

South Asia Biosafety Program

NEWSLETTER FOR PRIVATE CIRCULATION ONLY – NOT FOR SALE



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BANGLADESH

Biosafety Research: A Tool for Science-Based Decision Making

Dr. Aparna Islam, Brac University



Farmers working in a field in Bangladesh © Jahangir Alam | Dreamstime.com.

Let us begin with three events in the 1990s in Bangladesh that were related to sustainable agriculture. First, the Bangladesh Environment Conservation Act (1995) was adopted in light of the Convention on Biological Diversity (CBD). The next two events that happened will enumerate their connection with agriculture. Bangladesh's first Agriculture Policy was gazetted in 1999. In this document, the introduction, utilization, and extension of modern biotechnology for food security were put forth as one of the objectives. Thereafter, the first Biosafety Guidelines of Bangladesh were gazetted in the same year.

In the 1990s, research in crop genetic transformation using modern biotechnology started in Bangladesh. The agricultural policy also

supported this. Furthermore, as safeguarding the environment is also a government mandate, Bangladesh ratified the Cartagena Protocol on Biosafety in the following decade. This reinforces the country's pledge to uphold the safe use of modern biotechnology and Living Modified Organisms (LMOs).

As time passed, a robust regulatory regime was established in Bangladesh. Subsequently, the research on Genetically Modified (GM) crop development progressed, and presently, several projects are at various stages of research and development. Moreover, scientists have been trained to comply with the regulatory requirements and follow them as research activities are carried out.

For sound and effective implementation of biosafety, two things are needed: first, a regulatory regime, and second, research for safety assessments so that the biosafety regulators can make a science-based decision.

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We need to implement our regulatory system to get research products to the market. For sound and effective implementation of biosafety, two things are needed: first, a regulatory regime, and second, research for safety assessment so that the biosafety regulators can make a science-based decision. Bangladesh has already achieved considerable progress in the first part. For the second part, i.e., safety evaluation, the process for the safety assessment has to be understood. In Bangladesh, there are relevant guidelines to guide the entire safety assessment process. The safety assessment principles are based on internationally accepted guidance involving comparing GM organisms, i.e., modern biotech products, with their conventional counterparts. For example, for the safety assessment of a GM eggplant, evaluation was done through a comparison between the GM eggplant and its non-GM counterpart. For these comparisons, usually, non-GM organisms are considered the standard because they have a long history of safe use and have been accepted by consumers for generations. So, if a GM crop is to be assessed, the non-GM crop's physiology, reproductive nature, cultivation practice, other relevant traits, and environment, including biota, are studied to know the plant

To get an understanding of baseline data for several crops, between 2019-2021, under the "Biosafety Research in Bangladesh Grants Program," the United States Agency for International Development (USAID) funded several projects.

completely, and then, that is compared with those of the GM crop(s). Of course, along with these studies, the efficiency of the introduced trait(s) in the GM crop is also evaluated and compared with the natural counterpart to see the performance of the introduced novel trait in the plant.

For the efficiency test of the novel trait, experiments are conducted where the trait's efficiency is analyzed, and the best-performing plant is selected. As the trait is introduced and was not present earlier in the non-GM/natural counterpart crop, the decision is made easily by evaluating the performance of the trait in the GM crop. However, how can we check the inherent characteristics and decide whether the GM crop is as safe as its non-GM crop counterpart? To do so, a proper study and recording of the conventional plant's characteristics is a pre-requisite. As we have grown the specific crop for generations, there is a presumption that we know everything about the plant, but nothing is documented in an organized manner. We all agree that knowing something and documenting it are very different things.

To have these data documented, scientists need to properly study the plant system and record all the information. This indicates that research is needed to generate relevant information, which will



Eggplant field in Bangladesh © Jahangir Alam | Dreamstime.com

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ultimately be used for biosafety decisions. These activities comprise “Biosafety Research,” which focuses on generating the baseline data for the evaluation. This can be either survey-based, such as going to the field and collecting the data, or experiment-based, such as collecting data on cultivation practices, analyzing the active ingredient in pesticides used in cultivation, or studying the residue/effects of those on the plant.

