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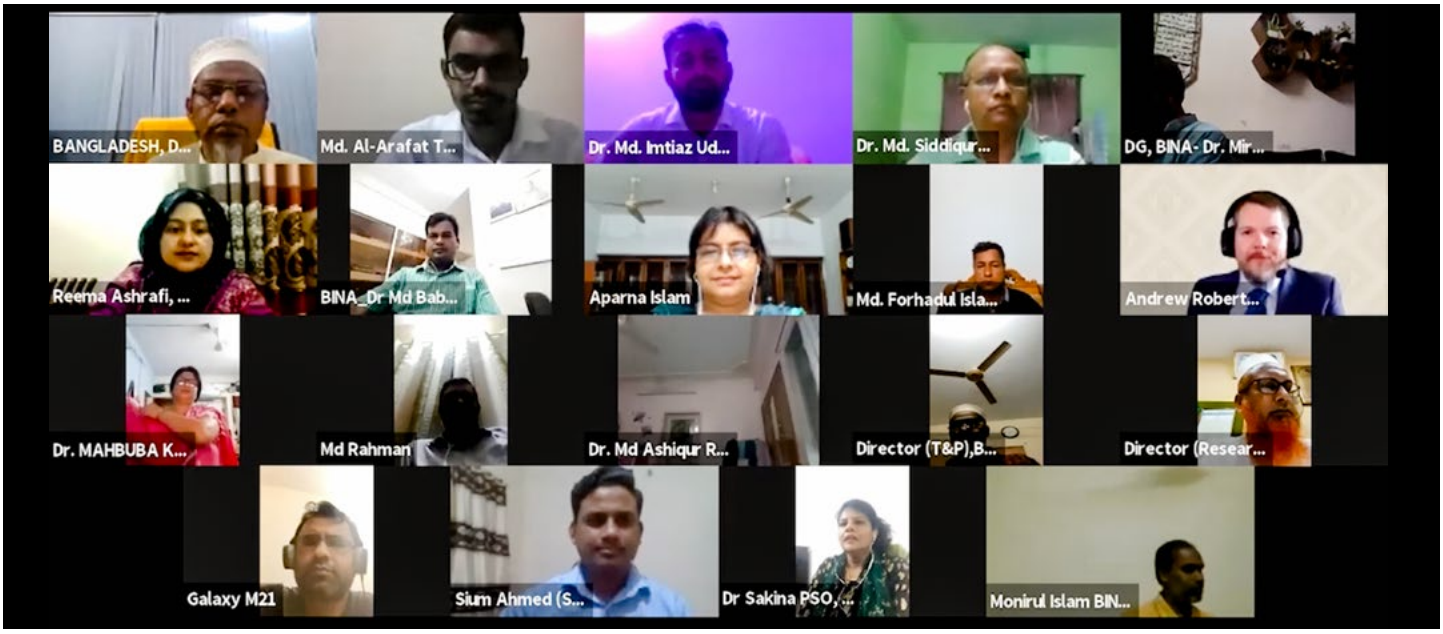
South Asia Biosafety Program

BANGLADESH

Biosafety in Biotechnology Research and Development in Bangladesh

Dr. Sakina Khanam, Principal Scientific Officer, Plant Breeding Division, Bangladesh Institute of Nuclear Agriculture (BINA)



Participants and speakers at the webinar on Biosafety in Biotechnology Research and Development in Bangladesh (June 10, 2021)

Biosafety in Biotechnology Research and Development in Bangladesh was a webinar jointly organized by the Bangladesh Institute of Nuclear Agriculture (BINA) and the South Asia Biosafety Program (SABP) on June 10, 2021. The objective of the webinar was to facilitate awareness of biosafety requirements at different stages of plant biotechnology research. For the event, Dr. Mirza Mofazzal Islam, Director General, BINA was the Chief Guest. Dr. Md. Abul Kalam Azad, Director (Administration and Support Service), BINA and Dr. Md. Abdul Malek, Director (Research) BINA were present as special guests. Dr. Andrew F. Roberts, Chief Executive Officer, Agriculture & Food Systems Institute (AFSI) and Dr. Aparna Islam, Professor, Biotechnology Program, BRAC University were present as keynote speakers. Dr. Md. Jahangir Alam, Director (Training & Planning), BINA chaired the event. The whole event was facilitated by Dr. Sakina Khanam, Principal Scientific Officer, Plant Breeding Division, BINA.

