

# South Asia Biosafety Program

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## SRI LANKA

### Capacity Building Workshop on Food Safety Assessment of Genetically Modified Plants in Colombo, Sri Lanka

Dr. D.G.C. Jeewani, Additional Director, Plant Genetic Resources Centre and Dr. Ranjith Fernando, Principal Scientist, Horticultural Crops Research and Development Institute



Group photo of participants and speakers at the Capacity Building Workshop on Food Safety Assessment of Genetically Modified Plants in Colombo (22 September 2025).

The two-day *Capacity Building Workshop on Food Safety Assessment of Genetically Modified (GM) Plants* was held on 22-23 September 2025 in Colombo, Sri Lanka. The workshop was organized by the Department of Agriculture, Ministry of Agriculture, Livestock, Land, and Irrigation and Ministry of Health, Government of Sri Lanka, in association with the Agriculture and Food Systems Institute (AFSI) and Biotech Consortium India Limited (BCIL). The workshop was aimed at the regional harmonization of safety assessment for foods derived from GM plants among participating countries of the South Asia Harmonization Initiative–Bangladesh, Bhutan, India, and Sri Lanka. The initiative seeks to advance research, facilitate regional trade, and provide access to international markets by creating common regulatory standards.

#### WORKSHOP HIGHLIGHTS AND KEY TAKEAWAYS

About 49 officials from Sri Lanka's Ministries of Agriculture, Health, and Environment, along with scientists from research institutions and universities, attended the event. Members of the Expert Working Group from the four participating countries and speakers from India, the Philippines, and the USA delivered the presentations, followed by discussions and case studies.

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Dr. W.A.R.T. Wickramaarachchi, Director General of Agriculture, Sri Lanka stated that he welcomed the initiative and emphasized the country's need to adopt new technologies to ensure self-sufficiency in food and feed. Dr. Vibha Ahuja, Chief General Manager, BCIL delivered the keynote address. She highlighted the global scientific consensus that approved GM foods are as safe as their conventional counterparts, citing over 30 years of safe consumption and no documented adverse health effects. She noted that approved GM crops undergo extensive pre-market regulation. Dr. Ananda Jayalal, Deputy Director General, Ministry of Health, Sri Lanka, pointed out the need to review and update Sri Lanka's GM food regulations, which date back to 2001, to reflect the current extensive experience with GM crops. Mr. D.P. Wickramasinghe, Secretary, Ministry of Agriculture, Livestock, Land, and Irrigation, supported the call for a rules review and requested support from AFSI and BCIL for collaboration in developing and using GM and gene-edited technologies for crop improvement. Dr. Bhavneet Bajaj, Senior Manager–Scientific Programs, AFSI briefed attendees on the work done by the Expert Working Group and associated regional capacity building efforts.

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Dr. Ananda Jayal, Deputy Director General, Environmental Health, Occupational Health, and Food Safety Unit, Ministry of Health, Sri Lanka (22 September 2025).



Mr. D.P. Wickramasinghe, Secretary, Ministry of Agriculture, Livestock, Land, and Irrigation, Sri Lanka (22 September 2025).

### TECHNICAL DELIBERATIONS ON SAFETY ASSESSMENT

The program was structured into the following four sessions, which included country-specific perspectives and a deep dive into the science of safety assessment.

**Regional Harmonization Tools:** Dr. Lalitha Gowda detailed the tools developed under the South Asia Harmonization Initiative to support both product developers and regulators. These tools include recommended information for safety assessment, a common application format, and a recommended format for a risk assessment summary. She noted that using the common formats will enable developers to submit a single dossier and facilitate synchronous approvals across the region.

**Science of Safety Assessment:** Dr. Flerida A. Carino explained the comparative approach used for genetically engineered foods, where they are benchmarked against traditional counterparts with an established history of safe use (HOSU). Detailed presentations covered key

**Dr. D.G.C. Jeewani [...] emphasiz[ed] the need for continuing capacity building and stakeholder engagement to explore GM and gene-edited technology for national crop improvement.**

considerations for safety assessment, including evaluations for toxicity, allergenicity, and compositional analysis.

