

South Asia Biosafety Program

NEWSLETTER FOR PRIVATE CIRCULATION ONLY – NOT FOR SALE



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BANGLADESH

Bangladeshi Regulatory Approval for Bt Cotton Field Release

Md. Kamrul Islam, Senior Scientific Officer, Cotton Development Board



Cotton (*Gossypium hirsutum*). © Wasana Jaigunta | Dreamstime.com

In the 2023-2024 growing season, Bangladeshi farmers will plant Bt cotton for the first time. The National Committee on Biosafety (NCB) approved the field release of two Bt hybrids, JKCH 1947 Bt and JKCH 1050 Bt, at its 14th meeting on 7 May 2023. It is understood that biotech crop research and regulatory approval must occur simultaneously to facilitate the biotech crops to be released for cultivation in Bangladesh.

Adoption of Bt cotton in Bangladesh is subject to step-by-step approval under the Bangladesh Biosafety Guidelines developed by the Ministry of Environment, Forests, and Climate Change. Accordingly, the approval of Bt cotton cultivation in Bangladesh required the involvement of several designated committees, including the Institutional Biosafety Committee (IBC) of the Cotton Development Board (CDB), National Technical Committee on Crop Biotechnology (NTCCB) at the Ministry of Agriculture, the core committee of the NTCCB at the Bangladesh Agricultural Research Council (BARC), the Department of Environment's Biosafety Core Committee (BCC), and the National Committee on Biosafety (NCB) at the Ministry of Forests and Climate Change.

The Material Transfer Agreement (MTA) with the Bt cotton seed supplier was signed earlier through the approval of NCB. Following the

acquisition of Bt cotton seeds, the contained greenhouse trials, confined field trials, and multi-location trials were completed within three years in succession before the field release. The CDB signed an MTA with JK Agri-Genetics Ltd., India, for the acquisition of JKCH 1947 Bt and JKCH 1050 Bt hybrids containing Bt gene truncated *Cry1Ac* (Event-1) in Bangladesh after receiving approval from the NCB at its 9th meeting, which was held on 8 October 2017.

In the 2023-2024 growing season, Bangladeshi farmers will plant Bt cotton for the first time. The National Committee on Biosafety (NCB) approved the field release of two Bt hybrids, JKCH 1947 Bt and JKCH 1050 Bt, at its 14th meeting.

revealed that JKCH 1947 Bt and JKCH 1050 Bt were bollworm resistant.

Following an evaluation of the results from the contained trial, the CDB received approval from the NCB on its 11th meeting for a confined field trial (CFT) in the 2020-2021 cotton growing season. The CFT was set up in Sreepur, Gazipur. The results showed that the yield of two Bt hybrids (JKCH 1947 Bt and JKCH 1050 Bt) was higher, and the bollworm infestation was lower than in the non-Bt control variety (CB-9).

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Bt cotton CFT at the Cotton Research Center in Sreepur, Gazipur, Bangladesh.

Based on the results of the CFT, the CDB received approval from the NCB at its 12th meeting for a multi-location field trial in the cotton growing season of 2021-2022. Multi-location trials were established at the farmer's field in the CDB's Dhaka, Jashore, Rangpur, and Chittagong regions. A Field Level Biosafety Committee was formed at each location to monitor the progress of the trials. Two Bt hybrids' yields were compared to non-Bt cotton yields. CB-9 (non-Bt control), JKCH 1947 Bt, and JKCH 1050 Bt yielded 3024, 4173, and 4479 kg/ha, respectively.

According to the partial cost-benefit analysis, farmers can obtain a gross benefit of 112668 Taka/ha and 140273.00 Taka/ha over the control variety (CB-9) by cultivating JKCH 1947 Bt and JKCH 1050 Bt, respectively.

The Cotton Development Board has taken the necessary steps to establish 168 Bt cotton demonstrations in farmers' fields during the 2023-2024 growing season, in order to capitalize on the potential benefits of agro-biotechnology for the socioeconomic development of farmers in Bangladesh.



Researchers working with Bt cotton in Bangladesh.

