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South Asia Biosafety Program

INDIA

Environmental Release of GM Mustard Approved by the Government of India

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Mustard Field © Rudra Narayan Mitra | Dreamstime.com

The Ministry of Environment, Forests and Climate Change (MoEFCC), Government of India has approved the environmental release of transgenic mustard hybrid DMH-11 and its two parental lines Varuna bn 3.6 and EH-2 modbs 2.99 containing the *bar*, *barnase*, and *barstar* genes for hybrid seed production. The genetic engineering (GE) based hybrid seed production system was developed by the Centre for Genetic Manipulation of Crop Plants, University of Delhi. This is the first genetically modified (GM) food crop to have been approved in India after a long gap. The only other GM crop to have gotten approval for cultivation in India is GM cotton in 2002. This is, indeed, a welcome step.

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Hybrid DMH-11 was developed using a GE-based pollination control system by deploying three transgenes–*barnase*, *barstar* and *bar*. Line Varuna bn 3.6 contains bar::barnase genes and is male sterile. EH-2 modbs 2.99 is the fertility restorer line developed using bar::barstar genes. The *bar* gene has been introduced for *in vitro* selection of transgenic plants and for hybrid seed production in the field (Figure 1). Hybrid DMH-11 is produced by crossing lines Varuna bn 3.6 and EH-2 modbs 2.99, has all the three genes, *barnase*, *barstar* and *bar*, and is fully fertile. This technology was first deployed in rapeseed, a sister crop of mustard. The barnase/barstar based system of hybrid seed production provides hybrid seed with high purity and can be transferred to any set of combiners using backcross breeding, as compared to conventional Cytoplasmic Male Sterility (CMS) systems.

Yields of oilseed crops have been stagnating in India for the last 10-15 years. As a consequence, the deficit between consumption and production is increasing. Mustard (*Brassica juncea*) is one of the important oil seed crops of India and is grown on 6-7 million ha of land. The average mustard yield in India is around 1.3 tonnes/hectare, which needs to be improved to around 2 tonnes/hectare to the meet the global trends. India is currently importing almost 50-60% of its total

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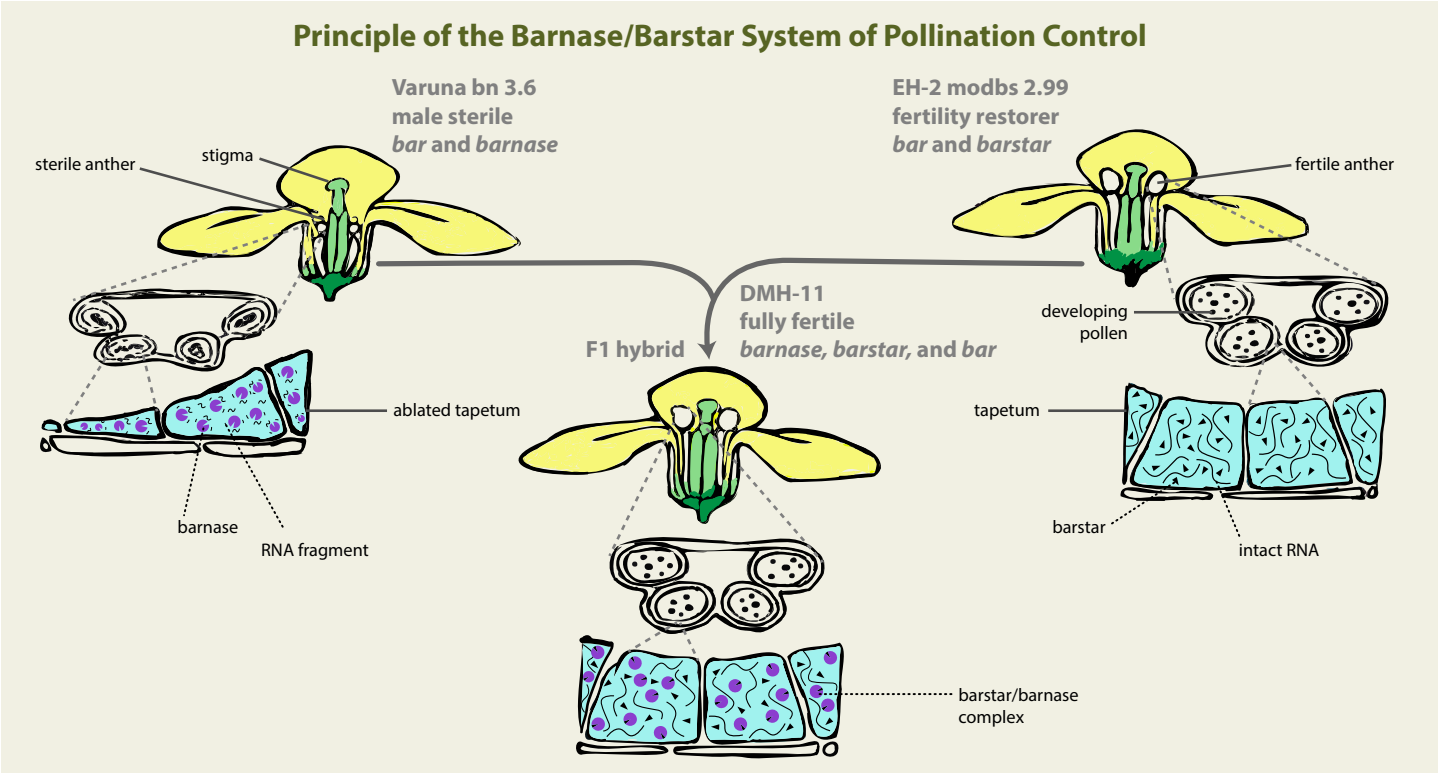


