Program



Dr. Andrew Roberts, introducing the speakers at the webinar on Agricultural Biotechnology: Global and Local Experience (December 9, 2020)

The South Asia Biosafety Program (SABP), in collaboration with the United States Agency for International Development (USAID), United States Department of Agriculture (USDA), and United States Department of State organized a webinar on December 9, 2020. The objective of the webinar was to share information and to have an open discussion on biotechnology developments and biosafety practices, worldwide and in Bangladesh. The event was attended by 57 participants, including government officials, policy makers, regulators, researchers, academicians, and other stakeholders. Mr. John Smith-Sreen, Director, Economic Growth Office, USAID chaired the occasion, and the event was moderated by Dr. Andrew F. Roberts, Chief Executive Officer, Agriculture and Food Systems Institute (AFSI).

In his speech, Mr. Smith-Sreen emphasized the enhanced partnership that has been built between the governments of Bangladesh and the United States through the dissemination of innovative technologies and research activities. The impact of such successful and effective partnership has been proven by the leadership of Bangladesh in

agricultural production. During the scientific session, the global experience on agricultural biotechnology was discussed by Dr. Stuart Smyth, Associate Professor, University of Saskatchewan. He concretized that, regardless of the debate, GE technology is the safest innovation to be commercialized, as no adverse effect has been seen in the last 30 years. Dr. Smyth gave a global snapshot of GE crops and their benefits. To shed light on the local experiences, first Dr. Md. Abdullah Yousuf Akhond, Chief Scientific Officer and Head, Biotechnology Division, Bangladesh Agricultural Research Institute (BARI) discussed Bangladesh's experience with Bt Brinjal and biotech potato. He briefed the audience on the accomplishments of Bt Brinjal in field trials for regulatory approval and regulatory compliance after the approval. He explained the involvement of multiple organizations, including BARI, Bangladesh Agricultural Development Corporation (BADC), and Department of Agricultural Extension (DAE) in Bt Brinjal seed production and distribution. He also talked about the development of single gene late blight resistant potato

and subsequent advancement on the event with three genes. Afterwards, Dr. Md. Abdul Kader, Principal Scientific Officer, Plant Breeding Division, Bangladesh Rice Research Institute (BRRI) shared experiences with Golden Rice at BRRI. He outlined the major events including gene integration, phenotypic and agronomic evaluation, environmental and food safety assessment through multi-location confined field trials, and lastly, gave an overview of the regulatory status of Golden Rice in Bangladesh. A presentation on biosafety considerations was given by Dr. Roberts, AFSI, who explained the biosafety regulatory structure in Bangladesh, guidelines, and review process that is outlined in various documents.

Mr. Smith-Sreen emphasized the enhanced partnership that has been built between the governments of Bangladesh and the United States through the dissemination of innovative technologies and research activities. The impact of such successful and effective partnership has been proven by the leadership of Bangladesh in agricultural production.

After the scientific session, a lively discussion on various GE crops and products took place. Regarding the stewardship and value chain of Bt Brinjal, Dr. Akhond informed participants that an effective stewardship is already in place, combining seed distribution, field monitoring, and cultivation evaluation.Inresponsetobeta-carotenedegradation and resulting efficacy of Golden Rice,

Dr. Kader gave assurance that, after months of storage, the amount of beta-carotene remaining in golden rice meets a significant proportion of the daily requirement. He also added that the gradual loss is very low when compared to other Vitamin A-rich fruits and vegetables. Questions raised regarding the abundance of insect populations in Bt cotton fields were addressed by Dr. Roberts, who informed participants that researchers found an increase in the number of non-target insects in the Bt fields compared to fields treated with insecticides. Dr. Smyth pointed that all the information should be shared to build an effective communication system to capitalize the benefits of this technology. Dr. Roberts added that it was better for the scientific community, researchers, and regulators to be open to the questions and concerns that are raised.

The webinar delineated an engaging conversation between the diversified audiences, and the discussion aimed to clarify any confusion or concerns shared by the audience.

### Webinar on Gene Editing for Agriculture, Society, and Sustainable Development: Prospects and Perspectives

Dr. Vibha Ahuja, Biotech Consortium India Limited



# SCIENCE SERVING SOCIETY WEBINAR SERIES GENE EDITING FOR AGRICULTURE, SOCIETY AND SUSTAINABLE DEVELOPMENT: PROSPECTS AND PERSPECTIVES 15 DECEMBER 2020, 10 AM IST





Dr. Vibha Ahuja, Chief General Manager,

**BCIL** informed participants that gene

editing, though a relatively recent

technology, has enormous potential and

is being widely applied for dealing with

several challenges in agriculture.

