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South Asia Biosafety Program

NEWSLETTER FOR PRIVATE CIRCULATION ONLY – NOT FOR SALE

INDIA

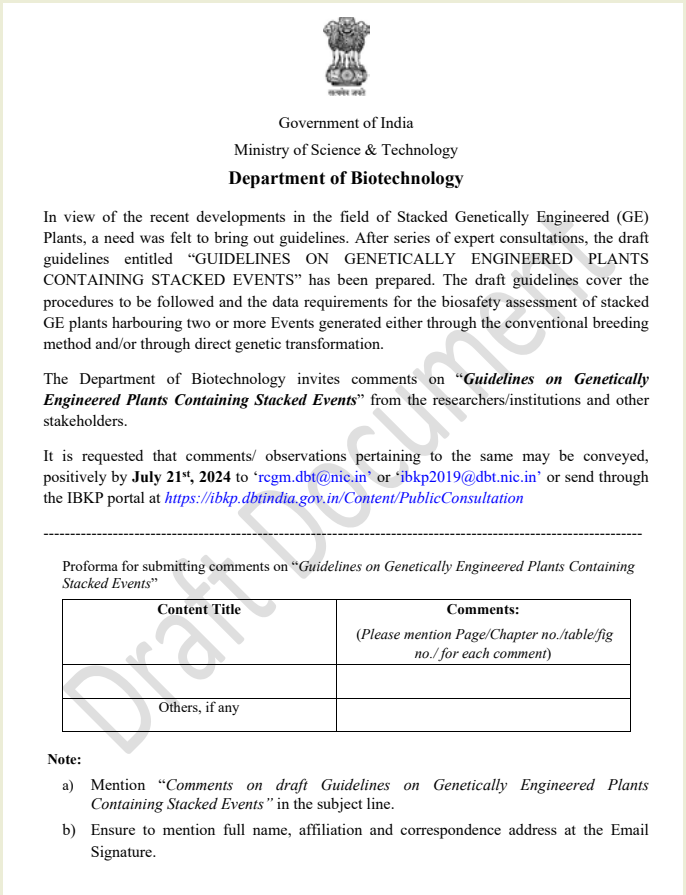
Public Consultation on the Draft Guidelines on Genetically Engineered Plants Containing Stacked Events, 2024 by the Department of Biotechnology, Government of India

Dr. Vibha Ahuja, Biotech Consortium India Limited

The Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India published draft guidelines entitled *Guidelines on Genetically Engineered Plants Containing Stacked Events*. The draft guidelines cover the procedures to be followed and the data requirements for the biosafety assessment of stacked genetically engineered plants harboring two or more events, generated either through the conventional breeding method and/or through genetic transformation.

The guidelines have been published at Indian Biosafety Knowledge Portal (IBKP) for comments from researchers/institutions and other stakeholders. Comments/observations have to be conveyed **21 July 2024**. Responses to the public consultation can be sent to rcgm.dbt@dbt.nic.in or ibkp2019@dbt.nic.in, or submitted through the IBKP portal.

The proforma for submitting comments on "Guidelines on Genetically Engineered Plants Containing Stacked Events" is also detailed on the IBKB portal linked below.



Government of India

Ministry of Science & Technology

Department of Biotechnology

In view of the recent developments in the field of Stacked Genetically Engineered (GE) Plants, a need was felt to bring out guidelines. After series of expert consultations, the draft guidelines entitled "GUIDELINES ON GENETICALLY ENGINEERED PLANTS CONTAINING STACKED EVENTS" has been prepared. The draft guidelines cover the procedures to be followed and the data requirements for the biosafety assessment of stacked GE plants harbouring two or more Events generated either through the conventional breeding method and/or through direct genetic transformation.

The Department of Biotechnology invites comments on "***Guidelines on Genetically Engineered Plants Containing Stacked Events***" from the researchers/institutions and other stakeholders.