Figure 1: The principle of the barnase/barstar system of pollination control (adopted from William, M.E. 1995. Genetic engineering for pollination control. Trends in Biotechnology. 13: 344-349.)

edible oil requirement, and to reduce this deficit, productivity has to increase. The challenge of higher yields can only be met with the development of productive hybrids.

GM mustard hybrid DMH-11, which has been approved by the Indian regulatory system for cultivation, has shown a yield advantage of around 25-30% over the best national and zonal checks grown in India. This is the first hybrid developed using the barnase/barstar system, and more will follow. This technology will now be made available to plant breeders in the public and private sectors to accelerate breeding efforts to produce new high yielding disease and pest resistant hybrids.

The decision of the Indian government to release GM mustard will also encourage more research and innovations in the area of GM crops, thereby helping the food and nutritional security of the country.

The minutes of 147th GEAC meeting can be accessed at: https://geacindia.gov.in/Uploads/MoMPublished/MoMPublishedOn20221025200345.pdf

ANNOUNCEMENT

Indian Biological Data Center

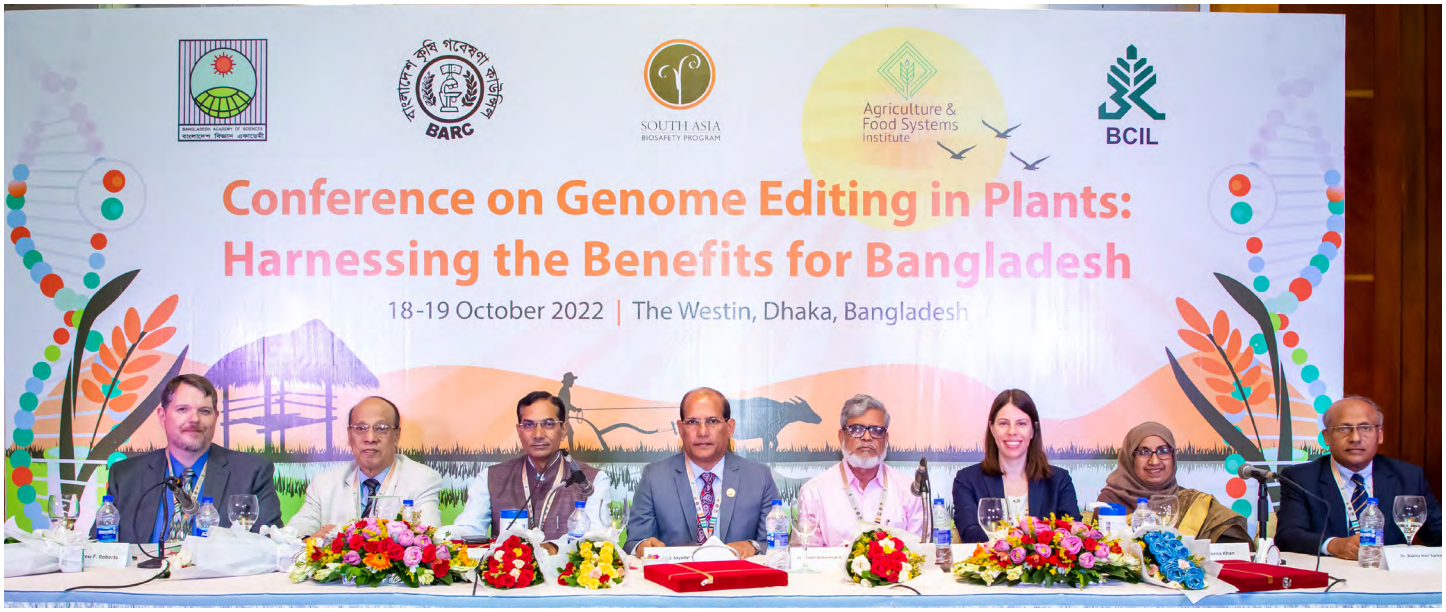
Prof. Saurabh Raghuvanshi, Lead, Indian Biological Data Center, Regional Center of Biotechnology

The "Indian Biological Data Centre (IBDC)" is the first national repository for life science data in India (**ibdc.rcb.res.in**). As per Biotech PRIDE guidelines, IBDC is mandated to archive all life science data generated from publicly funded research in India. The data center is supported by the Government of India (GOI), through the Department of Biotechnology (DBT). It has been established at