At the beginning of the webinar, as a welcome speaker, Dr. Khanam, talked about the importance and development of biotechnology research in Bangladesh and research activities of BINA. She also described the activities of SABP.

The Chief Guest of the webinar, Dr. Mirza Mofazzal Islam expressed his gratitude to the government of Bangladesh for support and co-operational effort regarding biosafety regulations. He added that, following the Cartagena Protocol, useful inventions in biotechnology should be rewarded and legally protected, which could be better achieved through more appropriate solutions, reflecting the interest of social security and food production.

The webinar was very effective for young scientists, increasing their knowledge about biosafety regulations and assessment guidelines and their contribution in conducting GE research and development.

While providing the address as the special guest, Dr. Azad emphasized the importance of appropriate biosafety regulations in Bangladesh. Dr. Malek, in his speech as another special guest, added his observation that biosafety guidelines are applicable for all kinds of observation and monitoring of research and development activities with modern biotechnology.

Dr. Roberts, while presenting the keynote, discussed biosafety with a global perspective, starting from the review of the history of GE plant risk assessment and regulations, including the development of the Cartagena Protocol, other relevant international agreements and organizations and the typical regulatory risk assessment framework. He suggested researchers should not conflate biosafety with other

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issues and the best way is to know and understand the requirement for biosafety. He emphasized the need to educate people to further understanding of these technologies.

Prof. Aparna Islam talked about the biosafety regulatory system, overall process, concerned committees, and their responsibilities in Bangladesh. She added that biosafety is nothing but the extension of biotechnology research. Bangladesh has all the regulatory documents in a robust system, which helps to open another area of research and by the implementation of our regulatory system, researchers can perform lots of positive research. Biosafety regulation is not restricted within contained or laboratory research only, but it has application in confined field trials and commercial cultivation.

During the open discussion, several queries came from participants, some of which are noted below:

To respond to the question of toxicity, allergenicity, health risk, and adoption of GE plants, Dr. Aparna Islam indicated that the safety assessment is concerned about food safety, health safety, and environmental safety, and the guidelines are established according to international standards. Dr. Roberts added that in genetic engineering, introduction of an unknown toxin is unlikely.

Questions on the presence and persistence of herbicide resistant, antibiotic resistant, or marker gene like NPTII in the gene construct was raised. Dr. Roberts mentioned that the safety of NPTII is already proven and the probability of moving into a bacterium is very low, and also, the NPTII gene is very common in the environment.

To answer another query about the marketing of GE foods and their safety guidelines, it was mentioned that Bangladesh has guidelines for food safety assessment and marketing and monitoring issues were described in Bangladesh Biosafety Framework.

Concerning the labeling of GMO products in Bangladesh, it was explained that Bangladesh Biosafety Rules, 2012 clearly stated the requirement for labeling. However, the reason for the labeling is consumers right to know, rather than any safety concern, and consumer labeling is not harmonized around the world.

Finally, the webinar was very effective for young scientists, increasing their knowledge about biosafety regulations and assessment guidelines and their contribution in conducting GE research and development at BINA. The webinar presented a detailed outline of biosafety from laboratory to field trials and release to the environment for commercial cultivation.

At the end, the Chair of the webinar, Dr. Alam, closed with thankful appreciation for SABP and BINA authority and stated his wish that SABP will continue such kind of work with BINA, which will help the scientists to perform biotechnology research to harness the benefits.