It is requested that comments/ observations pertaining to the same may be conveyed, positively by **July 21st, 2024** to 'rcgm.dbt@nic.in' or 'ibkp2019@dbt.nic.in' or send through the IBKP portal at *https://ibkp.dbtindia.gov.in/Content/PublicConsultation*

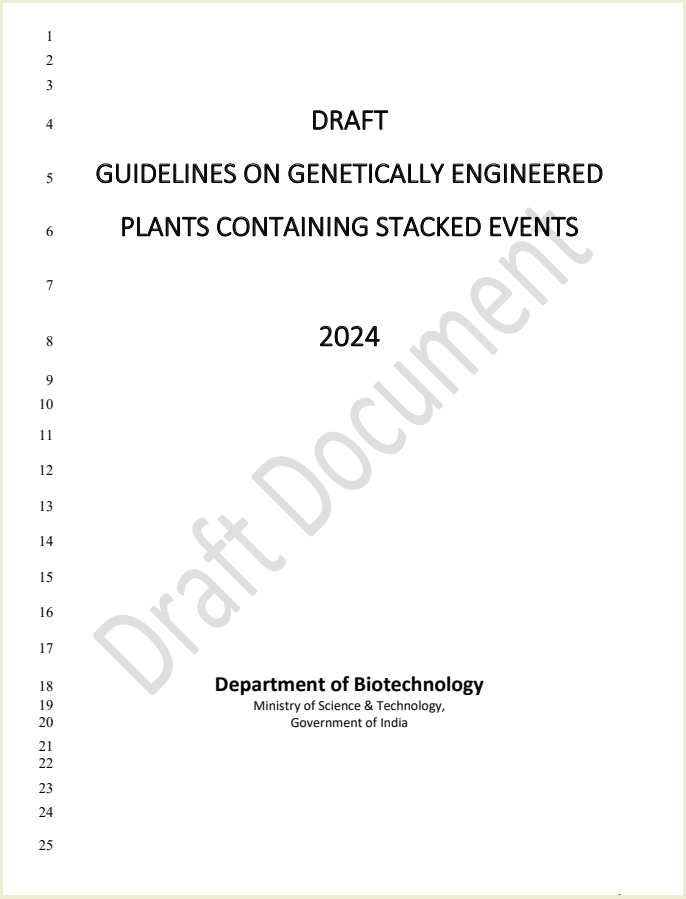
Proforma for submitting comments on "*Guidelines on Genetically Engineered Plants Containing Stacked Events*"

Content Title	Comments: (*Please mention Page/Chapter no./table/fig no./ for each comment*)
Others, if any	

Note:

a) Mention "*Comments on draft Guidelines on Genetically Engineered Plants Containing Stacked Events"* in the subject line.

b) Ensure to mention full name, affiliation and correspondence address at the Email Signature.



DRAFT

GUIDELINES ON GENETICALLY ENGINEERED

PLANTS CONTAINING STACKED EVENTS

2024

Department of Biotechnology

Ministry of Science & Technology,
Government of India

Public Consultation Link and Full Text of the Draft Guidelines:
https://ibkp.dbtindia.gov.in/Content/PublicConsultation

Advancing Genome Editing and Multi-Omics Technologies at NIB: Future Strategies for Stakeholders

Dr. Mst. Muslima Khatun, Senior Scientific Officer, Molecular Biotechnology Division and Project Director, TSR Project, National Institute of Biotechnology (NIB) and Visiting Research Scholar, The Pennsylvania State University

Group photo of participants at the "Advancing Genome Editing and Multi-Omics Technologies at NIB: Future Strategies for Stakeholders" seminar (29 June 2024).

The National Institute of Biotechnology (NIB) hosted a seminar titled "Advancing Genome Editing and Multi-Omics Technologies at NIB: Future Strategies for Stakeholders" on Saturday, 29 June 2024. The event attracted 110 expert representatives from the Ministry of Science and Technology (MoST), the Planning Commission, several research institutes under the Ministry of Agriculture, public and private universities, and related industries to explore novel approaches and foster collaborations for sustainable development in Bangladesh.

Dr. Md. Salimullah, Director General of NIB, presided over the seminar. The Chief Guest was Mr. Moinul Islam Titas, Additional Secretary of the MoST (Nuclear Power Plant). Dr. Rakha Hari Sarkar, supernumerary professor at the University of Dhaka and Country Coordinator of the South Asia Biosafety Program (SABP), and Dr. Tofazzal Islam, Fellow of the Bangladesh Science Academy and Professor at Bangabandhu Sheikh Mujibur Rahman Agricultural University (BSMRAU), presented as Special Guests.