the Regional Centre of Biotechnology (RCB), Faridabad and has a data "Disaster Recovery" site at the National Informatics Centre (NIC), Bhubaneshwar. Fundamentally, IBDC is committed to the spirit of data sharing as per FAIR (Findable, Accessible, Interoperable, and Reusable) principles. IBDC is being developed in a modular nature, wherein different sections would typically deal with particular type(s) of life science data. IBDC has started its services by providing nucleotide data submission services via two data portals *viz.* the "Indian Nucleotide Data Archive (INDA)" and "Indian Nucleotide Data Archive-Controlled Access (INDA-CA)," which primarily differ in their data access provisions. Data submitted to INDA is actively synced with the International Nucleotide Sequence Database Collaboration (INSDC) repositories like GenBank, ENA, and DDBJ and is simultaneously assigned accession ids from both IBDC and INSDC repositories. Submissions to INDA-CA remain under "controlled access" and are not shared with any international repositories. Users are free to submit data to any of these repositories as per their need. Currently, both the portals have accumulated over 200 billion bases from 2,08,055 submissions from more than 50 research labs across India. IBDC also hosts an online "Dashboard" for the genomic surveillance data generated by the INSACOG labs (**https://inda.rcb.ac.in/insacog/statisticsinsacog**). The dashboard provides customized data submission, access, data analysis services, and real-time SARS-CoV-2 variant monitoring across India. Data submission and access portals for other data types (structural biology data, metabolic data sets, crop phenotyping, various image data sets, etc.) are under development and would be launched shortly.