INDIA

Confined Field Trials of Genetically Modified Rubber in Assam, India

Dr. Jyoti Batra, Biotech Consortium India Limited, New Delhi

Inauguration of the Field Planting of Genetically Modified Rubber in Assam, India (June 22, 2021).

The world's first genetically modified (GM) rubber plant was planted in the state of Assam, India on June 22, 2021. Natural Rubber, a commercial plantation crop from the tree species *Hevea brasiliensis*, is grown in tropical humid climatic conditions. In India, traditional rubber-growing states, Kerala and Tamil Nadu, account for 81% of production in India. Major non-traditional rubber growing regions are the Northeast states of Tripura, Assam and Meghalaya, Odisha, Karnataka, Maharashtra, and West Bengal. Natural rubber is not naturally suited for the cold conditions, particularly in the Northeast region.

The Rubber Research Institute of India (RRII), based in Kerala, has developed GM rubber that contains additional copies of the *MnSOD* gene.

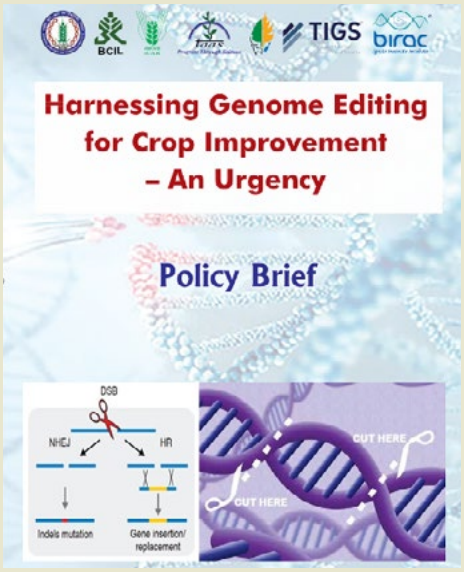
The Rubber Research Institute of India (RRII), based in Kerala, has developed GM rubber that contains additional copies of the *MnSOD* gene expressing manganese-containing superoxide dismutase enzyme. The *MnSOD* gene used in the GM rubber has been taken from the rubber plant itself. This gene has the ability to protect the plants from the adverse effects of severe environmental stresses such as cold, drought, etc., which is a major factor affecting the growth of young rubber plants. Growth of young rubber plants remain suspended during the winter months, which is also characterized by progressive drying of the soil. This is the reason for the long immaturity period of this crop in the Northeastern region. Laboratory studies conducted at RRII showed that overexpression of the *MnSOD* gene in GM rubber plants offers protection in harsh cultivation conditions.

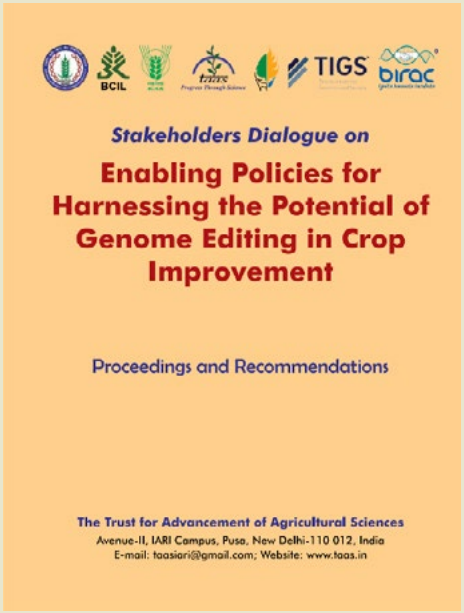
Confined field trials of GM rubber have been initiated after approval from regulatory authorities, *viz.* Review Committee of Genetic Manipulation (RCGM) and Genetic Engineering Appraisal Committee (GEAC). There are no plant species in India that can breed with natural rubber. Therefore, there is no risk of genes flowing from the GM rubber into any other native species.

Officials of the Rubber Board led by Dr. K. N. Raghavan, Chairman and Executive Director, RRII, state government officials, and local rubber growers participated in the planting event.