**Handling Derived Products:** Experts covered complex scenarios, such as low-level presence (LLP), low-risk products derived from genetically engineered plants, and detection methods. Dr. Bajaj shared the APEC–Policy Approaches Portal ([biotechpolicyportal.org](http://biotechpolicyportal.org)) as a resource for regional information sharing and led breakout group sessions that utilized case studies to facilitate practical understanding.

### CONCLUSION AND WAY FORWARD

Participants were actively engaged throughout the workshop, reflecting a high level of interest in the subject matter. Dr. D.G.C. Jeewani, Additional Director, Plant Genetic Resources Centre, Sri Lanka, delivered the closing remarks, emphasizing the need for continuing capacity building and stakeholder engagement to explore GM and gene-edited technology for national crop improvement.



Dr. Bhavneet Bajaj and Dr. Flerida Carino conducting a live polling exercise at the workshop (23 September 2025).



Dr. Vibha Ahuja assisting participants during a case study exercise at the workshop (23 September 2025)

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The workshop was well-received, and participants requested more interactive sessions, including hands-on training with case studies, to further deepen their understanding of the safety assessment processes.

This suggests a strong commitment within Sri Lanka's scientific and regulatory community to enhance their capabilities in this crucial field.

## INDIA

# Preparatory Webinar on Risk Assessment and Risk Management at SBSTTA-27: Discussions from an Asian Perspective

Tashi Yangzom, Korea Institute for Promoting Asia Biosafety Cooperation (KIPABiC)

On 1 October 2025, the Korea Institute for Promoting Asia Biosafety Cooperation (KIPABiC), in collaboration with the United Nations Environment Programme (UNEP), Biotech Consortium India Limited (BCIL), and the Korea Biosafety Clearing House (KBCH), hosted a preparatory webinar on "Risk Assessment and Risk Management at SBSTTA-27: Discussions from an Asian Perspective."

The webinar was organized as part of the activities under the Global Environment Facility (GEF) multi-country biosafety project (ID 10991) titled "Promoting the Safe Application of Biotechnology through Multi-country Cooperation in the Implementation of National Biosafety Frameworks in Asia." 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 (LMOs) in Asia," and involves Bangladesh, India, Mongolia, and the Philippines.

## CONTEXT

The Twenty-Seventh Meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA-27) is scheduled for 20-24 October 2025 in Panama. A key agenda item is risk assessment and risk management (RARM) of living modified organisms (LMOs), an essential component of the Cartagena Protocol on Biosafety (CPB). In view of continuous advances in biotechnology and the development of new categories of LMOs, SBSTTA-27 would discuss the need for voluntary guidance and technical considerations for various topics to strengthen case-by-case risk assessment and support effective biosafety governance in line with the decision (CP-11/7) of the Eleventh Meeting of the Conference of the Parties to the Convention on Biological Diversity (CBD) serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (CPB).

The 95-minute webinar aimed to: (i) provide participants with insights on RARM issues to be discussed at SBSTTA-27; and (ii) facilitate interactive discussion to enhance regional understanding and engagement.

## PROCEEDINGS

Dr. Homin Jang, Chief Director of KIPABiC, opened the session by welcoming experts and participants, emphasizing the importance of collaborative regional engagement on biosafety. Dr. Alex Owusu-Biney, Global Biosafety Portfolio Manager, United Nations Environment Programme (UNEP), presented an overview of SBSTTA-27 and its RARM agenda.

A panel discussion on "Scientific Perspectives on RARM of New Categories of LMOs" followed, moderated by Dr. Vibha Ahuja, Chief General Manager, BCIL, India. The panel comprised:

- Dr. Ju Seok Lee, Bio-Evaluation Center, Korea Research Institute of Bioscience and Biotechnology (KRIBB) and Member of the *Ad Hoc* Technical Expert Group on Risk Assessment
- Dr. Florida A. Carino, Consultant, Philippine Food and Drugs Administration and Former Professor of Biochemistry, University of the Philippines
- Dr. Felicity Keiper, Global Industry Coalition (GIC) and Member of the *Ad Hoc* Technical Expert Group on Risk Assessment.