Speakers for the Webinar on Gene Editing for Agriculture, Society, and Sustainable Development: Prospects and Perspectives (December 15, 2020)

Tata Institute for Genetics and Society (TIGS) in partnership with Biotech Consortium India Limited (BCIL) organized a webinar on Gene Editing for Agriculture, Society, and Sustainable Development: Prospects and Perspectives on December 15, 2020. The webinar was chaired by Padma Bhushan Dr. R.S. Paroda, Chairman, Trust for Advancement of Agricultural Sciences, Former Secretary, DARE and Former DG, ICAR. The deliberations of the webinar included two presentations and a panel discussion by eminent national and international experts in the field. The webinar was attended by more than 700 participants representing a cross section of stakeholders, including scientists, regulators, industry, research students, etc. The webinar drew interest from not only India, but other countries as well. Participants from more than 15 countries attended the webinar.

Introducing the objective of the webinar, Dr. Vibha Ahuja, Chief General Manager, BCIL informed participants that gene editing, though a relatively recent technology, has enormous potential and is being widely applied for dealing with several challenges in agriculture. The inven-

tors of CRISPR-CAS techniques used for gene editing have been recently awarded the Nobel prize for chemistry. She indicated that the webinar is being organized in view of extensive research efforts initiated in India and the need for an enabling environment to make use of these applications of gene editing for the benefit of farmers and society.

Dr. R.S. Paroda, in his opening address, indicated that in view of its immense potential, gene editing is being considered as a "disruptive innovation" to deal with. He stressed that a clear policy on regulation of gene editing is urgently required in the country to make use of the technology in dealing with challenges of agriculture and strengthening the hands of our farmers so that they can practice low input, high output agriculture. He emphasized that public awareness is also very important, and all doubts should be cleared to build an environment of trust and transparency for consumer acceptance.

Dr. Chinnusamy Viswanathan, Head, Division of Plant Physiology, ICAR-IARI, New Delhi introduced the techniques of gene editing and potential applications. He also shared information on some of the key initiatives in development of gene edited crops in the country, including bacterial blight resistant rice, nutritionally enriched banana, stress tolerant tomato, etc. Dr. Donald MacKenzie, Executive Director, Institute for International Crop Improvement, Donald Danforth Plant Science Centre informed participants about the evolving regulatory and policy landscape around the world. Based on the safety criteria and regulatory approaches, Dr. MacKenzie opined that nearly all the market-oriented plant breeding innovations derived from genome editing are suited to "regulation as conventional products" and not GMO regulation.

In the panel discussion, remarks were made by Dr. Deepak Pental, CSIR–Distinguished Scientist and former Vice-Chancellor, University of Delhi, Dr. K.V. Prabhu, Chairperson, Protection of Plant Varieties and Farmers' Rights Authority, Dr. Subhra Chakraborty, Director, National Institute of Plant Genome Research, Dr. N.K. Singh,

National Professor, B.P. Pal Chair, National Institute for Plant Biotechnology, and Dr. Amitabh Mohanty, Trait Discovery Ops Leader, Corteva Agriscience, Johnston, USA. Expert panelists spoke about different aspects on facilitating the use of gene editing viz. advances in research, status of regulations in India, public partnerships, etc. Recommendations made by the National Academy of Agricultural Sciences were also shared.

VIDEO

### The complete recording of the webinar can be accessed at:

https://tigs.res.in/2020/12/26/webinar-highlights-3/

### Harmonization of Existing Toxicological Guidelines/Protocols for **Registration of Biopesticides in India**



Directorate of Plant Protection, Quarantine and Storage, Ministry of Agriculture and Farmers Welfare, Government of India has invited comments of stakeholders on the guidelines/protocols for registration of biopesticides, vide public notice dated January 7, 2021. These protocols were approved by the Registration Committee in its meeting held on October 23, 2020. Stakeholders are required to submit comments within 30 days period from the date of uploading of the public notice.

The protocols under consideration include:

- Acute dermal (toxicity/infectivity/pathogenicity) study
- Acute inhalation (toxicity/infectivity/pathogenicity) study
- Acute intraperitoneal/intravenous (toxicity/infectivity/pathogenicity) study
- Acute oral (toxicity/infectivity/pathogenicity) study
- Acute pulmonary (toxicity/infectivity/pathogenicity) study
- Cell culture study
- Acute eye irritation study
- Proposed toxicological guidelines/data requirements for registration of antagonistic bacteria based biopesticides under Section 9(3B) and 9(3) of the Insecticide Act, 1968
- Proposed toxicological guidelines/data requirements for registration of antagonistic fungi based biopesticides under Section 9(3B) and 9(3) of the Insecticide Act, 1968
- Proposed toxicological guidelines/data requirements for registration of Baculoviruses-Nuclear Polyhedrosis Virus (NPV) and granulosis virus (GV) under Section 9(3B) and 9(3) of the Insecticide
- Proposed toxicological guidelines/data requirements for registration of entomopathogenic fungi based biopesticides under Section 9(3B) and 9(3) of the Insecticide Act, 1968
- Proposed toxicological guidelines/data requirements for registration of entomotoxic/entomopathogenic bacteria (technical and formulation) under Section 9(3B) and 9(3) of the Insecticide Act,
- Acute dermal irritation study
- Skin sensitization