The computational infrastructure at IBDC is also made available for researchers interested in performing computational intensive analysis. Users can contact the data center by submitting their requests at support@ibdc.rcb.res.in. Further, IBDC conducts regular workshops and orientations (**https://ibdc.rcb.res.in/news-and-announcement/**) to assist users in submitting the data. Video tutorials for data submission to IBDC are also available at the data center website. The data center team can also be contacted at support@ibdc.rcb.res.in for scheduling any workshop on data submission/analysis.

Conference on Genome Editing in Plants: Harnessing the Benefits for Bangladesh

Hridi Prova Saha & Seam, Brac University



Guests at the Inaugural Session (from left): Dr. Andrew F. Roberts, CEO, AFSI; Prof. Dr. A.K. Azad Chowdhury, President, BAS; Dr. Trilochan Mohapatra, President, National Academy of Agricultural Sciences, India; Mr. Md. Sayedul Islam, Honorable Secretary, Ministry of Agriculture, Bangladesh; Dr. Shaikh Mohammad Bokhtiar, Executive Chairman, BARC, Bangladesh; Ms. Megan Francic, Agricultural Attaché, Foreign Agricultural Service, USDA; Dr. Haseena Khan, Secretary, BAS; Prof. Dr. Rakha Hari Sarker, Country Coordinator, SABP.

In light of the recent surge in the use of genome editing tools in plants, a conference titled "Genome Editing in Plants: Harnessing the Benefits for Bangladesh" was held on October 18-19, 2022, at The Westin, Dhaka. The objective of the two-day outreach event was to discuss the global developments and adoption of genome editing technology and its potential application to improve sustainable agriculture production and food security in Bangladesh. This conference also provided a platform for discussion amongst stakeholders, including international experts and domestic scientists from the public sector, academia, and the private sector, to inform enabling policies on handling the products of genome editing in Bangladesh. The conference was hosted by the Bangladesh Academy of Sciences (BAS), in collaboration with the South Asia Biosafety Program (SABP) implemented by the Agriculture & Food Systems Institute (AFSI), Biotech Consortium India Limited (BCIL), and the Bangladesh Agriculture Research Council (BARC).

The objective of the two-day outreach event was to discuss the global developments and adoption of genome editing technology and its potential application to improve sustainable agriculture production and food security in Bangladesh.

The chief guest at the inauguration ceremony was Mr. Md. Sayedul Islam, Honorable Secretary, Ministry of Agriculture, Government of the People's Republic of Bangladesh. Dr. Andrew F. Roberts, Chief Executive Officer, AFSI, USA opened the conference with a welcome address. Prof. Dr. A.K. Azad Chowdhury, President, BAS provided introductory remarks on various aspects that the event aimed to achieve. Following this, Dr. Haseena Khan, Secretary, BAS gave a very informative speech on the status of genome editing research for crop improvement in Bangladesh. The keynote speaker, Dr. Trilochan Mohapatra, former Director General, Indian Council of Agricultural Research (ICAR) and President, National Academy of Agricultural Sciences (NAAS), India pointed out the prospects of genome editing in accelerating the pace and precision of plant breeding. Special remarks were given by Ms. Megan Francic, Agricultural Attaché, Foreign Agricultural Service, United States Department

Dr. Wayne Parrott, Distinguished Professor, University of Georgia presenting during Technical Session 1.

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Dr. Naoko Kato-Nitta, Associate Professor, Joint Support-Center for Data Science Research/The Institute of Statistical Mathematics Research Organization of Information and Systems, Japan answering questions during Technical Session 5, along with Dr. Zahurul Karim, Vice-President, BAS and Dr. Rakha Hari Sarkar, Country Coordinator, SABP and Professor, University of Dhaka.

of Agriculture (USDA), and Dr. Shaikh Mohammad Bokhtiar, Executive Chairman, BARC. The distinguished guests of the events were honored with crests and flowers for their valuable contribution in this field. At the end of the inaugural session, a vote of thanks was offered by Dr. Rakha Hari Sarkar, Country Coordinator, SABP and Professor, University of Dhaka.