Recent Amendments in the Biological Diversity Act (2023) and Its Implications for Indian Researchers

Dr. Suhas Nimbalkar, Partner & Consultant - IP & Regulatory Affairs, Eitimo Ventures, LLP

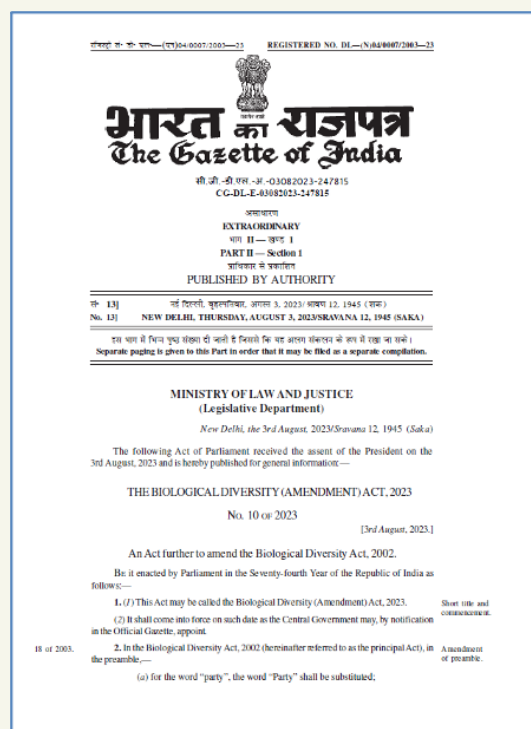


Vagamon, Kerala, India. © Libin John | Dreamstime.com

The Biological Diversity (BD) Act, 2002 was passed by the Indian Parliament on 5 February 2003 to address the conservation of biological diversity, sustainable use of its constituents, and equitable sharing of the benefits accrued from the use of biological resources occurring in the country. The access to biological resources is regulated if they are accessed for research, patents, transfer of results, and commercial utilization. The principal Act was drafted in pursuance to the country's obligations under the United Nations' 1992 Convention on Biological Diversity, to which India is a signatory. Nearly two decades after its enactment, an amendment to the Act was introduced in the Lok Sabha on 9 December 2021 and has now been passed by Parliament and Notified in the Gazette on 3 August 2023. The Biological Diversity (Amendment) Act, 2023 aims to address the concerns raised by stakeholders, especially the ones representing the Indian system of medicine sector, industry sector, and research sector. A quick summation of the relevant amendments and the implications for Indian researchers for compliance is presented in this article.

In tandem with the concerns raised by the stakeholders, the Amended BD Act, among other things, seeks to:

- i. encourage greater foreign investments in the utilization of biological resources for research, patenting, and commercialization without jeopardizing national interest;
- ii. encourage the cultivation of medicinal plants, as a sustainable model in the value chain;
- iii. encourage the Indian system of medicine; and
- iv. decriminalize certain provisions.



The first page of the Biological Diversity (Amendment) Act, 2023.

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FOR STARTUPS AND OTHER INDIAN COMPANIES:

Sec-3(2)(c)(ii) of the Amended Act has substituted “non-Indian participation in its share capital or management” for a “foreign controlled company.”

This would mean that companies incorporated or registered in India that have foreign participation in their share capital or management could be considered Indian entities under the Act and would not require the permission of the National Biodiversity Authority (NBA) to utilize Indian Biological Resources for research purposes.

In the current scenario of globalization and promotion of foreign direct investment (FDI) in businesses in India, it provides an impetus, especially for start-ups that are struggling with other compliance needs. Moreover, startups function on a shoestring budget, and not being able to begin the work with immediate effect adds to their troubles. Most of the time, the initial years of research are just exploratory in nature—to study the feasibility of the concept or idea. Now, they are expected to expend less time on the discussion of benefit-sharing aspects at the initial stage, which would be revisited after the research progresses to commercialization or when applying for intellectual property rights.

FOR INDIAN RESEARCHERS (AS PER SEC 7):

Research:

Indian researchers and scientists would continue not needing to seek prior approval from the NBA to access biological resources for their research work.

Transfers:

However, they would require permission from the NBA to transfer any biological resources or results of research to any person or entity under Sec 3 (foreign individual or entity). This will also include the carrying of research samples to universities outside India for the purpose of research.

It should also be noted that the requirement laid down by the second proviso, which is a new addition, now mandates prior registration with the NBA if the results of the research are being transferred to Sec 3 entities for the purpose of being used for further research.

Further, if the results of the research being transferred are used for commercial utilization or for obtaining any intellectual property rights within or outside India, then prior approval from the NBA shall be required.