Dr. Md. Salimullah welcomed the attendees by highlighting the revolutionary changes biotechnology brings to agriculture, medicine, the environment, and industry. He mentioned that NIB has undertaken a major project to establish advanced laboratory facilities for multi-omics research, supporting genome sequencing, proteomics, and metabolomics research. He also added notable achievements, such as the development of diabetic-friendly rice and research on recombinant endolysin against antibiotic-resistant bacteria.

The focus of the inaugural session was the keynote presentation by Dr. Mst. Muslima Khatun, Senior Scientific Officer, NIB entitled "Genome Editing and Multi-Omics Technologies at NIB: Future Strategies for Stakeholders." She emphasized the successful outcomes following the 4th meeting of the Bangladesh-India Joint Committee on Science and Technology Cooperation (JSTC) and highlighted the collaborative research program between NIB and the International Center for Genetic Engineering and Biotechnology (ICGEB) in New Delhi, India. Notable achievements from this collaboration include the development of transgenic brinjal and rice varieties that are tolerant to adverse environmental conditions. Dr. Khatun also detailed ongoing research projects to modify the starch composition of rice through genome editing to reduce amylopectin and increase amylose content, which would provide a source of resistant starch with a lower glycemic index (GI). This could help lower blood sugar levels, allowing diabetic patients to consume more rice without significant increases in blood glucose. She reported that genome editing has already been completed, and T2 generation rice is currently being tested. The amylose content in the edited rice variety has increased by 31%, which is 5% higher than the control BRRI dhan-92. She expressed optimism that this figure could rise to around 40% with ongoing analysis.

Notable achievements from this collaboration include the development of transgenic brinjal and rice varieties that are tolerant to adverse environmental conditions.

Dr. Aparna Islam, Professor at Brac University, delivered a presentation titled "From Research to Release of Genome Edited Plants: What Our Standard Operating Procedure (SOP) Says." Dr. Islam provided an insightful overview of the process involved in managing genome-edited plants and bringing developed varieties to the field. She emphasized the critical importance of data preservation, conducting thorough biosafety research, and adhering strictly to SOPs throughout the research and release stages of genome-edited plants.

At this stage, several experts in the seminar shared their valuable insights and recommendations. These discussions highlighted the vital role of NIB in advancing agriculture, medicine, environment, and industry through genome editing and multi-omics technology, emphasizing the need for capacity building, resource management, and biosafety.

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Speakers and guests at the seminar (29 June 2024).

After the discussions, Special Guest Prof. Dr. Rakha Hari Sarkar delivered his speech and highlighted that countries such as the United States, China, Japan, Korea, India, and various European nations are already utilizing CRISPR/Cas and multi-omics technology for genome editing in various plants. He noted that Bangladesh has also achieved this capability. Through this technology, it is possible to develop plant varieties that are resistant to drought, salinity, diseases, and insects. Additionally, there is potential for the discovery of new drugs and vaccines. Dr. Sarkar advocated prioritizing research on biosafety in genome editing and transgenic research to ensure safe advancements.

Mr. Moinul Islam Titas [...] assured the audience of the government's unwavering support for providing the necessary infrastructure and resources required for the application of genome editing and multi-omics technologies.

Then, Prof. Dr. Tofazzal Islam emphasized several critical issues in his speech. He discussed the need to establish a clear procedure for how biotechnologically developed products will reach the consumer level. He urged the government to consider tax exemptions on chemicals used in genome editing and sequencing to facilitate research. Dr. Islam further suggested that research activities should be conducted by coordinating scientists from research institutes, university teachers, and other experts, focusing on national priorities.

The Chief Guest, Mr. Moinul Islam Titas, Additional Secretary of the MoST (Nuclear Power Plant), emphasized the immense significance of biotechnology in the advancement of nations. He highlighted that the

Dr. Mst. Muslima Khatun, Senior Scientific Officer, NIB, delivering a presentation at the seminar (29 June 2024).

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NIB was established with the visionary goal of developing eco-friendly and sustainable technologies across various sectors, including agriculture, environment, industry, and human health. In his address, he assured the audience of the government's unwavering support for providing the necessary infrastructure and resources required for the application of genome editing and multi-omics technologies. He underscored the importance of these advanced scientific techniques in achieving significant breakthroughs that could propel Bangladesh to new heights in the field of biotechnology. Furthermore, Mr. Titas encouraged the scientific community to engage in innovative research that would yield tangible benefits for the country.