The conference was organized at an opportune time as several academic and research institutions in Bangladesh have ongoing research initiatives using genome editing tools to accelerate genetic improvement in various crops. The entire event was segmented into five technical sessions, which covered theoretical and practical applications of genome editing technology. The first technical session covered the applications of genome editing in agriculturally important crops, such as wheat and soybean, and the next generation traits that this new technology offers. It also included a discussion of breeding and selection, induced mutagenesis, and the precision of genome editing technologies for crop improvement. During the second technical session, speakers discussed ongoing research efforts in Bangladesh and the advantages that genome editing technology offers in terms of cost and efficient resource utilization. The third session covered the varietal approval system in Bangladesh, general criteria for assessing genome edited plants, and the challenges presented in the detection of genome edited plants. The fourth technical session included presentations on global policy developments and the need for an enabling environment in Bangladesh. The last session at the conference focused on the public perception of novel technologies, such as genome editing, followed by a discussion on the way forward in Bangladesh.

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Over the course of two days, presentations were provided by 16 speakers, including invited lectures from Brazil, China, India, Japan, the Philippines, and the USA. Each technical session was followed by a panel session that allowed the attendees to discuss relevant aspects of genome editing and its application to improve agriculture in Bangladesh.

LINKS

For more information on the presentations, please visit: https://foodsystems.org/event/ge-ag-bangladesh-2022-conference/

For a more in-depth version of this article, with details about each technical session, please visit: https://foodsystems.org/wp-content/uploads/2022/11/SABP_11_November_2022_Supplement.pdf

BANGLADESH

The Fifth Workshop of the Institutional Biosafety Officer (IBO) Training Program

Prof. Dr. Md. Shahidul Islam and Prof. Dr. Md. Shahidul Haque, Department of Biotechnology, Bangladesh Agricultural University

The fifth workshop of the Institutional Biosafety Officer (IBO) training program was held on October 15-16, 2022 at the BRAC Center for Development and Management (BCDM) Rajendrapur, Gazipur, Bangladesh. The workshop was organized by the Agriculture & Food Systems Institute (AFSI), USA, under the auspices of the South Asia Biosafety Program (SABP) and in collaboration with Biotech Consortium India Limited (BCIL) and the Ministry of Agriculture, Government of the People's Republic of Bangladesh. Participants from the Bangladesh Agricultural Research Institute (BARI), Bangladesh Rice Research Institute (BRRI), Bangladesh Institute of Nuclear Agriculture (BINA), Bangladesh Jute Research Institute (BJRI), Cotton Development Board (CDB), National Institute of Biotechnology (NIB), Bangladesh Agricultural University (BAU), Jahangirnagar University, and Dhaka University attended the program.

Prof. Dr. Rakha Hari Sarker, Country Coordinator, SABP and Professor, University of Dhaka welcomed all the participants and gave a brief introduction of the program to all. Dr. Andrew Roberts, Chief Executive Officer, AFSI recapped the previous training sessions in the series. Dr. Aparna Islam, Professor, Brac University gave a short presentation on "Regulatory Testing vs. Research Experiments: Why the Data for Your Dossier Is Different Than Your Thesis?" She stated that data for regulatory testing should provide information to answer specific regulatory questions, not to provide all possible academic knowledge.

In Technical Session 1, Dr. Vibha Ahuja, Chief General Manager, BCIL and Senior Advisor, SABP presented on "Regulatory Submissions: Context and Key Considerations," in which she provided guidance to the applicants submitting applications on genetically modified

