

South Asia Biosafety Program

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Workshop on Food Safety Concepts and the Bangladesh Guidelines

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BHUTAN

Workshops on Safety Assessment of GM Foods in Bhutan

Mr. Jambay Dorji, Dy. Chief Regulatory and Quarantine Officer, Food Quality and Safety Division, Bhutan Food and Drug Authority, Ministry of Health, Royal Government of Bhutan



Group photo of participants and faculty at the Workshop on Foods Derived from Modern Biotechnology: Context and Safety Assessment (9 October 2023).

The Food Quality and Safety Division of the Bhutan Food and Drug Authority (BFDA), Ministry of Health, organized a biosafety training activity on 9-11 October 2023 in Thimphu, Bhutan, under the aegis of the South Asia Biosafety Program (SABP), jointly with the Agriculture & Food Systems Institute (AFSI), USA and Biotech Consortium India Limited (BCIL), India, with financial support from the United States Department of Agriculture (USDA).

The program included a half-day “Workshop on Foods Derived from Modern Biotechnology: Context and Safety Assessment,” which provided a platform to sensitize government executives and relevant stakeholders, including the private sector, on:

- The Global Status of GMO Foods
- Key Concepts in Safety Assessment of GM Foods
- International Guidance for Assessing Foods and Feeds Derived from GM Plants—Role of *Codex Alimentarius*
- Regional Harmonization for the Safety Assessment of Foods Derived from GM Plants

Bhutan’s guidelines for GM food safety assessment published in 2014 are being revised in line with international best practices [...]. Enhancing the capacities of concerned stakeholders will help in strengthening the implementation of a biosafety framework for GM plants.

The remaining two and half days were dedicated to a “Capacity Building Workshop on Safety Assessment of Foods Derived from GM Plants” for members of the Biosafety Technical Working Group and BFDA officials. This workshop provided technical training to participants on the key steps as per the revised “Guideline for the Safety Assessment of GM Foods Derived from GM Plants.” Bhutan’s guidelines for GM food safety assessment published in 2014 are being revised in line with international best practices—in particular, the CODEX Principles for Risk Analysis of Foods Derived from Modern Biotechnology—and also to make them clearer and more understandable for implementation. Timely updating of guide-

lines and enhancing the capacities of concerned stakeholders will help in strengthening the implementation of a biosafety framework for GM plants.

During the workshops, the participants were exposed to various topics detailed below by experts from the Agriculture & Food Systems Institute, Biotech Consortium India Limited, U.S. Food and Drug

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Dr. Florida Carino, Dr. H.M. Jang, and Dr. Vibha Ahuja at the Capacity Building Workshop on Safety Assessment of Foods Derived from GM Plants (9 October 2023)

Administration (online), and Korea Institute for Promoting Asia Biosafety Cooperation:

- GM Foods—Introduction and Global Status
- Key Concepts in Safety Assessment of GM Foods
- International Guidance for Assessing Foods and Feeds Derived from GM Plants: Role of *Codex Alimentarius*
- Project on Regional Harmonization for the Safety Assessment of Foods Derived from GM Plants: Key Outcomes
- Initiatives Towards Regional Harmonization in Asia: Overview
- Biosafety Regulations for GM Foods in Bhutan
- Genome Editing for Crop Improvement: Science and Policy Update
- Applying Problem Formulation to the Safety Assessment of Genetically Engineered Foods and Feeds
- Characterization of the Genetic Modification and Newly Expressed Proteins for Food and Feed Safety Assessment
- Assessing Potential Allergenicity
- Understanding Animal Feeding Studies in the Context of Genetically Engineered Food/Feed Safety Assessments

- Key Concepts in Genetically Engineered Food/Feed Assessment: Compositional Analyses
- Accessing Crop Compositional Data to Inform Genetically Engineered Food/Feed Safety Assessment
- Accessing Information: Useful Resources for Genetically Engineered Food/Feed Safety Assessment
- Transportability of Data for Risk Assessments of Genetically Modified Plants
- Risk Communication

The capacity-building workshop was conducted with a judicious mix of lectures and group work for better learning, understanding, and keeping participants engaged. Bhutan became a party to the *International Convention on Biological Diversity (CBD)* in 1995 and subsequently ratified the *Cartagena Protocol on Biosafety (CPB)* in 2002. Currently, the cultivation of GM plants is prohibited in Bhutan, but it will allow the import of GM food and feed products in non-reproducible form after their safety is ascertained through a robust risk assessment process.



Dr. Andrew Roberts, delivering presentations during the first and second days of the training activity (9-10 October 2023).



Ms. Gyem Bidha, delivering the Opening Address at the workshop (9 October 2023).



Dr. Bhavneet Bajaj, Ms. Dechen Wangmo, and Ms. Gyem Bidha at the workshop.