All these experiments are done with the non-GM crops to generate the baseline data that will be used as the standard for the comparison. It includes studying the plant’s characteristics, surrounding environment (geo-ecological zones), cultivation practices, biodiversity in the crop fields, etc. In addition, this study may include studies on insect and disease management, chemical residual components, etc., which will be important information if we are dealing with the safety assessment of insect-resistant, herbicide-resistant, or disease-resistant transgenics.

To get an understanding of baseline data for several crops, between 2019-2021, under the “Biosafety Research in Bangladesh Grants Program,” the United States Agency for International Development (USAID) funded several projects. Some projects aimed to understand the farmers’ knowledge of pesticide/insecticide usage and practices, while others looked into the chemical residues on the plant parts consumed as food and feed. Weed management and disease management are also being explored under this grant. Data on the diversity of biota in agricultural fields is very important if the plan is to do an environmental safety evaluation. For this reason, some projects are going on to see the spectrum and abundance of insects prevailing in the field. When we deal with disease, we try to give ample quantity of fertilizer to the plant so that the plant remains healthy to combat pathogens. Surprisingly, we never look into the effect of this surplus on the plant life cycle.

Many such projects need to be initiated because several transgenic plants with different traits are under development in various public and private research institutes and universities.

Taking this into account, a project is running to explore this unexplored pathway. All these research projects aimed to record the current practices of cultivation of non-GM crops and were carried out on commercially valuable crops, such as rice, cotton, potato, and vegetables.

The results of these projects will give valuable data because according to the guidelines, on a case-by-case basis, these are the parameters for biosafety assessment for the environment. So, suppose we are developing an insect-resistant or herbicide-resistant transgenic crop. In that case, relevant data of the non-GM crop cultivation practice will provide baseline data or standard practices to evaluate the safety of transgenics with respect to pest control or weed management. Of course, the crop biology will also be compared, as in the case of any GM crop. So, when we plan to generate baseline data for any of our transgenic crops, we need to keep in mind what data will be relevant because it is determined by the traits that we introduce.

The research in this new arena has begun. We are waiting to see the outcome of the above projects. But many such projects need to be initiated because several transgenic plants with different traits are under development in various public and private research institutes and universities. So, we need to get started with this new field of study and get supporting information for future dossiers for a science-based biosafety decision. We also need to understand that many countries have already evaluated and introduced transgenics with the same traits following assessments similar to our requirements. As the repetition of experiments is time-consuming and involves a huge cost, we also should take advantage of previously existing experimentation data in making decisions. This is a consideration for many countries, and Bangladesh can do the same.



Farmer displaying newly harvested eggplant in Bangladesh. © Jahangir Alam | Dreamstime.com

Revised Guidelines for Registration of Plant Germplasm Issued by the Indian Council of Agricultural Research- National Bureau of Plant Genetic Resources

Dr. Arlene Asthana Ali, Biotech Consortium India Limited

ICAR-National Bureau of Plant Genetic Resources (NBPGR), the nodal agency for the registration of germplasm, issued revised *Guidelines for Registration of Plant Germplasm (Revised, 2023)* in February 2023. The main purpose of plant germplasm registration is to bring trait-specific germplasm into the public domain, provide facilitated access to the developed or identified potentially valuable germplasm for utilization in crop improvement programs, and recognize the contributions of researchers who have developed/identified the trait-specific germplasm. The present revision of the guidelines is an effort toward simplifying and including provisions required as per the changing scenario for submission of applications for registration, data requirements, and deposition of seed/genetic material, recommended by the Plant Germplasm Registration Committee (PGRC).