Intellectual Property (IP) Rights:

Indian researchers and scientists will have some ease in seeking IP rights for their work.

The scope of Sec 6 has been expanded to include associated traditional knowledge linked to a biological resource, including biological resources deposited in repositories outside India. Researchers have to be aware of the origins of the biological resources being accessed from repositories outside India so that they can comply with the requirements, if applicable.

A distinction has also been introduced between Indian and foreign applicants for intellectual property rights. An Indian applicant would now have to only register with the NBA before the granting of IP rights and need not seek prior approval from NBA to secure the IP rights. In contrast, a foreign applicant would need to continue to seek prior approval from the NBA to secure the IP rights.

However, the Indian applicant who, after obtaining the IP rights, in or outside India, wishes to commercialize the IP rights will have to obtain prior approval from the NBA at the time of commercialization.

Collaborative Research Projects:

The transfer or exchange of biological resources or traditional knowledge associated thereto between institutions, including government-sponsored institutions of India, and such institutions in other countries, would be exempt if being done under collaborative projects. However, such collaborative research projects need to satisfy the conditions of conforming to the policy guidelines issued by the central government and be approved by the central government.

Accessing Biological Resources from Outside India:

Section 36A is a new addition to the Principal Act since this requirement was largely lacking. The Principal Act (BD Act, 2002) had no reference to the biological resources sourced from foreign countries, which fall under the obligations of all Member States who are signatories to the Nagoya Protocol.

With this new section, necessary measures will be taken by authorizing NBA to monitor and regulate within the territory of India the access and utilization of biological resources obtained from a foreign country.

It remains to be understood with certain clarity how these measures will be drawn up and the operational obligations that will ensue for utilizing non-Indian biological resources within India. More clarity in the operational modalities and the finer nuances of compliance will keep emerging when the Rules would get amended accordingly. As we progress with the compliance regime, a better understanding and correct interpretations of the provisions in the true spirit should mature.

The activities and the corresponding compliance actions to be aware of by Indian researchers are summarized in the table below:

S. NO.	ACTIVITIES	EXPECTED COMPLIANCE ACTION
1.	Access for research	No prior approval needed
2.	Access for commercial utilization	Prior intimation to SBB
3.	Transferring the biological resource to foreign entity (including carrying of samples for research)	Prior approval from NBA
4.	Transferring the results of research for further research to a foreign entity	Registration with NBA
5.	Transferring the results of research for securing intellectual property rights to a foreign entity	Prior approval from NBA
6.	Transferring the results of research for commercial utilization to a foreign entity	Prior approval from NBA
7.	Securing any intellectual property rights in India or outside of India	Registration with NBA
8.	Securing Plant Variety Protection rights in India or outside of India	No prior approval from NBA
9.	Commercializing of the secured intellectual property rights	Prior approval from NBA

Workshop on Introduction to Concepts of Biosafety and Regulator’s Responsibilities During Biotechnology Research and Development

Farhana Mustari, Deputy Director (Natural Resource Management) and Kazi Nazmul Mahmud, Assistant Director (Natural Resource Management), Department of Environment



Participants and organizers at the first workshop in the *Origins of Biosafety Internationally, the Relevant Policies and Regulations in Bangladesh, and the Necessary Regulatory Process During Each Phase of Biotechnology Research, Development, and Release* series (14 July 2023).

The potential of modern biotechnology in agriculture, health, energy, and the environment is well recognized. However, there are concerns that genetically modified organisms (GMOs) may pose risks to human health and the environment. Therefore, it is essential to properly understand the concepts of biosafety and their application in order to obtain the maximum benefits of biotechnology.

To strengthen capacity on biosafety for the regulatory authority of Bangladesh, a two-day long residential training was held at the Brac University CDM, Rajendrapur, Gazipur during 14-15 July 2023 under the workshop series “Origins of Biosafety Internationally, the Relevant Policies and Regulations in Bangladesh, and the Necessary Regulatory Process During Each Phase of Biotechnology Research, Development, and Release.”

The first workshop jointly organized by the Department of Environment (DoE), South Asia Biosafety Program (SABP), and Agriculture & Food Systems Institute (AFSI) focused on the “Introduction to Concepts of Biosafety and Regulator’s Responsibilities During Biotechnology Research and Development.” The members of the biosafety core committee and other relevant officials from the DoE participated in this training.

