VOL 17 NO 11 NOVEMBER 2020

South Asia Biosafety Program

NEWSLETTER FOR PRIVATE CIRCULATION ONLY – NOT FOR SALE

BANGLADESH

Rapporteurs' Note on the BAU-SABP Webinar: Biosafety Regulatory Requirements in Agricultural Biotechnology

Dr. Aleya Ferdausi, Dr. Mohammad Rashed Hossain, and Dr. Arif Hasan Khan Robin, Department of Genetics and Plant Breeding, Bangladesh Agricultural University

Biosafety Regulatory Requirements in Agricultural Biotechnology Webinar (October 5, 2020): (from top) Dr. Aparna Islam, South Asia Biosafety Program; Prof. Dr. Arif Hasan Khan Robin, Department of Genetics and Plant Breeding, BAU; Prof. Dr. Md. Abu Hadi Noor Ali Khan, BAU Research System; and Mr. Sium Ahmed, South Asia Biosafety Program.

The webinar *Biosafety Regulatory Requirements in Agricultural Biotechnology* was jointly organized by Bangladesh Agricultural University (BAU) and the South Asia Biosafety Program (SABP) on October 5, 2020. At the beginning of the webinar, Prof. Dr. Arif Hasan Khan Robin, Department of Genetics and Plant Breeding, BAU introduced the activities of SABP and biotechnology-related research activities at BAU. Prof. Dr. Mahfuzul Haque, Associate Director of BAU Research Systems (BAURES) welcomed all participants and guests to the webinar.

Prof. Dr. Lutful Hassan, Honorable Vice-Chancellor of BAU, in his speech as Chief Guest, reemphasized the importance of food security and nutritional security through crop biotechnology by ensuring appropriate biosafety regulations in Bangladesh. Prof. Hassan highlighted the welfare program that has already been started in Bangladesh for children, urban people, and lactating and pregnant women, as well as explained the close association with advancing biotechnology to achieve this. He also emphasized the importance of risk assessment of genetically modified (GM) products so that they are evaluated for safety for human and animal consumption or release into the environment. Moreover, he suggested that the academic personnel, research institutes, different ministries of the Government of Bangladesh (GoB), including the Ministry of Environment, Forest and Climate Change, Ministry of Agriculture, and Ministry of Science and Technology should work together to ensure biosafety implementation. He also invited Dr. Andrew Roberts and Dr. Aparna Islam and other SABP personnel to visit BAU and provide their opinion on the on-going biotechnological research in different corners of BAU on crops, livestock, and fisheries. He mentioned that several research scholars at BAU have been using their knowledge and capabilities for research

VIDEO

Watch the full recording at:
https://foodsystems.org/event/sabp-webinar-2020-7/

Continued on page 2

Continued from page 1

on biotechnology. He emphasized that as a university, BAU can be an important stakeholder in biosafety regulations since the university is closely working in collaboration with NARS institutes, industry, international organizations, and different ministries of GoB.

Dr. Andrew Roberts, in his keynote speech, expressed his desire to collaborate with BAU and appreciated the participation of BAU in the webinar. He also appreciated the efforts of GoB on environment and food safety assessment in light of biosafety. After that, he briefly described the history of genetic engineering, which started with the domestication of animals and led to the basic concept of DNA, restriction enzymes, and transgenic technologies for the awareness of student participants. Later, he presented an interesting case-study on safety assessment of naturally bred Tilapia and genetically engineered (GE) salmon fish by the general consumer and regulatory authorities. He then explained basic biosafety concerns, such as assessment of the environment, growth and reproduction, ecosystem interaction, etc. He explained mutation in the context of natural hybridization, artificial mutation, and genetic engineering, and he compared their safety assessments. He put an emphasis on proper biosafety assessments that should be followed to get approval from authorities and highlighted that researchers should follow both basic and practical issues on biotechnological development, as well as practical realities, to meet the demand of local people.

BAU can be an important stakeholder in biosafety regulations since the university is closely working in collaboration with NARS institutes, industry, international organizations, and different ministries.

Dr. Aparna Islam, in her lecture on "Biosafety Regulatory Requirements in Agricultural Biotechnology" mainly focused on biosafety requirements in Bangladesh. She briefly explained existing guidelines and biosafety authorities for the implementation of biosafety regulations in Bangladesh. She reported that among the world's 193 countries, only 26 countries are cultivating GM crops and Bangladesh is one of them, following the country's regulations. Therefore, she was very hopeful about future biotechnological development in Bangladesh. Furthermore, she guided the participants to resources on the SABP website for students and research grants for researchers.