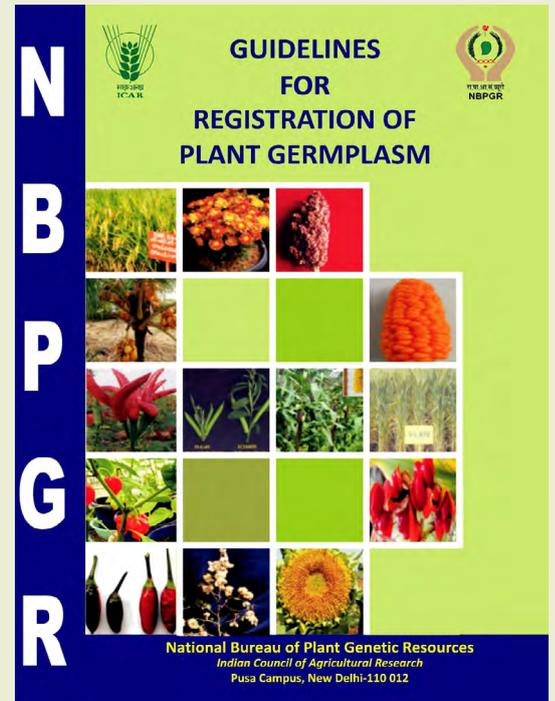
The *Guidelines for Registration of Plant Germplasm* provide details of the PGRC, application form, eligibility criteria for registration, germplasm ineligible for registration, the process of screening of application(s) and their consideration by the PGRC, validity of the registration, publication of registered germplasm, conservation, maintenance and sustainable utilization of registered germplasm, and de-registration.

The procedure for submission of proposals/germplasm material has been provided in detail, wherein plant germplasm proposed to be registered should be submitted online (Form A) at <http://www.nbpgr.ernet.in:8080/registration/>, along with the recommendation of the Institute Germplasm Identification Committee (IGIC) and other documentary evidence.

The document also provides separate sets of guidelines for submitting Orthodox Seed Germplasm, Recalcitrant/Intermediate Seed Germplasm, and Propagules. In addition, a series of Annexures provide further detail on National Active Germplasm Sites (NAGS), guidelines, proforma, checklists, etc., for submission to ICAR-NBPGR.

The revised guidelines can be accessed at:

<http://www.nbpgr.ernet.in/Downloadfile.aspx?EntryId=9279>



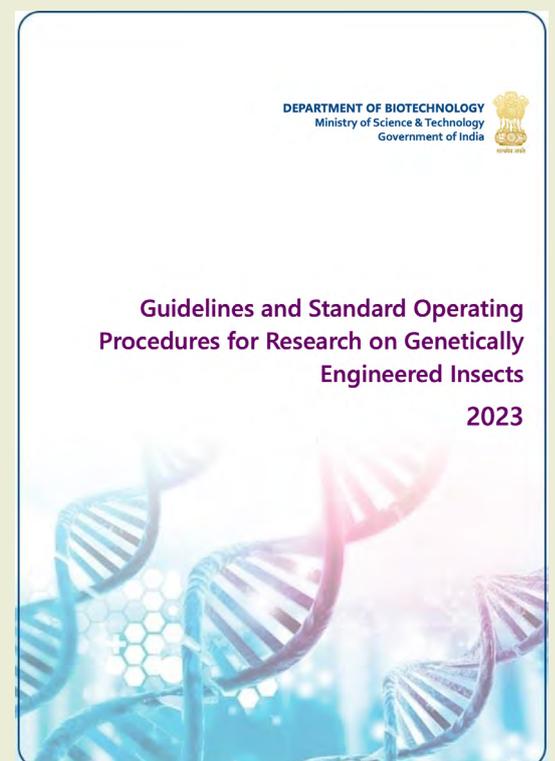
Guidelines and Standard Operating Procedures for Research on Genetically Engineered Insects, 2023 Released by Department of Biotechnology