Therefore, the key discussion points centered on several crucial areas for the advancement of genome editing and multi-omics technologies. Firstly, there is a significant need to develop the necessary infrastructure and activities to support these technologies. Building capacity and developing skilled human resources are also essential. Ensuring a continuous and adequate supply of chemicals and consumables is crucial for uninterrupted research activities and service delivery. Additionally, services related to genome editing and multi-omics technology should be priced rationally to ensure accessibility and sustainability. Research on biosafety in genome editing and transgenic research should be prioritized to ensure safe and responsible advancements. Lastly, NIB should serve as a focal point for training in biotechnology-related subjects to build expertise and foster innovation in the field.

BANGLADESH

Confined Field Trials (CFTs) at the Path of GE Crop: Study of Performance and Environmental Safety

Yasmin Uddin, Brac University

STUDENT SHOWCASE

To encourage written discourse on topics related to biosafety and biotechnology among the younger generation, the *SABP Newsletter* dedicates space in select issues to spotlight pieces written by students residing in South Asia. Since articles with the "Student Showcase" tag are meant to reflect the actual views and capabilities of the author(s), they are not revised for content and only lightly edited to conform with the newsletter's style guide.

Eggplant growing in a field. © Jahangir Alam | Dreamstime.com

In the current scenario we are living in, there is an increasing demand for food from units of land worldwide due to population growth, reduction of arable land, and climate change. To ensure long-term food security, scientists are looking into sustainable agriculture methods that can provide sufficient quantities of agricultural products and also ensure the conservation of the environment without any harmful effects from overuse. This is where modern biotechnology innovation, such as genetically engineered (GE) crops, may play a key role. Over the past 25 years, the acreage of GE crops has seen a more than 100-fold rise, with farmers now growing around 190 million hectares of biotech crops[1].

The crop is grown under confined conditions, commonly known as confined field trials (CFT), which is a small-scale experimental field trial of GE plants carried out to collect data about the plant as it grows outdoors.

While some people view GE crops as a technological miracle with the promise to solve global problems, like food insecurity, climate change, and global malnutrition, others view GE crops with scepticism, citing concerns about unintended effects[2]. Thus, each new GE crop goes through a pre-market safety assessment that looks into the potential adverse effects it may pose at every step of development and beyond. For example, after generating a GE crop, the performance of the crop is checked in the environment. However, this is also under strictly regulated procedures, so, along with performance studies, the possibility of any environmental effect is also checked. For this reason, at this

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Cotton field. © Taleeb Kazi | Dreamstime.com

stage, the crop is grown under confined conditions, commonly known as confined field trials (CFT), which is a small-scale experimental field trial of GE plants carried out to collect data about the plant as it grows outdoors. These tests are conducted in various regions and at different times of the year to evaluate how well the plant performs in various environmental conditions to choose the most promising single event that could be prepared for commercial release.

A CFT is also a time to evaluate the effect of GE crops on the environment. The researchers carefully monitor factors like gene flow and unintended interactions with non-target organisms (NTOs), along with cultivation practices for GE crops. Unintended biogeochemical effects, such as alteration in soil microbial populations due to chemical exudates from GE crops that regulate nutrient flow, are another critical risk evaluated by analyzing the soil during the harvesting and post-harvesting season. Another crucial risk assessed is the transmission of transgenes through pollination, hybridization, dispersal, or microbial transfer. This valuable information gives a good idea about the safety of GE crops in the environment in which they might be introduced.

Scientists have come to rely on CFTs to assess the performance and effects of GE crops in controlled settings. To understand the chance of any potential adverse effects from GE crops, it is essential to know how the natural counterpart crop behaves in the same condition.

In this context, scientists have come to rely on CFTs to assess the performance and effects of GE crops in controlled settings. To understand the chance of any potential adverse effects from GE crops, it is essential to know how the natural counterpart crop behaves in the same condition. For this reason, trials are designed to evaluate specific outcomes by comparing the GE crop and its traditional crop, all under identical weather and farming conditions.