Workshop on Food Safety Concepts and the Bangladesh Guidelines for Safety Assessment of Food Derived from Genetically Engineered Plants

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



Group photo of speakers and participants at Workshop II: Food Safety Concepts and the Bangladesh Guidelines for Safety Assessment of Food Derived from Genetically Engineered Plants (8 September 2023).

To strengthen the capacity on biosafety for the regulatory authority of Bangladesh, a three-day residential training was held on 8-10 September 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."

Like the preceding workshop, this activity was jointly organized by the Department of Environment (DoE), South Asia Biosafety Program (SABP), and Agriculture & Food System Institute (AFSI). The training focused on "Food Safety Concepts and the Bangladesh Guidelines for Safety Assessment of Food Derived from Genetically Engineered Plants." One of the very important topics was biosafety.

The workshop was graced with a speech by the Chief Guest, Dr. Abdul Hamid, the honorable Director General of the Department of Environment, who addressed issues related to biosafety in Bangladesh, as well as asked participants to share their views and opinions. He also had an informal meeting with the guests after his opening remarks. Honorable members of the Biosafety Core Committee (BCC), Prof. Dr. Zeba Islam Seraj, Dhaka University, and Mr. Monjur Morshed, Member, Bangladesh Food Safety Authority, also attended the program and shared their valuable remarks.

The workshop was attended by the following individuals from the Department of Environment: Syeda Masuma Khanam, Director (Natural Resource Management); A.K.M Rafiqul Islam, Deputy Director (Water & Bio); Farhana Mustari, Deputy Director (Natural Resources Management); 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 (Natural Resources Management). Dr. Kazi Kamrun Nahar, Joint Secretary, Ministry of Environment, Forest and Climate Change, also attended the program.

As the second workshop in a series of four, this event started with a recap of lessons from the first workshop on "Introduction to Concepts of Biosafety and Biosafety in Research & Development" by Prof. Dr. Rakha Hari Sarker, Professor, Dhaka University and Country Coordinator, South Asia Biosafety Program. It was a privilege to attend the lecture by Dr. Donald MacKenzie, Executive Director, Institute for International Crop Improvement, Donald Danforth Plant Science Center, who shared his vast first-hand experiences, as well as knowledge on the whole food

safety assessment and international guidance for assessing foods and feeds derived from genetically engineered plants. He presented the food safety assessment issues from a global perspective and shared activities done in his country to pursue food safety. The international guidance

presented the opportunity to make a country analysis through a comparative assessment. He also discussed the allergenicity assessment of GMOs, accompanied by detailed exercises.

Dr. Aparna Islam, Professor, BRAC University, gave a lecture on "Bangladesh Guidelines on Food Safety Assessment of Genetically Engineered Plants." She presented the holistic food safety assessment issues in the Bangladesh Guidelines. The session was very effective, especially for the government officers to have input in their respective positions.

Dr. Andrew F. Roberts, Chief Executive Officer, Agriculture & Food Systems Institute, gave a lecture on problem formulation and the key concepts for food safety assessment. Dr. Roberts pointed out the problems that might be formulated in practice, as well as the required concepts to conduct the proper safety assessment of foods. To explain this, he provided an overview of the activities and procedures in this field in the USA to ensure food safety for all. Here, the participants were extensively engaged in an exercise where problem formulation had to be applied to the safety assessment of foods and feeds derived from genetically engineered plants. This exercise was very participatory, and attendees had the opportunity to engage deeply with the concepts.

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Dr. Abdul Hamid, the honorable Director General of the Department of Environment, delivering his speech as the Chief Guest, with Dr. Andrew Roberts, Ms. Syeda Masuma Khanam, and Dr. Rakha Hari Sarker seated on stage (8 September 2023).

In another session, Dr. Roberts discussed the potential toxicity of proteins, which is very important for food safety assessment. Characterization of genetic modification and newly expressed proteins is very important to understand in order to perceive food safety concepts. There was an exercise on characterization processes, and it was definitely helpful for the participants to go into the details of the study.

Dr. Vibha Ahuja, Chief General Manager, Biotech Consortium India Limited, shared her knowledge on compositional assessment in food safety. Ms. Syeda Masuma Khanam, Director, Department of Environment, delivered a speech on the background and context of the workshop, where she revealed the food safety issues in Bangladesh. In her

presentation, she informed participants that the main stakeholder of the food safety system in Bangladesh is the Biosafety Core Committee (BCC) and the National Committee on Biosafety (NCB).

Like the first workshop, this second training activity was very effective and successful, with the significant difference being the exercises. Both the workshops were very goal-oriented, and there were about six exercises in the second workshop, during which participants got the opportunity to brainstorm. The presentations, classes, recorded sessions, and exercises were all very friendly ways for the participants to learn about issues related to the concept of food safety in detail.