Dr. Arlene Asthana Ali, Biotech Consortium India Limited, New Delhi

The Department of Biotechnology (DBT), Government of India released the *Guidelines and Standard Operating Procedures (SOPs) for Research on Genetically Engineered Insects, 2023* on 17 April 2023, via O.M. F. No. PID-15011(11)2/2022-PPB-DBT. These Guidelines and SOPs provide a regulatory roadmap and describe SOPs and data requirements for conducting research with genetically engineered (GE) insects under contained facilities, with the proper appraisal of biosafety concerns and to meet the highest global standards. These have been prepared through extensive deliberations by the expert committee constituted by DBT, with inputs from members of the Review Committee on Genetic Manipulation (RCGM) and various other experts to harness the wide applications of genetic engineering in insects, including pest control, disease transmission reduction, and ecological research. These Guidelines and SOPs are intended to serve as a resource tool for all those involved in the research of GE insects and to ensure the safe use and handling of GE insects, thereby streamlining GE insect research under contained conditions. In addition, the document describes the phase-wise categorization of R&D studies involving GE insects. It provides guidance for application submission, containment requirements, key parameters to be studied, and regulatory compliance for conducting Phase 1 and Phase 2 trials of GE insects in India. These Guidelines and SOPs shall apply to all public and private organizations involved in the research and handling of GE insects under containment from the date of notification.

The Guidelines and SOPs can be accessed at:

<https://dbtindia.gov.in/regulations-guidelines/guidelines/guidelines-and-standard-operating-procedures-research-genetically>



Intercountry Validation Workshop: Finalization of Full Project Proposal

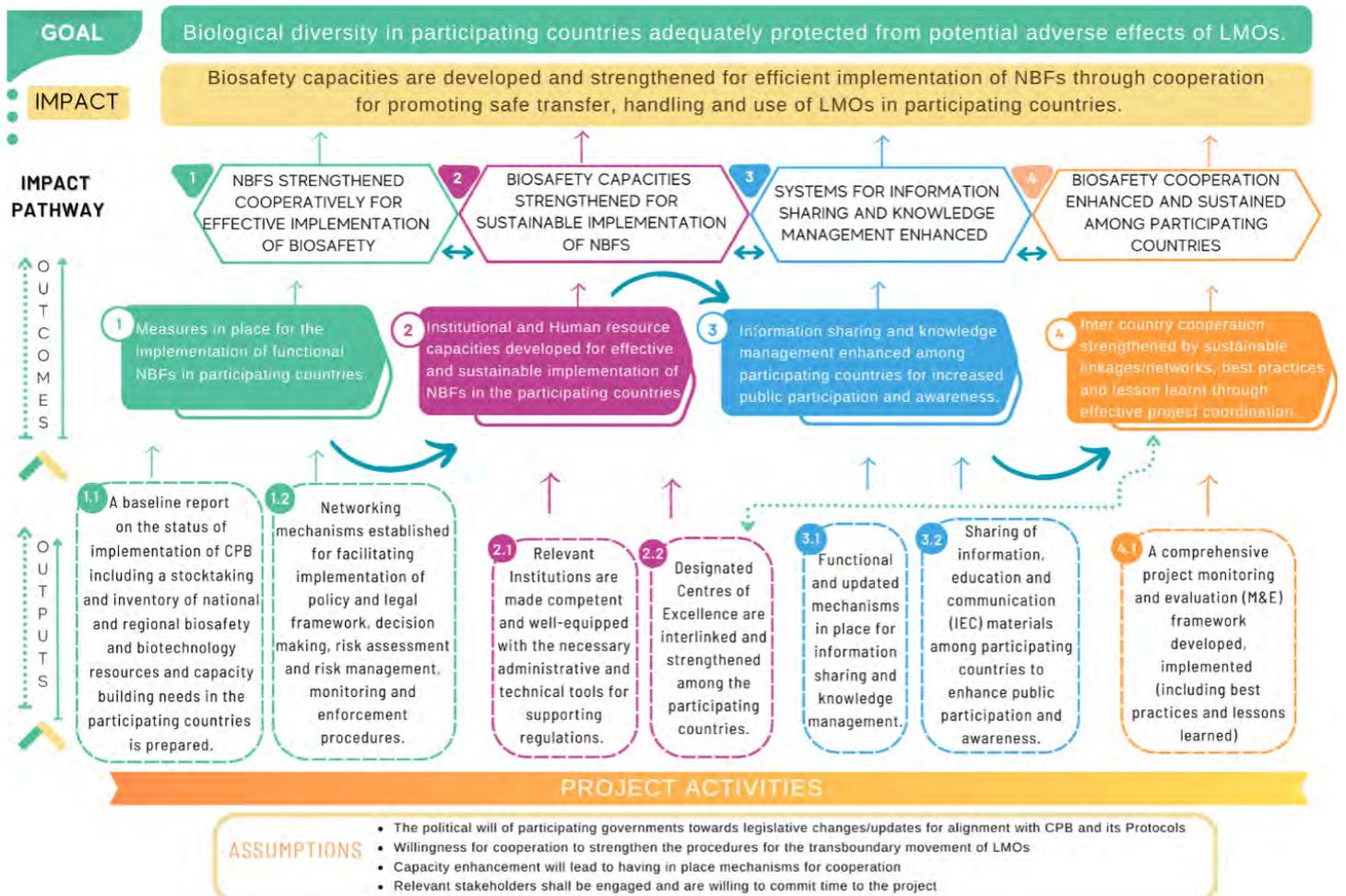
Dr. Vibha Ahuja, BCIL and Ms. Tashi Yangzom, KIPABiC