The open discussion session was very lively, with active participation from the participants. There was a lot of interest and questions. Below are some highlights from the webinar:

1. The safety assessment of transgenes for humans and the environment were discussed and explained in light of biosafety assessment reports available from various countries.
2. Research on GM crops in Bangladesh were discussed, which revealed that multiple laboratories such as BARI and BRRI are working on GM crops.
3. Bangladesh is rich in biodiversity and the effect of GM or GE organisms on the existing biodiversity was discussed. It was concluded that up to this point, GM or GE organisms have had no negative impact on biodiversity. The example of a highly biodiverse country, Brazil, where genetically modified organisms are grown was cited. It was suggested that any potential risks from GM should be considered in context and proportionately with known risks to biodiversity. Urbanization, industrialization, and deforestation, etc. present clear and ongoing threats to biodiversity when compared to GM or GE organisms, which have not produced any harm thus far.
4. Regulatory systems for GM/GE organisms and genome-editing through *CRISPR-cas9* was discussed. Regulatory approaches taken by various countries show variation. While there is no reason to believe that genome-edited organisms pose any greater risk than conventional organisms, Bangladesh has not formulated any policy to either include or exclude them from biosafety regulations.
5. Questions on off-target mutations in the case of gene editing were also raised. In this regard, steps taken to check the mutation at the research stage were explained. It is noteworthy that the mutation is on a specific gene and that subsequent assessments are taken to confirm that no deleterious off-target mutations exist in edited crops in the process of development. Further, gene editing produces fewer off-target mutations than conventional mutation breeding methods.
6. It was explained by Dr. Andrew Roberts that *Bacillus thuringiensis* (Bt) is widely used to kill insects and considered safe to the environment, as it is only toxic to target insects. Insect populations in and around Bt fields were discussed. There has not been any report of health hazards of this *bacterium* in humans or animals. Against this background, GE crops containing Bt genes have been developed and after proper biosafety assessments, they have been released in many countries.
7. In addition, while discussing the access and benefit sharing issue, the importance of regulations in safeguarding scientific research were emphasized.

Prof. Dr. Md. Jasimuddin Khan, in his speech as Special Guest, opined that Bangladesh has a great opportunity to work on GM crops, livestock, and fish along with proper biosafety programs. Finally, Prof. Dr. Md. Abu Hadi Noor Ali Khan, Chair of the event and Director of BAURES, thanked all participants and concluded the webinar.

INDIA

NAAS Policy Brief on Regulatory Framework for Genome Edited Plants: Accelerating the Pace and Precision of Plant Breeding

Dr. N.K. Singh, National Institute for Plant Biotechnology, New Delhi

A policy brief on *Regulatory Framework for Genome Edited Plants: Accelerating the Pace and Precision of Plant Breeding* has been published by the National Academy of Agricultural Sciences (NAAS), New Delhi that outlines not only the expected benefits of powerful genome editing technology to Indian agriculture, but also the global and national status of the regulatory framework for the commercialization of genome edited plants and recommendations for devising an efficient regulation for genome edited varieties of food grains, as well as horticultural and agroforestry plants.

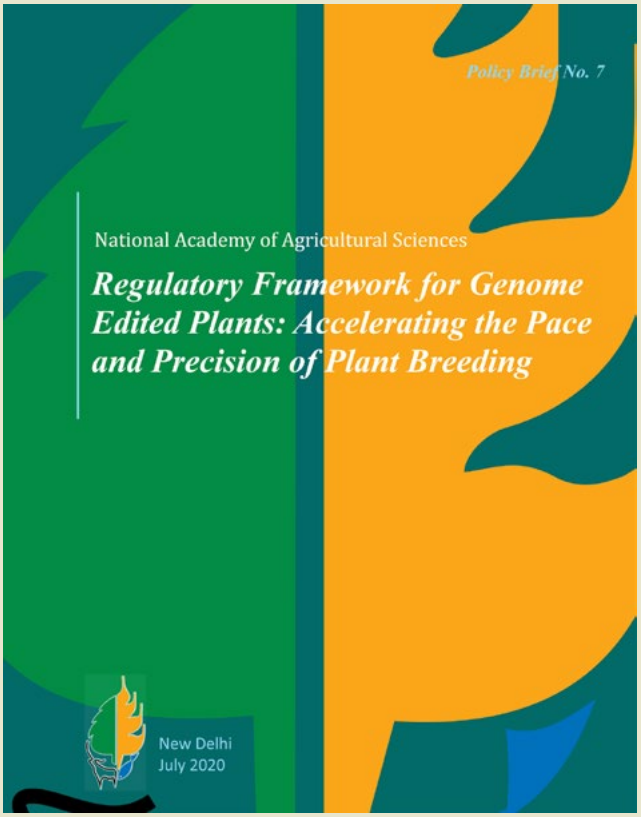
The policy brief outlines not only the expected benefits of powerful genome editing technology to Indian agriculture, but also the global and national status of the regulatory framework for the commercialization of genome edited plants [...].