RESOURCE SPOTLIGHT

OECD Consensus Document on Considerations for Collaborative Work on the Safety Assessments of Foods and Feeds Derived from rDNA Plants

Dr. Vibha Ahuja, Biotech Consortium India Limited

The Organisation for Economic Co-operation and Development (OECD) released a resource for regulatory agencies seeking to collaborate on the safety assessment of foods and feeds derived from rDNA plants on 28 September 2023. "Considerations for Collaborative Work on the Safety Assessment of Foods and Feeds Derived from rDNA Plants–Consensus Document" describes various types of collaborative work among agencies, potential benefits and challenges of implementing such activities, and underlying principles and foundations that may facilitate collaboration. It also highlights certain aspects to consider prior to implementing any collaborative process and how collaborating agencies may evaluate the success of their work.

Collaborative work refers to any collaboration between agencies whose remit is the safety assessment of foods and/or feeds derived from rDNA plants. This work could include inter-agency peer review of assessments, parallel or concurrent assessment, sharing of safety assessments, joint safety assessments, recognition/acceptance of conclusions of assessments or parts of assessments conducted by one or more agencies, or recognition of, or reference to, previous safety assessments conducted by one or more agencies.

The types of collaborative work described in this document, distinguished from more formal arrangements between governments, can be largely accomplished without complex, legally binding agreements among agencies. The real-world examples of collaborative work included in the document are as follows:

- Health Canada and Food Standards Australia New Zealand (FSANZ) Safety Assessment Sharing Initiative
- Harmonization initiative in South Asia
- Economic Community of West African States (ECOWAS) collaborative effort in biosafety regulation
- African Union member states and the approval of GMOs for direct use for food, feed, or processing (FFPs)
- Memorandum of Understanding between Brazil and Argentina for Cooperation in Biosafety of Modern Biotechnology Products (Oct. 2022)
- Multilateral forums in South America

The harmonization initiatives in South Asia mentioned in the document relate to the efforts under the South Asia Biosafety Program (SABP), formally undertaken by the Agriculture & Food Systems Institute (AFSI) in partnership with Biotech Consortium India Limited (BCIL).

Collaboration on the safety assessment of foods and feeds derived from rDNA plants has the potential to directly benefit both the agencies involved in the assessment of products and the applicants bringing forward products for review. Depending on the type and breadth of collaborative work, there may also be wider-reaching indirect benefits for both the regulatory and regulated communities.

The document may be accessed at:

<https://www.oecd.org/chemicalsafety/biotrack/consensus-documents-for-work-on-safety-novel-foods-feeds-facilitating-harmonisation.htm>

CALENDAR OF EVENTS

EVENT	ORGANIZED BY	DATE	WEBSITE
INDIA			
Asian Citrus Congress - 2023	Indian Society of Citriculture (ISC)	28-30 October 2023 Nagpur	https://accindia2023.iscindia.org.in
National Conclave on Promotion of Millets (Shree Anna) for Sustainable Agriculture and Nutritional Security Towards Global Prosperity: Key Challenges and Future Prospects	Sardarkrushinagar Dantiwada Agricultural University, in collaboration with Gujarat Society of Genetics & Plant Breeding and Deendayal Research Institute (DRI)	30 October-1 November 2023 Sardarkrushinagar	http://www.sdau.edu.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
10 th Indian Horticulture Congress-2023 on Unleashing Horticultural Potential for Self-Reliant India	Indian Academy of Horticultural Sciences (IAHS)	6-9 November 2023 Jorhat	http://www.aau.ac.in http://www.iahs.org.in
ICGEB-DBT International Hands-on Workshop on Redesigning Crops for Smart Agriculture	International Centre for Genetic Engineering and Biotechnology (ICGEB)	November 6-10, 2023 New Delhi	https://www.icgeb.org/re-designing-smart-crops-for-sustainable-agriculture-workshop-2023/
International Conference on Feeding the Future through Sustainable Eco-friendly Innovations in Rangeland, Forages and Animal Sciences	Range Management Society of India and ICAR-Indian Grassland and Fodder Research Institute	December 2-4, 2023 Bengaluru	https://uasbangalore.edu.in/index.php/kannada-uas
INTERNATIONAL			
18 th Meeting of the Compliance Committee Under the Cartagena Protocol on Biosafety		24-26 October 2023 Montreal, Canada	https://bch.cbd.int/protocol#tab=2
1 st Meeting of the Ad Hoc Technical Expert Group on Risk Assessment		1-3 November 2023 Montreal, Canada	
Online Forum of the Network of Laboratories for the Detection and Identification of Living Modified Organisms		17-24 November 2023 Online	
Asian Seed Congress 2023	Asia and Pacific Seed Association (APSA) and New Zealand Grain and Seed Trade Association (NZGSTA)	20-24 November 2023 Christchurch, New Zealand	https://web.apsaseed.org/asc2023



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.



USAID
FROM THE AMERICAN PEOPLE



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