Participants at the Intercountry Final Validation Workshop (14 April 2023)

The Project Identification Form (PIF) for the Global Environment Facility (GEF ID 10991) project on “Promoting the safe application of biotechnology through multi-country cooperation in the implementation of National Biosafety Frameworks (NBFs) in Asia” was endorsed by GEF on 16 June 2022. It was initiated by Mongolia, the Philippines, India, Bangladesh, the Republic of Korea, and the United Nations Environment

Programme (UNEP). The project aims to strengthen institutional, human, and regulatory capacities and promote cooperative measures in the implementation of NBFs for the safe transfer, handling, and use of living modified organisms (LMOs) in Asia. The project is an effort to contribute to cooperation in line with Article 14 of the Cartagena Protocol on Biosafety (CPB) and Decision CP-9/4, calling for cooperation



An overview of the project as presented in the proposed Theory of Change.

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at the regional and sub-regional level by implementing joint projects for maximizing synergies and opportunities for sharing experiences, information, and expertise.

The intercountry final validation workshop was convened from 12-14 April 2023 in Jeju Island, Republic of Korea. It was organized by the Korea Institute for Promoting Asia Biosafety Cooperation (KIPABiC), with financial support from the Ministry of Trade, Industry and Energy (MOTIE) of the Republic of Korea and technical support from the UNEP. The workshop's objective was to review, validate, and finalize the full project document that reflects the national priorities, multi-country joint areas for cooperation, and fulfillment of the GEF guidelines and requirements. The workshop was convened in hybrid mode, attended by a total of nineteen participants from four participating countries, UNEP, MOTIE, Korea Biosafety Clearing House (KBCH), and KIPABiC. Sixteen participated onsite while three participated virtually via Zoom. Over three days, the project proposal was reviewed, and the countries provided feedback and endorsement

The project aims to strengthen institutional, human, and regulatory capacities and promote cooperative measures in the implementation of National Biosafety Frameworks for the safe transfer, handling, and use of living modified organisms in Asia.

of the project activities, workplan, deliverables, timelines, budget, and implementation plans. At the end of the workshop, the full project document was finalized and readied for submission to UNEP and GEF.