Under these circumstances, scientists first make a record of detailed information about the GE crop, including the genetic modifications, altered genetic material, and history of its safe use, intended uses, and known potential effects. To do a proper evaluation, it is imperative to understand the non-GE natural counterpart, too. So, scientists gather information on (1) details about the parent plant, (2) details about the donor of the transgene and regulatory sequences, transgenes, and how they are delivered, (3) description of the gene products, (the desired outcomes), and (4) description of any other products that might vary between the genetically modified variety and its closest relative (unintended outcomes)[3]. This sets the baseline for safety assessments, which goes side-by-side with the performance studies for the GE crop.

Conducting the experiment and collecting assessment data is not all. Careful steps are also taken after trials are over to ensure GE crops or any part of the crop does not get outside of the trial site. In addition, it is critical that the test material does not end up in the human food or feed chain. Researchers and experts involved in trial management make these factors their priority while designing and executing CFTs. Several steps are taken for proper disposition at this stage.

Buffer zones, physical obstacles, and stringent access controls are placed to prevent the GE crop and crop materials from spreading outside the trial site. To ensure the modified genetic material does not spread through horizontal transfer, necessary steps include spatial and temporal isolation, bagging the pollen, harvesting control plants as border crops, and physical isolation, such as using a tent. The isolation measures also vary depending on the species of the GE crop.

Even after all these precautionary approaches, if a breach occurs, what should be done? To tackle such a situation, the whole team must make an emergency response plan before the trial begins. So, a well-designed plan is in place before a GE crop is taken to the confined environment to evaluate its performance and collect data to assess safety. All these activities are taken to mitigate the unintentional spread and manage potential adverse effects. This may include removing the GE crop materials from the ground, marking the site of release, and observing it.

CFTs also require the transportation and storage of GE materials, which should be transported and stored in ways that prevent

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contamination and unauthorized access[4]. This includes the use of secure containers and keeping detailed records of all movement and storage locations. Planting and management protocols are followed throughout the growing season to ensure that GE crops are grown in optimal conditions while minimizing risk. This includes detailed planting and pest control plans, as well as monitoring the growth and health of GE plants throughout the growing season. Once the growing season is over, the harvest and disposal of GE materials need to be carefully managed, which incorporates securely collecting and disposing of plant materials to avoid any accidental release or contamination. Post-harvest management is critical to ensure that residual GE material does not remain in the environment after the trial site is harvested. This includes monitoring for volunteer plants and any remaining plant material that needs to be managed and disposed of in accordance with regulatory and safety requirements. Finally, documentation is essential throughout the entire process as it guarantees transparency, traceability, and compliance with regulations.

During a CFT, rigorous risk assessments are carried out to look into the possibility of risks and ensure management procedures for any accidents to reduce environmental and human health risks.

From the brief discussion, it is evident that CFTs are not just performance studies of the GE crop. Rather, it is much more. During a CFT, rigorous risk assessments are carried out to look into the possibility of risks and ensure management procedures for any accidents to reduce environmental and human health risks. All the concerns that are raised about the GE innovations get scientific evidence and solutions from the CFT before they are released to a less contained environment. We, as future scientists, have the responsibility to learn about these international and national standards of CFTs so that we can conduct experiments to raise sound data to assess safety and comply with standards when we are working on GMOs. In the end, proper experimentation during CFTs is essential for the successful commercialization of GE crops.