Source: Rubber Research Institute of India press release.

Policy Brief: Harnessing Genome Editing for Crop Improvement – An Urgency





A Stakeholders' Dialogue was held on March 17, 2021 in order to identify the required policy actions that would facilitate harnessing of genome editing for crop improvement. The Dialogue was organized jointly by the Trust for Advancement in Agricultural Sciences (TAAS), a neutral "Think Tank", in collaboration with the Indian Council of Agricultural Research (ICAR), National Academy of Agricultural Sciences (NAAS), Biotech Consortium India Limited (BCIL), Tata Institute for Genetics and Society (TIGS), National Agri-Food Biotechnology Institute (NABI), and Biotechnology Industry Research Assistance Council (BIRAC). The objectives of the Dialogue were to:

i. develop consensus on regulation of genome edited plants and catalyze approval of the regulatory policies,
ii. deliberate on the mechanism of access to genome editing technologies for development and commercialization of genome edited crops by public and private sector enterprises, and
iii. discuss policy directions for promoting application of genome editing technology for sustainable agriculture.

More than 70 participants representing a cross section of diverse stakeholders attended and participated in the deliberations, including: Secretary, Department of Biotechnology (DBT); Secretary, Department of Agricultural Research and Education (DARE) & Director General, ICAR; Members of the Genetic Engineering Appraisal Committee (GEAC); Chairman and Members of the Review Committee of Genetic Modification (RCGM); senior policymakers; regulators; senior scientists; and representatives from the seed industry

The key recommendations are summarized below:

1. Draft regulatory guidelines on genome editing as recommended by the DBT, using a consultative process involving the National Academy of Agricultural Sciences (NAAS) and reviewed by RCGM, be cleared without delay by the GEAC. This will ensure quick Government approval for scaling the technology in the national interest. The participants of the dialogue were unanimous in recommending that products of genome editing that are shown to contain no foreign genetic material (SDN1) or whose altered genetic material is indistinguishable from the natural gene pool, or is sourced from primary or secondary gene pools (SDN2), be exempted from biosafety testing as otherwise prescribed under the existing "Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/Genetically Engineered Organisms or Cells (Rules, 1989)". Hence, the genome edited plants exploiting available genetic variability within the same genus (cis) be simply treated as products of normal breeding methods, including mutation, and be allowed for cultivation like normal varieties/hybrids.
2. A mission-mode inter-institutional platform comprising centres of excellence on genome editing for specified crops be established on priority, having mandate to: i) develop novel and more efficient genome editing tools, and have a national repository for newly developed vectors and reagents, ii) develop genome edited crop varieties with desired traits for commercialization, and iii) build required human resource to effectively use genome editing.
3. Institutional Biosafety Committee (IBSC) be strengthened and funded well to undertake its responsibilities more effectively. These be periodically monitored through an oversight role by RCGM.
4. Strong public-private partnership is essential to reap the benefits of genome editing. It needs to be strengthened through incentives and enabling policy support by the government as also negotiated access to intellectual properties on genome editing and other technologies related to its use for development of crop varieties. Also, an effective coordination between the state and central government is needed to harmonise decisions relating to use of genome editing and commercialisation of end products.
5. Outreach and effective communication strategy for much-needed public perception is critical to reap the benefits of genome edited products. This would demand an aggressive public awareness campaign to ensure acceptance both by consumers and farmers. The role of NGOs/CSOs in creating the right perception needs to be appreciated and encouraged through desired incentives and rewards. In addition, a Status Paper on benefits of genome editing will help in creating needed awareness and ownership of this new technology.
6. Greater national effort to apply genome editing technology for targeted crop improvement by all concerned organisations/institutions such as DBT, ICAR, CSIR, DST, DRDO, and State Agricultural Universities (SAUs), through a national flagship program/platform, is highly justified, for which initial funding of Rs 1,000 crore be provided as a special grant. This could be a Mission Mode program with defined targets and outcomes in next 5 years, monitored jointly by DBT and ICAR.