The project will be implemented using an "incremental approach," through which achievements accrued from earlier projects, as highlighted by the stocktaking exercise, will constitute the baseline for the project's activities. In addition, the project will address common needs using the central multi-country strategy and replicate it at the national level. To cater to the different national needs, the participating countries will retain nation-specific responsibilities, while collaborating with the other countries for joint multi-country activities under the coordination of KIPABiC. We believe that the multi-country level project activities would help avoid duplication of efforts, build synergies, and enhance efficiency and cost-effectiveness through shared expertise and resources, while providing lessons and best practices for potential uptake by other countries in the region.

For more information, please contact: kipabic@gmail.com

RESOURCE

FAO Report on Gene Editing & Agrifood Systems

Mr. Vinod Kumar, Biotech Consortium India Limited, New Delhi

The Food and Agriculture Organization of the United Nations (FAO) released a report on *Gene Editing and Agrifood Systems*. Recognizing that a major transformation of agrifood systems is required for eliminating hunger and nutritional improvement, gene-editing technology, including CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats), is recognized as one of the most recent advances in genetics. Beyond its ease of use, precision, reduced cost, and shortened timeline for development, CRISPR stands out as a powerful democratizing tool that scientists can use globally, with the potential to help satisfy the increasing global demand for food and agricultural products.

The gene-editing technology is outlined, and a brief history of plant and animal breeding is presented. Applications of gene editing are discussed in terms of their merits and demerits for various traits introduced into crops, livestock, and fish that enhance production. Governance aspects of gene-edited products include sanitary and phytosanitary regulations. Governance and regulation issues are addressed, and the roles of the public and private sectors, alone and in partnership, are summarized. Finally, various scenarios are suggested for how this new technology might be used to improve agrifood systems. Thus, this report will serve as a guiding document for those seeking to responsibly and equitably deploy genome editing technologies.



Access the Full Report: <https://doi.org/10.4060/cc3579en>

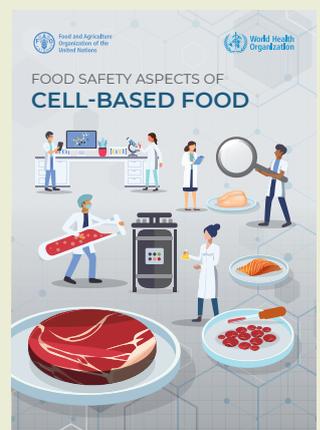
RESOURCE

Report on Food Safety Aspects of Cell-Based Foods by FAO & WHO

Mr. Vinod Kumar, Biotech Consortium India Limited

The Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) have released the first-ever global report to ascertain the potential food safety implications of cell-based food products. *Food Safety Aspects of Cell-Based Foods* explores an apparent sustainable alternative to the conventional livestock agricultural system.

The report includes a literature synthesis of relevant terminology issues, principles of cell-based food production processes, and the global landscape of regulatory frameworks. It includes case studies from Israel, Qatar, and Singapore to highlight the scope, structure, and context surrounding the regulatory framework for cell-based food. The document summarizes the results of the FAO-led Expert Consultation, wherein all potential hazards were discussed in the four stages of cell-based food production: 1) cell-sourcing 2) cell growth and production 3) cell harvesting, and 4) food processing. Experts agreed that while many hazards are already well known and exist equally in conventionally produced food, the focus may need to be put on the specific materials, inputs, ingredients (including potential allergens), and equipment that are more unique to cell-based food production. The report provides readers with up-to-date technical knowledge on the multidisciplinary topic of cell-based food production. It aims to provide a scientific basis that could be used in establishing regulatory frameworks and effective systems that will ensure the safety of these products before reaching consumers in various markets.