### For details please visit:

http://www.ppqs.gov.in/sites/default/files/public\_notice\_ for\_harmonization\_of\_exsting\_toxicological\_guidelines\_ and protocols.pdf



ent of Agriculture, Co-operation & Farmers Welfare वनस्पति संरक्षण, संगरोध एवं संग्रह निदेशालय वनस्थाने सरक्षण, स्थानीय एवं साइन नियंशालय DIRECTORATE OF PLANT PROTECTION, QUARANTINE & STORAGE केंद्रीय कीटनाशी बोर्ड ए वम पंजीकरण समिति Central Insecticides Board and Registration Committee एन. एवं. ५, कर्षतिवादा (हरियाणा)-121001 N.H. IV, FARIDABAD (HARYANA)-121001

Dated: 04-January, 2021

#### PUBLIC NOTICE

Subject-Harmonization of existing toxicological guidelines/protocols for registration of biopesticides in India-regarding.

The matter was placed before the RC at agenda item No. 10.16 in  $422^{nd}$  meeting held on 23.10.2020 and RC has approved the guidelines/protocols drafted by the sub-committee and decided that a public notice may be displayed on the website for seeking comments of the stakeholders.

In view of the above, stakeholders are requested to submit their co from the date of uploading of the Public Notice on the website of Dte. of PPQ&S. The reply may be sent through email to cibsecy@nic.in, sarita.bhalla@nic.in and socir2.ppqs-agri@gov.in.

This has the approval of Secretary (CIB&RC).

PPS to Secretary (CIB&RC) IT Cell, HQ, Faridabad for uploading the same on the website

CALENDAR OF EVENTS			
EVENT	ORGANIZED BY	DATE	WEBSITE

EVENT	ORGANIZED BY	DATE	WEBSITE	
BANGLADESH				
International Biotech Symposium 2021	Community of Biotechnology, in collaboration with the Institute of Biotechnology and Genetic Engineering, Bangabandhu Sheikh Mujibur Rahman Agricultural University (BSMRAU)	February 13-20, 2021 Virtual	https://www.ibs2021.info/	
INDIA				
Plantation Crop Genomics: An Overview of Current Research	Indian Society for Plantation Crops	January 18-20, 2021 Virtual	http://bionivid.com/ispc	
Webinar on Research Priorities for the Indian Seed Sector	Federation of Seed Industry of India	January 23, 2021 Virtual	https://fsii.in	
Technology Awareness Session on the Need for Biotechnology in Indian Agriculture	University of Agricultural Sciences, GKVK, Bangalore, in collaboration with the Federation of Seed Industry of India and Alliance for Agri Innovation	January 28, 2021 Virtual	https://us02web.zoom. us/webinar/register/WN_ P0qIVyI5SqyInF7gikvmiA	
Pulse WebCon 2021: National Webinar on Sustaining Pulse Production for Self Sufficiency and Nutritional Security	Indian Society of Pulses Research and Development and ICAR-Indian Institute of Pulses Research, Kanpur	February 9-11, 2021 Virtual	https://iipr.icar.gov.in/	
Indian Seed Congress 2021	National Seed Association of India	February 24-26, 2021 Bengaluru	https://isc2021.nsai.co.in/	
International Conference on Sugarcane Research	ICAR-Sugarcane Breeding Institute, Tamil Nadu Agricultural University, and Society for Sugarcane Research and Development	June 19-22, 2021 Coimbatore	https://sugarcane.icar.gov.in/index.php/en/canecon-2020 https://tnau.ac.in/wp-content/uploads/2020/10/1601938688. pdf	
INTERNATIONAL				
Briefing Webinar on Agenda Items 4-6 of the 24 <sup>th</sup> Meeting of the Subsidiary Body on Scientific, Technical, and Technological Advice	Secretariat of the Convention on Biological Diversity	January 28, 2021 Virtual	https://www.cbd.int/meetings/	
7 <sup>th</sup> Plant Genomics and Gene Editing Congress: Asia	Global Engage Ltd.	April 20-21, 2021 Virtual	http://www.global-engage.com/ event/plant-genomics-asia/	



The South Asia Biosafety Program (SABP) is an international developmental program implemented in India and Bangladesh with support from the United States Agency for International Development. SABP aims to work with national governmental agencies and other public sector partners to facilitate the implementation of transparent, efficient, and responsive regulatory frameworks for products of modern biotechnology that meet national goals as regards the safety of novel foods and feeds, and environmental protection.







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