NAAS organized a roundtable discussion involving a wide range of stakeholders, including Fellows of the Academy, representatives from the seed industry, progressive farmers, and other relevant experts under the Chairmanship of the President of NAAS, Dr. T. Mohapatra, and past Presidents of NAAS, Dr. R.S. Paroda and Dr. R.B. Singh, on the potential of emerging powerful genome editing tools in solving the problems of entrenched low farm productivity, malnutrition, and hidden hunger in a large section of the Indian population. It also included a focused discussion on the *Draft Document on Genome Edited Organisms: Regulatory Framework and Guidelines for Risk Assessment* circulated by Department of Biotechnology (DBT), Government of India and the following recommendations have been made:

Continued on page 3

- The regulatory requirements and guidelines on genome editing should focus on plants in the first phase of regulation.
- Internationally accepted and clear definition of SDN1, SDN2, and SDN3 for plants should be adopted.
- Although the genome edited product development usually starts with genetic transformation of the cell, certain categories of the final products (SDN1 and SDN2) developed through genome editing are free from foreign DNA and indistinguishable from the products developed through conventional breeding utilizing natural genetic variation or induced mutations. Hence, it is not necessary and also not scientifically possible to regulate these products under Rules 1989 of the Environment (Protection) Act 1986.
- Since genome editing is a precise and targeted mutagenesis tool and the final products of genome editing using SDN-1 and SDN-2 approaches do not carry any vector DNA and are similar to the products of spontaneous or induced mutations, these should be exempted from regulations and risk assessment.
- Provision for such exemption exists under rule 20 of the Rules 1989. Also, there is precedence wherein exemptions have been granted earlier for rDNA pharma products.
- Initial generation of genome edited plants involves rDNA techniques, hence their registration with IBSC with information to RCGM should continue. However, for commercial release, the final product, which is devoid of any foreign DNA, the guidelines for evaluation of trait efficacy and field performance shall be carried out as per the ICAR-AICRP guidelines or any other extant procedure for evaluation, release, and notification as per the legislations for seed quality regulations (Seeds Act 1966, Seeds (Control) Order 1983, Seeds Rules, PPVFRA Act, National Seed Policy, and the proposed New Seeds Bill).
- The foods derived from the SDN-1 and SDN-2 categories should not be treated as "genetically engineered or genetically modified food" under the Food Safety and Standards Act, 2006.
- The national regulatory system on genome edited plants should be in harmony with countries such as Australia, Brazil, Canada, China, Japan, and the USA to facilitate smooth international trade of genome edited products, and for effective exchange and sharing of genetic material for research and development.
- Tremendous benefits and safety of the new genome editing tools should be communicated to the general public, policy makers, and farmers in a simplified manner. Particularly, the message should be conveyed that these products are as safe as those developed by conventional breeding. Most importantly, these tools allow precision and rapid delivery of the desired products.
- Public and private sectors in India should develop a joint strategy for product development through enhanced investment, with a view to ensure affordable access to improved technologies for all farmers, small or large. This is also essential for self-reliance (*Atmanirbhar Bharat*) in harnessing the upcoming billion-dollar genome editing industry.