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BANGLADESH

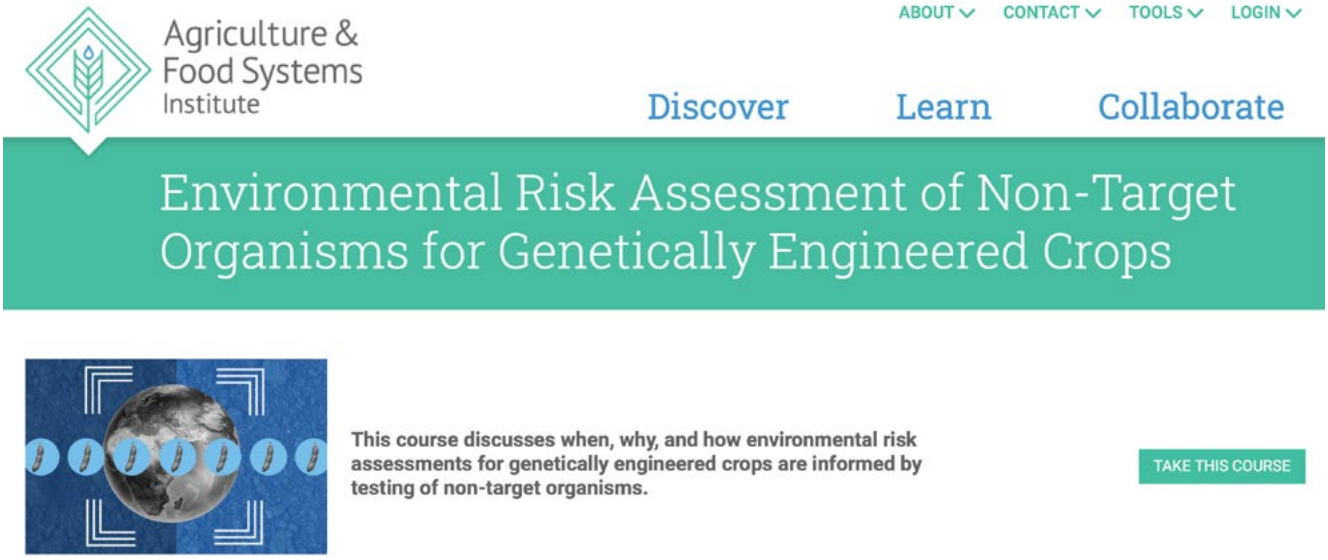
My Enriching Experience with the Agriculture & Food Systems Institute's E-Learning Course on Biosafety

Naila Masfiqua Malek, Biotechnology Program, Brac University

STUDENT SHOWCASE

To encourage written discourse on topics related to biosafety and biotechnology among the younger generation, the *SABP Newsletter* dedicates space in select issues to spotlight pieces written by students residing in South Asia. Since articles with the "Student Showcase" tag are meant to reflect the actual views and capabilities of the author(s), they are not revised for content and only lightly edited to conform with the newsletter's style guide.

Due to an in-course requirement, I was able to explore the Agriculture and Food Systems Institute's online course on the topic: "Environmental Risk Assessment of Non-Target Organisms for Genetically Engineered Crops." The course is designed simply and effectively and contains three basic lessons with several relevant topics. At the end of each topic, there were quizzes to know how well the topic had been understood. It took me almost a week to complete all the lessons and the quizzes, but it was worth it as I was able to familiarize myself with



Course page for the "Environmental Risk Assessment of Non-Target Organisms for Genetically Engineered Crops" e-learning course on foodsystems.org (15 July 2024).

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the concepts around non-target organisms (NTOs) and their assessment in the context of GE crops and a certificate in my name came at the end.

The problem formulation approach used in identifying the right non-target organisms and the multiple-tier approach used in the Environmental Risk Assessment (ERA) of genetically engineered crops were also well explained. The first lesson I learned is entitled "What are NTOs and When is NTO Testing Informative?" and under this title, there are eleven topics with one quiz. This also entails a description of what NTOs are and why they are important, how the NTOs can be measured, and when the testing and assessment processes are necessary. Last, the lesson includes information about the selection and categorization of proper NTOs, the roles of ecosystems, the need for several functional groups to be tested, crop biology regarding NTO testing, and stress exposure concerns. This lesson was very interesting for me, and I learned a lot of new things, for example, what type of NTOs should be included in the assessment, how the ecosystem is connected to crop biology, how to bear in mind the stressor, and so on.

I was introduced to the "Guidelines for Environmental Risk Assessments of GE Crops of Bangladesh," and I found the knowledge gained in the e-learning course very helpful for understanding our own guidelines on NTO assessment.

The second lesson is on "Problem Formulation for NTO Testing for Environmental Risk Assessment (ERA)" and has 22 topics along with one quiz section. The second lesson focuses on initiating the Environmental Risk Assessment (ERA) for non-target organisms (NTOs). It starts with problem formulation, emphasizing contexts like protection goals and biodiversity. The lesson then describes relevant information about crop biology and introduces genetic elements and certain GE crops, such as GE apples. Key concepts of risk, exposure, and hazard are introduced, and realistic comparisons are made in initial risk characterization. The lesson also covers topics, such as information selection, measurement endpoints, and finalizing the initial risk characterization.