- Dr. Sandagdorj Bayarkhuu, Director, Biosafety Research Institute, Mongolia

The 30-minute Q&A session allowed participants to share queries and perspectives, with responses provided both live and in writing. The discussion underscored the following points.

- **Adequacy of Existing Guidance:** Annex III of the CPB and existing voluntary guidance, including the 2024 materials on gene drives, were deemed methodologically sufficient for case-by-case risk assessment of LMOs.
- **Problem Formulation:** Problem formulation was underscored as the central framework for risk assessment, ensuring clarity on what is at risk, identifying plausible pathways to harm, and enabling proportionate risk management.

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- **National Capacity Gaps:** The urgent need to build and sustain technical capacity for biosafety decision-making at the national level was highlighted.

• **Emerging Biotechnologies:** Genome editing, synthetic biology, and gene drives were identified as raising new considerations and challenges. However, panelists agreed that existing methodologies for case-by-case risk assessment are sufficiently adequate, with adjustments required mainly in the type of data considered.

- **Regional and Global Cooperation:** The importance of collaboration among Asian countries to share experiences, harmonize technical approaches, and strengthen the region's role in global forums was emphasized.

## ENGAGEMENT AND FEEDBACK

The webinar attracted 599 registrants from 57 countries, with 230 participants joining live, representing government agencies, research institutions, academia, NGOs, civil society, and the private sector. A total of 41 entries were posted via the Q&A feature, and 28 participants completed the post-event survey.

Feedback indicated strong appreciation for the organization, relevance, and structure of the event. Over 95% of respondents found the discussions highly informative, while participants expressed keen interest in future events focusing on practical capacity-building, case studies from Asian countries, and deeper exploration of emerging technologies, such as synthetic biology, gene editing, and digital sequence information (DSI).

Dr. Jang concluded the session by thanking the speakers and participants, reaffirming KIPABiC's commitment as a regional platform for biosafety cooperation and encouraging continued collaboration and peer learning across Asia.

## LINKS

Access a recording of the webinar at:

<https://youtu.be/YQHJuN4lme0>

More information is available at:

<https://bch.cbd.int/en/database/BCHN/BCH-BCHN-SCBD-280515-1>

## Acceptance of the Institutional Biosafety Committee (IBSC) Clearance by the Central Drugs Standard Control Organization (CDSCO) for Permission to Manufacture Test Items

Dr. Arlene Asthana Ali, Senior Project Executive, Biotech Consortium India Limited

Notification/Circular No.: File No.: VAC-11011(11)/10/2025-eoffice dated September 03, 2025

Applicable Act/Rule: Drugs and Cosmetics Act, 1940 and Rules thereunder

The Central Drugs Standard Control Organization (CDSCO), under the Ministry of Health and Family Welfare, has issued a circular accepting Institutional Biosafety Committee (IBSC) approval for manufacturing test items for examination, testing, and analysis using Form CT 10. This decision follows the recommendation of the 314<sup>th</sup> Review Committee on Genetic Manipulation (RCGM) meeting held on 9 July 2025. The circular references earlier communications from the Department of Biotechnology and is intended for the information and necessary action of stakeholders involved in research and testing activities.