RESOURCE



Access the Policy Brief:
http://naasindia.org/Policy%20Briefs/PB7-Regulaory%20Framework.pdf

ANNOUNCEMENT

Indian Good Laboratory Practice Programme and the OECD

Regulatory data includes data, pharmacology data, chemistry, manufacturing and control data, preclinical data, and clinical data submitted to **Regulatory Authorities**/Government Agencies for grant of marketing approval of a new drug/pesticide/cosmetic product/food/feed additive, etc. in the respective country. Good Laboratory Practice (GLP) is a quality system, which has been evolved by the **Organisation for Economic Co-operation and Development (OECD)** to ensure that safety data generated on various chemicals, such as industrial chemicals, pharmaceuticals (human and veterinary), agrochemicals, cosmetic products, food/ feed additives, and medical devices, etc., can be relied upon by regulatory authorities.

The Department of Science and Technology (DST), Government of India, established the **National GLP Compliance Monitoring Authority (NGCMA)** with the approval of the UnionCabinet on April 24, 2002. NGCMA is the National body which grants GLP certification to **test facilities (TFs)** conducting safety studies on new chemicals of the above-mentioned categories in accordance with OECD Principles of GLP and OECD Council norms. India became a full adherent to the **Mutual Acceptance of Data (MAD)** in the OECD, which was a historical event. The MAD status has given global recognition to India's non-clinical safety data by tremendously augmenting its credibility and acceptability across the globe.

Recognizing the contribution of India's GLP programme, OECD has designated Dr. Ekta Kapoor, Scientist E, NGCMA, DST as the Vice-Chair of the OECD Working Group on GLP for 2021 and 2022. With continued Government commitment and emphasis on further capacity building on GLP in the country, India's leadership in GLP brings greater recognition of certification of quality for global business.

More information about GLP programme can be accessed at: https://dst.gov.in/ngcma

Source: https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1664688

CALENDAR OF EVENTS

EVENT	ORGANIZED BY	DATE	WEBSITE
INDIA			
India Bio @ Bengaluru Tech Summit	Department of IT & Biotechnology, Government of Karnataka	November 19-21, 2020 Bengaluru	http://www.indiabio.in/
International E-Conference on Advances and Future Outlook in Biotechnology and Crop Improvement for Sustainable Productivity	University of Horticultural Sciences, Bagalkot and College of Horticulture, Bengaluru	November 24-27, 2020 Online	http://www.uhsbagalkot.edu.in/images/Training_Seminar_Conf/IntE-confBCI-COHB_reduce.pdf
Role of Science & Technology in Climate Smart Agriculture and Rural Development	Centre for Rural Technology, Indian Institute of Technology Guwahati	December 7-9, 2020 Online	https://www.iitg.ac.in/home/eventsall/events
Biotechnology and Intellectual Property Law	Rajiv Gandhi School of Intellectual Property Law, IIT Kharagpur	December 13-19, 2020 Online	http://www.iitkgp.ac.in/events
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			
1st Extraordinary Meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety	Secretariat of the Convention on Biological Diversity	November 16-19, 2021 Online	http://bch.cbd.int/protocol#tab=2
3rd Asian Short Course on Agri-Biotech, Biosafety Regulation, and Communication	ISAAA Southeast Asia Center	November 23-26, 2020 Online	https://zoom.us/meeting/register/ tJMvcO6oqTgjG9UyXluukBoh57wUacbPLAoR
24th Meeting of the Subsidiary Body on Scientific, Technical, and Technological Advice	Secretariat of the Convention on Biological Diversity	January 2-7, 2021 Montreal, Canada	http://bch.cbd.int/protocol#tab=2
3rd Meeting of the Subsidiary Body on Implementation	Secretariat of the Convention on Biological Diversity	January 9-14, 2020 Montreal, Canada	http://bch.cbd.int/protocol#tab=2

SOUTH ASIA BIOSAFETY PROGRAM

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.

Agriculture & Food Systems Institute

USAID FROM THE AMERICAN PEOPLE

IFPRI

CONTACT SABP

BANGLADESH
Aparna Islam, Ph.D.
Country Manager
South Asia Biosafety Program
c/o CIMMYT
House-10/B, Road-53, Gulshan-2
Dhaka-1212, Bangladesh
Email: aparnaislam@southasiabiosafety.org

UNITED STATES
Layla Tarar
Manager, Communications & Digital Learning
Agriculture & Food Systems Institute
740 Fifteenth Street NW, Suite 600
Washington, DC 20005, USA
Email: ltarar@foodsystems.org
Twitter: @AgFoodSystems

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

To receive an electronic copy of this newsletter, please fill out the online form at: **foodsystems.org/sabp-newsletter**