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plants, which are evaluated by regulatory bodies. The next trainer was Dr. Flerida Carino, Consultant, Food and Drug Administration, the Philippines, who gave a presentation on "Molecular Characterization: Data Requirements." In her presentation, Dr. Carino discussed different state-of-the-art technologies, including available protein-based detection technologies, DNA-based amplification and hybridization methods, and database information for harmonized interpretation of data and reporting of GMO detection. Dr. Bhavneet Bajaj, Manager-Scientific Programs, AFSI presented on "Data Needs for Safety Assessment of Foods Derived from GE Plants." She started by describing the meaning of case-by-case assessment of safety for GE plants. She also discussed the assessment of possible toxins and potential allergens, as well as using different methods, including serum testing. She discussed in detail instances of intended genetic modification that resulted in the expression of a substance that has, or is closely related to a substance that has, a history of safe (dietary) use or exposure to humans and animals, and if further toxicological testing would be required. She also described the importance of the nucleotide sequence and amino acid sequence similarity determination against peer-reviewed allergens or toxins in databases, digestibility test using an *in vitro* pepsin digestion assay, evaluation of the stability of the protein to heat and processing, acute oral toxicity testing, etc. during the safety assessment. Moreover, she highlighted the compositional analysis, intended nutritional modifications, and unintended effects of GMO-derived foods.

Dr. Md. Abdul Kader, Principal Scientific Officer, Plant Breeding Division, BRRI and Dr. Md. Kamrul Islam, Senior Scientific Officer, CDB shared their experiences in the preparation, submission, and revision of dossiers for Golden Rice and Bt cotton.

Technical Session 2 started with a presentation on "Data Needs for the Environmental Risk Assessment of GE Plants" by Dr. Andrew Roberts. He described the concept of case-by-case assessment, the use of comparative assessments, and focused on the environmental risk assessment of characteristics of the plant, the introduced trait, and the receiving environment, as well as the intended use. Following the Dr. Roberts' presentation, Mr. Sium Ahmed, Biosafety Officer, SABP coordinated a group exercise on the relevance of data requirements. The objective of the exercise was to critically assess the relevance of data requirements on a case-by-case basis. After that, Dr. Rakha Hari Sarker presented on "Regulatory Submissions: How To Make Use of Resources and Existing Information." He described uses of different resources, e.g., the FAO GM Foods Platform, USDA APHIS, OECD BIOTRACK, CODEX-Food Safety Guidelines, and Procedural Manual of the Codex Alimentarius Commission, for the collection of relevant safety information in the preparation of a dossier for application to regulatory bodies. The last topic of Technical Session 2 was experience sharing. Dr. Md. Abdul Kader, Principal Scientific Officer, Plant Breeding Division, BRRI and Dr. Md. Kamrul Islam, Senior Scientific Officer, CDB shared their experiences in the preparation, submission, and revision of dossiers for Golden Rice and Bt cotton, respectively.

The second day of the program started with a recap of Day 1 by Dr. Bhavneet Bajaj. In Technical Session 3, Dr. Andrew Roberts delivered a talk on "Product Developer Expectations and Needs from the Regulatory System." He mentioned that an applicant or product developer should have clarity and flexibility during the data submission process to the regulators, and they can get support from IBOs in understanding the regulatory system, risk assessment process, and preparation of a good regulatory dossier following a specific format and relevant biosafety guidelines. Dr. Flerida Carino trained the IBOs on "Interpreting Regulatory Requirements: Knowing When Data Are Not Necessary." She stressed "substantial equivalence" as a starting point to understand data requirements. If the GMO is substantially equivalent to its conventional counterpart, no safety assessment is necessary, whereas if there is a defined difference between them, specific safety testing is necessary. In other words, a more rigorous safety assessment is required when the GMO

Participants at the Fifth Workshop of the Institutional Biosafety Officer (IBO) Training Program.

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is not substantially equivalent to its conventional counterpart. Finally, Dr. Vibha Ahuja discussed the issue of "Best Practices in Regulatory Dossier Development." According to her, a dossier should contain relevant data supported by study reports and/or publications that will help evaluators find information and speed up the review process.

At the end of each session, participants attended a very interactive question and answer session where they provided their opinions and thoughts. The workshop concluded with the appreciation and written feedback from participants, as well as closing remarks by the organizers.