The final lesson, "Tiered Testing Approach for Non-Target Organisms," covers 24 topics and one quiz. This lesson outlines the steps in problem formulation to arrive at the testing for the ERA. It states the data needs addressed here, the tiered testing strategy and the stepwise methods, and how early-tier testing of surrogate species is handled. The lesson introduces the choice of surrogate species, prevalent arthropods, and the shift to higher-tier testing, including thresholds and triggers. It covers early-tier testing methods, extended laboratory or semi-field test methods, and conducting higher-tier tests. The field tests section involves the issues of selecting representative taxa, focused sampling, proper controls, experimental design, plot size, and sampling. Finally, at the end of the lesson, the main ideas are again highlighted, and the general procedure is reviewed.

It has been a pleasure to take the "Environmental Risk Assessment of Non-Target Organisms for Genetically Engineered Crops" course. The course structure is detailed and allows students to clearly understand the concepts in ERA of GE crops. Moreover, when in the final year of my bachelor's degree, I was introduced to the "Guidelines for Environmental Risk Assessments of GE Crops of Bangladesh," and I found the knowledge gained in the e-learning course very helpful for understanding our own guidelines on NTO assessment. It is noteworthy that Bangladesh has had ERA guidelines since 2016, which is very much in line with international standards.

The e-learning course is very beneficial for one's growth and knowledge because it provides more information and practical experience dealing with the evaluation of potential environmental hazards. It helps students understand the challenges of NTO assessment and design proper experiments. Finally, it helps researchers better comply with their own country's guidelines.

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Butterfly in a field. © Lars | Dreamstime.com

CALENDAR OF EVENTS

EVENT	ORGANIZED BY	DATE	WEBSITE
INDIA			
UPDA International Summit - 2024	UP Distillers' Association	19 July 2024 New Delhi	https://updaindia.com/portfolio-items/upda-international-summit-exhibition-2024/
National Training on Genomics of Agriculturally Important Pathogens, Microbes, and Insects	Center for Advanced Agricultural Science and Technology (CAAST) ICAR-IARI	22 July-2 August 2024 New Delhi	https://www.iari.res.in/bms/announcements/training.php
DST-SERB Karyashala: Hands-on Training on Gene Editing in Plants for Basic Biology and Crop Improvement	ICAR-National Rice Research Institute	1-9 August 2024 Cuttack	https://icar-nrri.in
Global Conference on Nano Connect 2024	Centre for Agricultural Nanotechnology, Directorate of Natural Resource Management, Tamil Nadu Agricultural University	20-24 August 2024 Coimbatore	https://tnau.ac.in/
International Conference on Futuristic Horticulture (ICFH'24)	Horticultural College and Research Institute, Tamil Nadu Agricultural University, in association with the Society for Promotion of Horticultural Science & Technology (SoPHoST)	14-15 November 2024 Coimbatore	https://tnau.ac.in/news-2/
National Conference-cum-Workshop on Sustainable Biotech Solutions for Global Challenges	Jamia Hamdard University	19-21 February 2025 New Delhi	http://jamiahamdard.edu
INTERNATIONAL			
3rd International Wheat Congress (IWC)	Murdoch University Centre for Crop and Food Innovation, in collaboration with Grains Research & Development Corporation and Wheat Initiative	22-27 September 2024 Perth, Australia	https://www.iwc2024.com/
11th Meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety	CBD Secretariat	21 October-1 November 2024 Cali, Colombia	https://bch.cbd.int/protocol#tab=2
Asian Seed Congress 2024	Asia & Pacific Seed Alliance (APSA) and the China National Seed Trade Association (CNSTA)	2-6 December 2024 Sanya, China	https://web.apsaseed.org/asc2024

SOUTH ASIA BIOSAFETY PROGRAM

The South Asia Biosafety Program (SABP) is an international development program implemented in India and Bangladesh by the Agriculture & Food Systems Institute (AFSI). 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

CONTACT SABP

BANGLADESH
Dil Afroj Moni
Program Officer
South Asia Biosafety Program
c/o CIMMYT
House-10/B, Road-53, Gulshan-2
Dhaka-1212, Bangladesh
Email: dilafroj@southasiabiosafety.org

UNITED STATES
Layla Tarar
Manager, Communications & Digital Learning
Agriculture & Food Systems Institute
1900 L Street NW, Suite 302
Washington, DC 20036, 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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