The workshop was attended by the following individuals from the DoE: Syeda Masuma Khanam, Director (Natural Resource Management - NRM); A.K.M Rafiqul Islam, Deputy Director (Water & Bio); Farhana Mustari, Deputy Director (NRM); Md Kamrul Hasan, Deputy Director (Chittagong Lab); Sonia Afsana, Deputy Director; Zawata Afnan, Assistant Director (Water & Bio); Md Mahbubur Rahman Khan, Assistant Director (Environmental Clearance); Kazi Nazmul Mahmud, Assistant Director (NRM); and Hossen Suvo Munjuri, Assistant Director (Dhaka Metro). In addition, Dr. Kazi Kamrun Nahar, Deputy Secretary, Ministry of Environment, Forest and Climate Change and Mst. Najnin Aktar, Scientific officer (Nutritional Coordination Branch), Bangladesh Food Safety

Authority, also attended the program. Prof. Dr. Emdadul Haque Chowdhury, Honorable Vice-Chancellor, Bangladesh Agricultural University, graced the program with his insightful presentation.

Dr. Andrew F. Roberts, Chief Executive Officer, AFSI, provided the welcome address and conducted the participants’ introduction. Prof. Dr. Rakha Hari Sarker, Country Coordinator of SABP, gave the overview of the workshop and shared the outline of the program. Dr. Roberts briefed participants on the history and context of biosafety, addressing the evolution of the concept of agriculture, recombinant DNA technology, and risk assessment.

Dr. Karen Hokanson of the University of Minnesota described the development process of genetically engineered plants and elaborated on regulatory and biosafety aspects in each stage of the development process in her presentation. She also discussed data generation and relevant data for regulatory submissions. Dr. Vibha Ahuja, Chief General Manager, Biotech Consortium of India Ltd. and Senior Advisor, SABP, conducted a discussion and question and answer session. Prof. Dr. Aparna Islam, Biotechnology Program, Brac University, discussed the biosafety obligations during GE plant research and development. In her presentation, she narrated the procedure from lab to the field for the research and development of GE crops, considering the scenario of Bangladesh, and very particularly mentioned the role of the government and other bodies in making overall decisions on the developed product following the existing rules, laws, and policies.

In another presentation, Dr. Roberts pointed out the ways to apply problem formulation, as well as the principles of risk assessment. Moreover, he particularly elaborated on the process of environmental risk assessment in his presentation. After the deliberation, Dr. Roberts conducted an interactive discussion where he guided participants through the relevant protection goals in the context of Bangladesh.

As a whole, the first workshop in the series was very effective in addressing the issues, starting with very rudimentary concepts, and the enthusiastic and interactive discussions made the workshop a very successful learning event.

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Participants during the presentation sessions.

On the second day, Dr. Roberts discussed international obligations and standards of biosafety. In addition, Prof. Sarker gave an in-depth presentation introducing the *Biosafety Guidelines of Bangladesh* and the *Biosafety Rules*. He also shared the historic context of the activities done previously and future needs regarding biosafety and biotechnology research and development. Finally, Prof. Dr. Aparna Islam discussed other relevant laws, rules, and policies.



Participants during the presentation sessions.

As a whole, the first workshop in the series was very effective in addressing the issues, starting with very rudimentary concepts, and the enthusiastic and interactive discussions made the workshop a very successful learning event. All participants are looking forward to getting knowledge at the upcoming second workshop on food safety concepts and the *Bangladesh Guidelines for Food Safety Assessment of GE Plants*.

ANNOUNCEMENT

OECD Consensus Document on Environmental Considerations for the Release of Transgenic Plants