Access the Full Report: <https://doi.org/10.4060/cc4855en>

Report on the Awareness Workshop on the Use of GM Crops and Their Derivatives for the Aqua Sector

Dr. S. R. Krupesha Sharma, Principal Scientist & Head-in-Charge, Marine Biotechnology, Fish Nutrition & Health Division, ICAR-CMFRI and Dr. K. Ambasankar, Principal Scientist and Acting HOD, Nutrition, Genetics, and Biotechnology Division, ICAR-Central Institute of Brackishwater Aquaculture (CIBA)



Participants at the Workshop on the Use of GM Crops and Their Derivatives for the Aqua Sector (20 April 2023)

The workshop on the “Use of GM Crops and Their Derivatives for the Aqua Sector,” jointly organized by Biotech Consortium India Limited (BCIL) and ICAR-Central Marine Fisheries Research Institute (CMFRI), on 20 April 2023 at ICAR-CMFRI, Kochi was attended by 47 participants, which included representatives from research institutes, universities, Export Inspection Agency (EIA), Marine Products Export Development Authority (MPEDA), and the agri-food/feed industry. The workshop began with a welcome address by Dr. Krupesha Sharma, Head in-Charge, Marine Biotechnology, Fish Nutrition and Health Division, ICAR-CMFRI and Nodal Officer for the workshop. Dr. A. Gopalakrishnan, Director, CMFRI, delivered the opening address wherein he highlighted the benefits of GM crops in the aqua-feed sector. Emphasizing the many advantages of GM crops, Dr. Gopalakrishnan suggested that GM soybeans can be engineered to produce omega-3 fatty acids, which are important for the growth and health of farmed fish. He further stressed that feed constitutes 50-55 percent of the total input cost in aquaculture operations and serious efforts may be made towards reducing the share of fish meal in aqua feed and minimizing the cost of feed production. He also emphasized the need for streamlining regulatory efforts for using GM plant ingredients in aqua feeds.

Ms. Neenu Peter, Deputy Director, MPEDA, spoke on the growth of the Indian aqua sector, feed demand, and availability. She highlighted the export trends in aqua products, the contribution of capture and culture fisheries, and India’s contribution to world seafood exports. Ms. Peter also deliberated on farmed shrimp production and their value chain in India, feed and other input requirements in Indian aquaculture, and challenges faced by the sector.

This was followed by a comprehensive presentation by Dr. K. Ambasankar, Principal Scientist and Head, Nutrition Genetics and Biotechnology Division, ICAR-CIBA, on nutritional interventions for better aquatic animal productivity. He elaborated on the research initiatives towards sustainable aquaculture in India in particular and globally as well. He further emphasized the nutritional superiority of aquaculture products and feed ingredients. He also underscored the importance of plant protein as an alternative to conventional animal protein and the use of modern research tools and techniques for improved aquaculture production and sustainability. The importance of using GM feed ingredients in India and the immediate research needs on the utility and safety of GM feed ingredients were also highlighted.

Dr. A. Gopalakrishnan, Director, CMFRI, delivered the opening address wherein he highlighted the benefits of GM crops in the aqua-feed sector [... and] suggested that GM soybeans can be engineered to produce omega-3 fatty acids, which are important for the growth and health of farmed fish.

Dr. Vibha Ahuja, Chief General Manager, BCIL, spoke about GM crops and their derivatives, discussing safety and nutritional aspects, including the safety and regulatory assessment of GM crops for use as animal feed, focusing on the aquaculture sector. She explained the concerns, safety aspects, and prospects of using GM crops as feed ingredients in aquaculture. Dr. Ahuja stressed the need to bust the common myths about GM crops and stated that with a regulatory framework and scientific expertise, India could capitalize on the opportunities thrown open by GM crops. She also presented the international scenario of the GM crop-based aquafeed sector and elaborated on experiences

where the cost of production was lowered through GM-based technical interventions. One such notable case is the use of Dried Distillers Grain Solubles (DDGS) in shrimp feed production.

Dr. Bharath Char, Mahyco Pvt. Ltd., in his presentation on enhancing crop productivity of feed grains, highlighted the current status of feed grains in India, limitations to increasing productivity, and the impact of GMOs in the United States, South Africa, and Vietnam. He also explained the previous experiences in using GM crops, such as the case of Bt cotton in India, besides matters related to regulatory constraints for introducing GM crops.