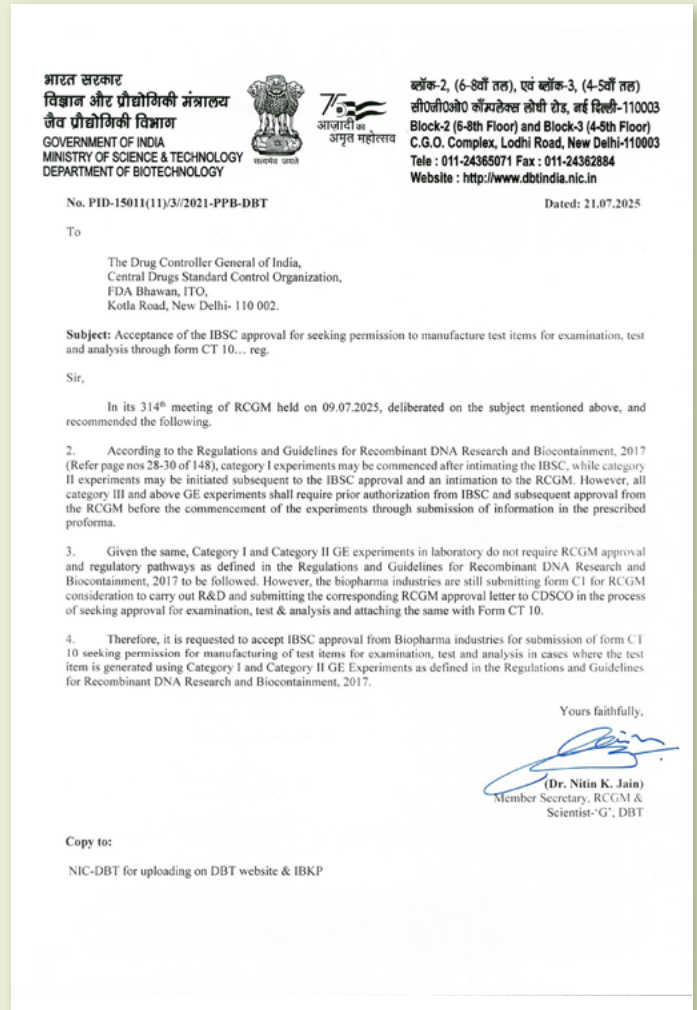
The change addresses a redundancy in the previous approval process. According to the *Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017*:

- **Category I** experiments can begin after informing the IBSC.
- **Category II** experiments require IBSC approval and an intimation to the RCGM.
- **Category III** and higher experiments require prior authorization from the IBSC and subsequent approval from the RCGM.

Despite these guidelines, biopharma industries were often submitting Form CT 10 for RCGM consideration for Category I and II R&D experiments and then submitting the RCGM approval letter to the CDSCO as part of their Form CT 10 application for manufacturing test items.

As a result, the CDSCO has now directed that for test items generated using Category I and Category II Genetic Engineering (GE) experiments, as defined in the 2017 regulations, manufacturers can now submit their IBSC approval in lieu of RCGM approval when seeking permission to manufacture test items for examination, test, and analysis.

The acceptance of IBSC approval is expected to streamline the process for entities seeking permission to manufacture test items, ensuring alignment with biosafety protocols and regulatory requirements. A copy of the circular has been circulated to all biopharmaceutical manufacturers (Vaccine/r-DNA/others).



Access the circular at:

[https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=MTMyNzE=](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTMyNzE=)

## Global Policy on Synthetic Biology Adopted by the International Union for Conservation of Nature (IUCN)

Dr. Vibha Ahuja, Biotech Consortium India Limited

The International Union for Conservation of Nature (IUCN) is a membership union of government and civil society organizations. The IUCN World Conservation Congress was recently held on 9-15 October 2025 in Abu Dhabi. In a landmark decision, the Members' Assembly adopted the IUCN's first-ever global policy on synthetic biology and nature conservation and rejected a moratorium on genetic engineering of wild species. The global conservation community took a decisive step forward by voting a strong majority (88%) to adopt Motion 87, the IUCN Policy on Synthetic Biology, while narrowly defeating Motion 133, which called for a blanket moratorium on genetically modified wild species. The newly adopted policy provides a balanced, science-based framework for the potential application of synthetic biology for conservation.