BANGLADESH

Progress Review Meeting of the Biosafety Research in Bangladesh Grants Program (BRBGP), 2022

Kazi Toqi Yasir, South Asia Biosafety Program

The South Asia Biosafety Program (SABP) convened a progress review meeting on October 22, 2022 at Doreen Hotels and Resorts in Dhaka, Bangladesh to gain insight into the most recent developments of the research projects supported by the Biosafety Research in Bangladesh Grants Program (BRBGP). Initiated in 2019, the USAID-funded BRGBP is a part of the SABP and is implemented by the Agriculture & Food Systems Institute (AFSI). The BRBGP provides funding for research that supports biosafety and science-based decision-making and policy development in Bangladesh. To date, the program has awarded grants to seven scientists for the years 2019-2021 to conduct research aimed at increasing local knowledge and collecting baseline data that can be used to determine the potential impacts of agricultural biotechnology on the environment and biodiversity in Bangladesh.

The meeting was moderated by Mr. Sium Ahmed, Biosafety Officer, SABP. Dr. Andrew F. Roberts, Chief Executive Officer, AFSI was present at the event to provide his insightful feedback and comments to the grantees. Prof. Dr. Rakha Hari Sarker, Country Coordinator, SABP and Dr. Aparna Islam, Professor, Brac University also attended the meeting.

Dr. Roberts opened the meeting with an address in which he thanked everyone for their presence. All the scientists then presented their work to the other scientists and attendees. Dr. Gopal Das, Professor, Department of Entomology, Bangladesh Agricultural University (BAU), who received his grant in 2021, gave an overview of the outcomes of his project entitled "Assessment of Impacts of Pesticide Application in the Cultivation of High-Yielding Maize Varieties in Bangladesh." The project addressed the use, composition, and handling of pesticides in the cultivation of high-yielding maize varieties in Bangladesh. The project also investigated the effects of pesticides on the maize ecosystem.

Initiated in 2019, the USAID-funded BRGBP is a part of the SABP and is implemented by the Agriculture & Food Systems Institute (AFSI). The BRBGP provides funding for research that supports biosafety and science-based decision-making and policy development in Bangladesh.

Dr. Mohammad Tofazzal Hossain Howlader, Professor, Department of Entomology, BAU then presented his research work on "Baseline Information of Pest and Beneficial Insect Biodiversity of Cotton in Bangladesh." Dr. Howlader also received his grant in 2021. In his presentation, Dr. Howlader briefed participants on his findings concerning the biodiversity of the prevailing pests and beneficial insects in the cotton ecosystem.

Dr. Md. Fuad Mondal, Professor, Department of Entomology, Sylhet Agricultural University then discussed the results of his study on "Insect Pest Management Practices and Biosafety Status of Country Bean (*Lablab purpureus* L.) in Bangladesh." Dr. Mondal is a 2020 grant recipient. His discussion included data on the variety of insect pests in country beans and their management practices.

Dr. Abu Shamim Mohammad Nahiyan, Senior Scientist, Advanced Seed Research and Biotech Centre (ASRBC), ACI Ltd., also a 2020 grant recipient, presented the findings of his research on "Study on Fertilizer Management and Agricultural Practices of Potato Cultivation in Bangladesh." Dr. Nahiyan's results included information on crop management practices and fertilizer use in potato cultivation in Bangladesh. The effects of the current practices on the surrounding ecosystems were also covered in his study.

Participants at the Progress Review Meeting of the Biosafety Research in Bangladesh Grants Program (BRBGP), 2022.

Dr. A.N.M. Iftekhar Alam, Senior Scientific Officer, National Institute of Biotechnology and a grant recipient from 2019, then presented the findings of his project titled "Assessment of Weed Management Practices in Rice Cultivation in Bangladesh." Dr. Alam's work provided information on the weed management strategies of rice farmers and the herbicide resistance of weeds in rice fields. Also included was an evaluation of farmers' knowledge and perceptions of herbicides, as well as information on the availability of herbicides in rural markets.