Dr. Vibha Ahuja, Chief General Manager, Biotech Consortium India Limited

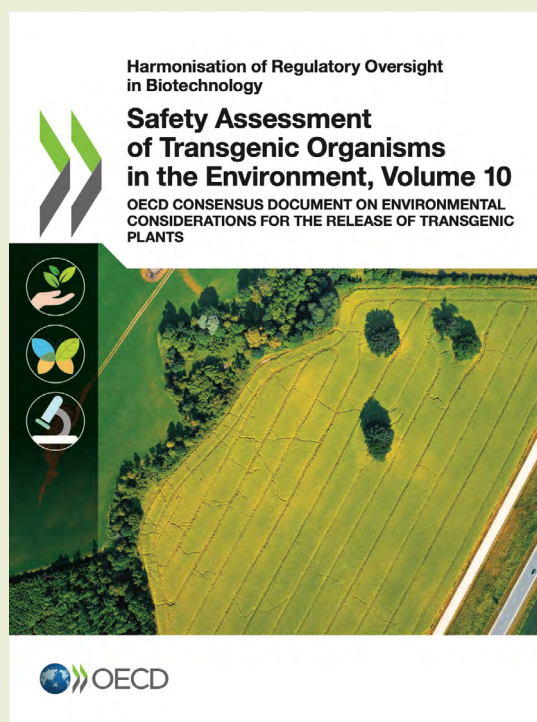
Transgenic plant varieties are subject to official risk/safety assessment, science-based and case-by-case, before their potential release into the environment. On 27 July 2023, the OECD released the consensus document on the "Environmental Considerations for Risk/Safety Assessment for the Release of Transgenic Plants." The document is part of Volume 10 of the series of OECD consensus documents on the *Safety Assessment of Transgenic Organisms in the Environment*.

The document provides general information on key concepts and important points that risk/safety assessors should focus on when planning such assessments. These key features include the comparative approach, the familiarity with the biology of the unmodified plant species, the general protection goals, the assessment endpoints, the potential adverse effects associated with the environmental release, the pathways to harm and corresponding risk hypotheses, relevant information elements, and the use of environmental considerations in planning such assessment.

Annexes describe seven examples of environmental considerations routinely examined by assessors, taken from experience gained during assessments. These include:

1. Invasiveness and weediness
2. Vertical gene flow
3. Organisms (animals)
4. Soil functions
5. Plant health
6. Crop management practices
7. Biodiversity (protected species and habitats/ecosystems)

The purpose of this document is not to elaborate new terminology or to describe how to undertake an actual risk/safety assessment, but rather to outline an approach and provide illustrative examples for helping assessors in planning and structuring an environmental risk/safety assessment. The set of science-based information and data contained in this volume, previously agreed by consensus and published by the OECD, constitutes a solid reference and a practical tool for use during the biosafety assessment planning process. This document is expected to be extremely useful for regulators and safety assessors, as well as to plant breeders and the wider scientific community. More information, including other tools for environmental risk/safety assessment, such as OECD consensus documents on the biology of crop species, are found at BioTrack Online.



The publication can be accessed at:

<https://www.oecd.org/publications/safety-assessment-of-transgenic-organisms-in-the-environment-volume-10-62ed0e04-en.htm>

Workshop on GM Crops and Their Derivatives for the Aqua Sector: Opportunities and Way Forward

Dr. K. Ambasankar, Head Nutrition and Genetics and Biotechnology, ICAR-Central Institute of Brackishwater Aquaculture (CIBA)



Participants and speakers at the workshop on GM Crops and Their Derivatives for the Aqua Sector: Opportunities and Way Forward (25 July 2023)

The workshop on GM Crops and Their Derivatives for the Aqua Sector: Opportunities and Way Forward was jointly organized by the ICAR-Central Institute of Brackishwater Aquaculture (CIBA) and Biotech Consortium India Ltd. (BCIL), on 25 July 2023 at ICAR-CIBA, Chennai. The main objective of this workshop was to create awareness and explore the market potential for the use of GM ingredients in aqua feed in the challenging context of the cost-effectiveness of feeds for aquaculture. This program was attended by more than 60 participants from various stakeholder groups comprising scientists and academicians from research institutes, feed millers, nutritionists, formulators, and state fisheries department.

Dr. K. Ambasankar, Head of Nutrition, Genetics, and Biotechnology, welcomed the gathering. Dr. Kuldeep K. Lal, Director, CIBA, delivered the opening address wherein he emphasized the importance of this workshop and the need for diversified ingredients in the aqua-feed sector where GM crops have a significant role to play. He further stressed that in aquaculture operations, feed constitutes 60 percent of total input cost, and serious efforts may be made towards the use of sustainable ingredients. There is a need to bring out the scientific basis of GM crops with respect to metabolism in biological systems to address certain unfounded apprehensions regarding the use of GM crop materials.