The policy recognizes that governments must make decisions about synthetic biology that reflect their unique national priorities and contexts, while maintaining rigorous standards for scientific evidence and risk assessment.

The adoption of Motion 87 aligns the IUCN with international frameworks already established in other key fora, including the United Nations Convention on Biological Diversity (CBD) and the Cartagena Protocol.

Further details can be viewed at:

<https://iucn.org/news/202510/iucn-agrees-first-global-policy-synthetic-biology>

## Symposium on Enhancing Functionality of Crops and Improving Nutrition Status Through Gene Editing

Rekha Sinha, Executive Director, International Life Sciences Institute-India (ILSI-India)



Speakers at the Symposium on Enhancing Functionality of Crops and Improving Nutrition Status Through Gene Editing (11 October 2025).

The ILSI-India Knowledge Centre on Functional Foods, Immunity and Gut Health (K-FFIG) organized the “Symposium on Enhancing Functionality of Crops and Improving Nutrition Status Through Gene Editing” on 11 October 2025 at Hotel Le Meridien, New Delhi.

Thirteen national experts on gene editing and nutrition came together to discuss the latest advancements in gene editing technologies and their application for improving the nutritional traits of crops, national and international approaches to safety assessment, and the differences in new breeding technologies—gene editing technologies and genetically modified/engineered crops. They also identified nutritional benefits and implications for health and explored how scientific advancement can be communicated to stakeholders. The symposium was attended by 250 stakeholders from government, industry, and academia.

Dr. B. Sesikeran, Chairman, K-FFIG, Dr. B. K. Nandi, Chairman, ILSI India, and Ms. Rekha Sinha, Executive Director, ILSI India, addressed participants in the Opening Session. The symposium’s theme was discussed in the following three sessions.

- **Session 1:** Advancing Nutrition & Health through Gene Editing, chaired by Dr. B. Sesikeran and co-chaired by Dr. B. K. Nandi
- **Session 2:** Safety Assessment, chaired by Dr. Raman Meenakshi Sundaram, Director, ICAR-Indian Institute of Rice Research, Hyderabad and co-chaired by Dr. M. S. Sheshshayee, Professor, Department of Crop Physiology, University of Agricultural Sciences, Bengaluru.
- **Session 3:** Bridging Gap between Science and Consumer Knowledge—Addressing Concerns and Issues, chaired by Dr. B. Sesikeran and co-chaired by Dr. S. R. Rao, Senior Advisor, Department of Biotechnology (Retd.) and Founder, Genentech Regulatory Solutions, Hyderabad.

Experts highlighted the fact that genome editing technologies, especially CRISPR/Cas systems, have brought transformative changes to agriculture. These technologies enable precise, efficient, and cost-effective

modifications to a plant’s own DNA—without introducing foreign genes—making them superior to traditional breeding methods. CRISPR/Cas9-induced mutations mimic naturally occurring genetic changes but are far quicker and more targeted. Recent regulatory reforms in India, such as the exemption of SDN1 and SDN2 genome-edited plants from strict biosafety regulations, reflect a supportive stance towards adopting innovations for crop improvement.

The global applications of gene editing technologies span a wide range of crops like rice, maize, mustard, banana, and tomato, offering traits like higher yield, pest resistance, improved nutritional content, and environmental benefits, such as reduced emissions. Japan launched the world’s first genome-edited GABA rich tomato, which can aid improvements in life-style related diseases, such as hypertension, diabetes, and hyperlipidemia. Another beneficial finding is that knocking out a single gene creates tomatoes that could each provide 20% of the recommended daily allowance of vitamin D. Researchers at the ICAR-Indian Institute of Rice Research (ICAR-IIRR) have successfully demonstrated gene editing as a powerful tool for rice improvement. Notably, high-yielding gene-edited varieties of Samba Mahsuri developed at ICAR-IIRR, and drought- and salt-tolerant MTU1010 developed by the ICAR-Indian Agricultural Research Institute (ICAR-IARI), represent landmark achievements in Indian plant breeding.