Mr. Amit Sachdev, Regional Consultant – South Asia, U.S. Grains Council, spoke about global feed availability and the role of GM crops, which was followed by a presentation on Indian aqua sector scenarios and feed quality by Mr. Chandrasekar Sankaranarayanan, Head – Aquaculture Utilization South Asia and Mr. Jaison John, Team Lead, U.S. Soybean Export Council.

The presentations were followed by a panel discussion involving Dr. P. Vijayagopal, former Head of the Marine Biotechnology Division, ICAR-CMFRI, Dr. Imelda Joseph, Principal Scientist, CMFRI, Dr. Toms Joseph, Principal Scientist, ICAR-CIFT, and Shri S. Mahesh, Joint Director, Department of Fisheries, Government of Kerala. Several potential researchable issues like (i) biosafety risk assessment of GM feed ingredients in shrimp and fish, (ii) environmental impact, if any, arising from excess fish feed containing non-living GM ingredients, and (iii) development of customized feed products with desired nutritive value were identified during the panel discussion. The experts suggested that these issues should be taken up at the earliest and that scientists and the public should be made aware of the benefits of GM ingredients vis-a-vis feeding the ever-increasing population.

Dr. Grinson George, Principal Scientist, CMFRI, proposed the vote of thanks and ended the workshop at 2:30 PM.

CALENDAR OF EVENTS

EVENT	ORGANIZED BY	DATE	WEBSITE
INDIA			
International Conference on Millet Production Value Addition Enterprising and Global Marketing (ICMVEG 2023)	Department of Millets, Centre for Plant Breeding and Genetics, Tamil Nadu Agricultural University, and Indian Society of Plant Breeders	May 24-26, 2023 Coimbatore	https://tnau.ac.in/news-events/
National Symposium on Confluencing Indigenous and Modern Strategies for Plant Health Management	Himalayan Phytopathological Society & Department of Plant Pathology, Dr. YS Parmar University of Horticulture & Forestry	May 26-27, 2023 Solan	https://www.yspuniversity.ac.in/
5 th International Conference on Climate Change and its Impact (CCI-2023)	Sher-e-Kashmir University of Agricultural Sciences and Technology of Kashmir (SKUAST-K)	June 9-11, 2023 Srinagar	http://www.uasraichur.edu.in/index.php/en/news-list https://skuastkashmir.co.in/
XVI Agricultural Science Congress and ASC Expo	National Academy of Agricultural Sciences (NAAS)	October 10-13, 2023 Kochi	http://www.16asc2023.in
International Conference on Biochemical and Biotechnological Approaches for Crop Improvement	Society for Plant Biochemistry and Biotechnology, ICAR-Indian Agricultural Research Institute (IARI), ICAR-National Institute for Plant Biotechnology (NIPB), and CSIR- National Botanical Research Institute (NBRI)	October 30-November 1, 2023 New Delhi	https://www.ibbaci.org/
10 th Indian Horticulture Congress (2023): Unleashing Horticultural Potential for Self-Reliant India	Indian Academy of Horticultural Sciences (IAHS)	November 6-9, 2023 Jorhat	http://www.aau.ac.in/
Training Programme on Recent Technological Advancements in Horticulture and Forest Crops	Department of Biotechnology, College of Horticulture, Dr. Yashwant Singh Parmar University of Horticulture and Forestry	December 23-30, 2023 Solan	https://www.yspuniversity.ac.in
INTERNATIONAL			
BIO International Convention	Biotechnology Innovation Organization (BIO)	June 5-8, 2023 Boston, MA, USA	https://www.bio.org/events/bio-international-convention
6 th International Rice Congress 2023	International Rice Research Institute and Department of Agriculture, Republic of the Philippines	October 16-19, 2023 Manila, Philippines	https://www.irri.org/IRC2023-teaser.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



CONTACT SABP

BANGLADESH

Sium Ahmed
Deputy Manager
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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