The policy brief and the detailed proceedings and recommendations of the Stakeholder Dialogue can be accessed at:
http://www.taas.in/documents/pub-pb-05.pdf
https://www.taas.in/documents/pub-activity-46.pdf

CALENDAR OF EVENTS

EVENT	ORGANIZED BY	DATE	WEBSITE
INDIA			
Webinar Series on Applications of Gene Editing in Sustainable Agriculture and Food Security in the Asia-Pacific Region Webinar 1: Genome Editing Tools and Its Applications for Targeted Plant Breeding Webinar 2: Advancing Genome Edited Plants from Lab to Land Webinar 3: Enabling Policies for Genome Editing in Agriculture	**Asia-Pacific Association of Agricultural Research Institutions, Asia-Pacific Consortium on Agricultural Biotechnology and Bioresources (APCoAB), Korea Biosafety-Clearing House, and Biotech Consortium India Limited**	**July 21-August 8, 2021 Virtual** July 21, 2021 August 4, 2021 August 8, 2021	**https://www.apaari.org/** **https://www.biotech.co.in/en** **Registration: https://zoom.us/meeting/register/ tJAqdumsqDooGNApndwbg1Z t6ldtYcsrLM5y**
International e-Conference on Postharvest Disease Management and Value Addition of Horticultural Crops	**ICAR-Indian Agricultural Research Institute**	**August 18-20, 2021 Virtual**	**http://www.uhsbagalkot.edu.in/**
International Horticulture Conference – Next Generation Horticulture (NEXTGEN – HORT)	**Tamil Nadu Agricultural University**	**September 16-19, 2021 Coimbatore**	**https://tnau.ac.in/news-events/**
Global Rice Conference	**Tamil Nadu Agricultural University**	**September 24–25, 2021 Thanjavur, Tamil Nadu**	**https://tnau.ac.in/news-events/**
INTERNATIONAL			
Gene Drive Webinar Series 4: Regulatory and Governance Considerations for Gene Drive Research	**ISAAA Southeast Asia Center, Outreach Network for Gene Drive Research, and the ISAAA Biotechnology Information Centers**	**July 22, 2021 Virtual**	**https://www.isaaa.org/webinars/default.asp**
International Webinar on Monitoring and Early Warning of Plant Pest and Disease Epidemics in Response to Climate Change	**Food and Fertilizer Technology Center (FFTC), Taiwan's Bureau of Animal and Plant Health Inspection and Quarantine (BAPHIQ) ,Taiwan Agricultural Research Institute (TARI), and Asia-Pacific Association of Agricultural Research Institutions (APAARI)**	**July 27-28, 2021 Virtual**	**https://bit.ly/2SwZe2M**
International Agriculture Innovation Conference 2021	**International Association for Agricultural Sustainability and Waseda Business School**	**September 3-4, 2021 Tokyo, Japan**	**https://app.glueup.com/event/2021-international-agriculture-innovation-conference-32451/home.html**

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

Agriculture & Food Systems Institute

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CONTACT SABP

BANGLADESH
Sium Ahmed
Biosafety Support Officer
South Asia Biosafety Program
c/o CIMMYT
House-10/B, Road-53, Gulshan-2
Dhaka-1212, Bangladesh
Email: sahmed@southasiabiosafety.org

UNITED STATES
Layla Tarar
Manager, Communications & Digital Learning
Agriculture & Food Systems Institute
1010 Vermont Avenue NW, Suite 202
Washington, DC, 20005, USA
Twitter: @AgFoodSystems
Email: ltarar@foodsystems.org

INDIA
Vibha Ahuja, Ph.D.
Chief General Manager
Biotech Consortium India Limited
Anuvrat Bhawan, 5th Floor
210, Deendayal Upadhyaya Marg
New Delhi 110 002, India
Email: vibhaahuja@biotech.co.in

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