The research at the BRIC-National Agri-food and Manufacturing Institute (BRIC-NABI) has successfully shown how metabolic engineering of banana can improve its nutritional content, particularly pro-vitamin A (beta-carotene) content in fruit.

**“Thirteen national experts on gene editing and nutrition came together to discuss the latest advancements in gene editing technologies.”**

LINK

Further details, including PowerPoint presentations, have been uploaded on the ILSI-India website in PDF format and can be viewed at:

<https://tinyurl.com/24wckcpsy>

## CALENDAR OF EVENTS

EVENT	ORGANIZED BY	DATE	WEBSITE
<b>INDIA</b>			
7 <sup>th</sup> South Asian Biotechnology Conference	South Asian University and the International Centre for Genetic Engineering & Biotechnology (ICGEB)	29-31 October 2025 New Delhi	<a href="https://sabc.sau.ac.in">https://sabc.sau.ac.in</a> <a href="https://www.icgeb.org/south-asian-biotechnology-conference-india-2025/">https://www.icgeb.org/south-asian-biotechnology-conference-india-2025/</a>
First National Seminar on Innovations and Sustainability in Agriculture for Achieving Sustainable Development Goals (SDGs)	CCSHAU College of Agriculture, Bawal and Society for Agriculture and Allied Sciences (SAAS)	30-31 October 2025 Bawal	<a href="https://www.hau.ac.in/">https://www.hau.ac.in/</a>
International Conference on Resource Management for Sustainable Agriculture, Food, Environment and Health	CCSHAU, Society for Sustainable Agriculture and Resource Management, and International Foundation for Sustainable Development	3-4 November 2025 Hisar	<a href="https://www.hau.ac.in/">https://www.hau.ac.in/</a>
Short-term Hands-on Training Program on Recent Advances in Mutation Breeding for Crop Improvement	Bhabha Atomic Research Centre (BARC) and Assam Agricultural University (AAU)	10-19 November 2025 Jorhat	<a href="https://www.aau.ac.in/">https://www.aau.ac.in/</a>
21 <sup>st</sup> Biennial International Conference on Global Resilience in Animal Nutrition: Innovations for Sustainable Future	Animal Nutrition Society of India	19-21 November 2025 Ayodhya	<a href="https://ansi.org.in/conferences/Ayodhya">https://ansi.org.in/conferences/Ayodhya</a>
International Seminar on Climate-Weed Nexus: Innovations for Sustainable Farming	Kerala Agricultural University	27-28 November 2025 Thiruvananthapuram	<a href="https://www.kau.in/events">https://www.kau.in/events</a>
Hands-on Training on Molecular Breeding for Crop Improvement-2025	Tamil Nadu Agricultural University	3-4 December 2025 Coimbatore	<a href="https://tnau.ac.in/news-2/">https://tnau.ac.in/news-2/</a>
40 <sup>th</sup> Annual Conference and National Symposium of the Indian Poultry Science Association (IPSAACON 2025)	ICAR-Directorate of Poultry Research	9-11 December 2025 Hyderabad	<a href="https://www.ipsacon2025.com/">https://www.ipsacon2025.com/</a>
Hands on Training in Plant Tissue Culture Techniques	Tamil Nadu Agricultural University	9-12 December 2025 Coimbatore	<a href="https://tnau.ac.in/news-2/">https://tnau.ac.in/news-2/</a>
<b>INTERNATIONAL</b>			
17 <sup>th</sup> ISBR Symposium (ISBR 2025)	International Society for Biosafety Research (ISBR)	2-6 November 2025 Ghent, Belgium	<a href="https://isbr.info/">https://isbr.info/</a>
2025 Asian Seed Congress	Asia and Pacific Seed Alliance (APSA), National Seed Association of India (NSAI), and Federation of Seed Industry of India (FSII)	17-21 November 2025 Mumbai, India	<a href="https://web.apsaseed.org/asc2025">https://web.apsaseed.org/asc2025</a>



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.



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