Dr. Vibha Ahuja, Chief General Manager, BCIL spoke on the use of GM crops and derivatives and their safety and nutritional aspects, wherein she elaborated on the safety and regulatory assessment of GM crops for use as animal feed, with a focus on the aquaculture sector. She

explained the concerns, safety aspects, and prospects associated with using GM crops as feed ingredients in aquaculture. She further underscored the need to bust the common myths associated with GM crops and informed participants that a well-structured biosafety regulatory framework is in place for science-based evaluation of GM crops prior to their environmental release and use for food, feed, and other processes.

Mr. Palanisamy Ravi, Vice President, The Waterbase Limited, delivered a talk titled "Fostering the Aquaculture Industry: Managing the Demands and Accessibility of Feeds. Mr. Raghavan Sampathkumar, Executive Director, Federation of Seed Industry of India, spoke about the status and challenges in implementing biotech interventions for crop

improvement. The other talks on global feed availability and the role of GM crops, as well as feed quality issues in the Indian aqua sector, were delivered by Mr. Amit Sachdev of the US Grains Council and Mr. Jaison John of the US Soybean Export Council, respectively.

The presentations were followed by a panel discussion involving industry experts, academicians, and policy-makers. Dr. P. Krishnaiah, IAS, Former Commissioner of Fisheries, Andhra Pradesh, impressed upon participants the need to reduce the cost of feed for sustainability and to help small and medium farmers fulfill their needs for affordable feed. The discussions clearly debunked the myths about GM crop usage and highlighted the importance of the use of GM crop-based ingredients for consistent quality and price, with an aim for sustainability. Dr. J. Syama Dayal, Principal Scientist, CIBA proposed a vote of thanks.

Dr. P. Krishnaiah, IAS, Former Commissioner of Fisheries, Andhra Pradesh, impressed upon participants the need to reduce the cost of feed for sustainability and to help small and medium farmers fulfill their needs for affordable feed.

More information: https://ciba.icar.gov.in/?post_type=edmento_events&p=15305 and <https://icar.org.in/icar-ciba-and-biotech-consortium-india-limited-conducted-awareness-workshop-gm-crops-and-their>

CALENDAR OF EVENTS

EVENT	ORGANIZED BY	DATE	WEBSITE
BANGLADESH			
5 th International Conference on Biotechnology in Health and Agriculture (ICBHA)	Global Network of Bangladeshi Biotechnologists (GNOBB), Bangladesh Biosafety and Biosecurity Society (BBBS), and the Federation of Asian Biotech Associations (FABA)	1-3 September 2023	https://gnobb.org/conference
INDIA			
Workshop on Progress in Agricultural Biotechnology: Policies and Practices	University of Agricultural Sciences (UAS) and BCIL	18 August 2023 Dharwad	https://www.biotech.co.in
ASGC 2023: 8 th Agricultural Graduate Students Conference	Tamil Nadu Agricultural University (TNAU)	22-23 August 2023 Coimbatore	https://tnau.ac.in/site/pgschooltnau/agsc-2023/
Training Programme on Genomic Approaches for Insect Pest Management	Center for Advanced Agricultural Science and Technology (CAAST) and ICAR-Indian Agricultural Research Institute	12-22 September 2023 New Delhi	https://www.iari.res.in/bms/announcements/training.php
XVI Agricultural Science Congress and ASC Expo	National Academy of Agricultural Sciences (NAAS)	10-13 October 2023 Kochi	http://www.16asc2023.in
National Conference on Transformation of Agro-Technologies for Enhancing Production Under Diverse Agro-Ecosystem	Navsari Agricultural University	12-14 October 2023 Saputara	https://nau.in/index
Asian Citrus Congress - 2023	Indian Society of Citriculture (ISC)	28-30 October 2023 Nagpur	https://accindia2023.iscindia.org.in/
International Conference on Biochemical and Biotechnological Approaches for Crop Improvement	Society for Plant Biochemistry and Biotechnology, ICAR-IARI, ICAR-NIPB, and CSIR-NBRI	30 October-1 November 2023 New Delhi	https://www.ibbaci.org/
INTERNATIONAL			
1 st Global Congress on New and Emerging Genetic Biocontrol Technologies	African Genetic Biocontrol Consortium	28-31 August 2023 Nairobi, Kenya	https://conference2023.genbioconsortium.africa/about-us/
6 th International Rice Congress 2023	International Rice Research Institute and Department of Agriculture, Republic of the Philippines	16-19 October 2023 Manila, Philippines	https://www.irri.org/IRC2023-teaser.html



SOUTH ASIA
BIOSAFETY PROGRAM

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.


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