Dr. Muhammad Shahidul Haque, Professor, Department of Biotechnology, BAU presented his research outcomes thereafter. Dr. Haque was also a grant recipient for 2019. His project, titled "Vegetable Pest Management Practices in Bangladesh and Their Impacts on the Environment," provided information on pest management practices, as well as a list of pesticides commonly used in selected summer and winter vegetables in Bangladesh. The research also provided information on the pesticide residues in vegetables, soil, and water and the effects of the use of pesticides on the environment.

Dr. Mohammad Zabed Hossain, Professor, Department of Botany, University of Dhaka delivered the concluding presentation on his investigation of "Use and Handling Practices of Pesticides Used in the Cultivation of High Yielding Potato Varieties in Bangladesh." Dr. Hossain, a 2019 grant recipient, discussed his findings on pesticides and their handling practices in the cultivation of high-yielding varieties of potatoes in Bangladesh. His research also gave an idea of the farmers' knowledge about the impacts of pesticides on the environment.

The results of the studies indicated the widespread use of pesticides in Bangladesh, which inflict damage to human health, the environment, and beneficial insects. The studies also showed that pesticides are not used and handled appropriately by most farmers. Additionally, the studies revealed an inefficient use of fertilizers in some regions. The findings of the BRBGP projects can contribute to developing mechanisms for improving agricultural risk management and the sustainable use of fertilizers. Furthermore, the findings may also assist policymakers in Bangladesh in assessing the feasibility of adopting pest- and disease-resistant GE plants derived from modern biotechnology, which can help reduce the use of pesticides while increasing crop yields.

CALENDAR OF EVENTS

EVENT	ORGANIZED BY	DATE	WEBSITE
BANGLADESH			
10th International Plant Tissue Culture & Biotechnology Conference	Bangladesh Association for Plant Tissue Culture and Biotechnology (BAPTC&B) and University of Dhaka	February 9-11, 2023 Dhaka	https://www.baptcb.org/conference
INDIA			
1st National Conference on Plant Genetic Resource Management (NCPGRM 2022)	Indian Society of Plant Genetic Resources (ISPGR), ICAR-IARI, ICAR-National Bureau of Plant Genetic Resources (NBPGR), Alliance of Bioversity International, and CIAT-India Office	November 22-24, 2022 New Delhi	http://www.nbpgr.ernet.in/
National Conference on Biotechnology for Sustainable Development and Human Welfare	Department of Biotechnology, School of Chemical and Life Sciences, Jamia Hamdard	November 23-24, 2022 New Delhi	https://jamiahamdard.edu/
Workshop on Genome Editing in Agriculture: Opportunities and Enabling Policies	Tamil Nadu Agricultural University (TNAU), Biotech Consortium India Limited (BCIL), and Federation of Seed Industry of India	November 29, 2022 Coimbatore	https://tnau.ac.in
International Conference on Biotechnology, Sustainable Bioresources, and Bioeconomy	Indian Institute of Technology Guwahati	December 7-11, 2022 Guwahati	https://www.iitg.ac.in/iitg_events_all https://www.bsb2iitg2022.in/
International Conference on System of Crop Intensification (ICSCI 2022) for Climate-Smart Livelihood and Nutritional Security	The Society for Advancement of Rice Research	December 12-14, 2022 Hyderabad	https://www.icar-iirr.org/ICSCI%20Brochure-2022.pdf
INTERNATIONAL			
Fifteenth Meeting of the Conference of the Parties to the Convention on Biological Diversity (Part Two) Tenth Meeting of the Conference of the Parties Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (Part Two) Fourth Meeting of the Conference of the Parties Serving as the Meeting of the Parties to the Nagoya Protocol on Access and Benefit-Sharing (Part Two)	CBD Secretariat	December 7-19, 2022 Montreal, Canada	https://www.cbd.int/meetings/

The South Asia Biosafety Program (SABP) is an international development program implemented in India and Bangladesh with support from the United States Agency for International Development (USAID). 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.

SOUTH ASIA BIOSAFETY PROGRAM

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