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South Asia Biosafety Program

INDIA

Synthetic Biology, Gene Drives, and Digital Sequence Information: Discussions Under the Convention on Biological Diversity (CBD) and Its Protocols

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A pair of cranes walking through a wheat field in India © Ranjit Talwar | Dreamstime.com

The Sixteenth Meeting of the Conference of the Parties to the Convention on Biological Diversity (COP16) and concurrent meetings of its two protocols, *viz.* the Cartagena Protocol on Biosafety (CP-MOP11) and Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization (NP-MOP5), are scheduled to be held from 21 October to 1 November 2024 in Cali, Colombia.

The topics to be discussed at these meetings include: Synthetic Biology, Gene Drives, and Benefit Sharing from the Use of Digital Sequence Information (DSI).

The topics to be discussed at these meetings include: Synthetic Biology, Gene Drives, and Benefit Sharing from the Use of Digital Sequence Information (DSI). The discussions have direct implications for the development of modern biotechnology and biosafety considerations. Below is a brief overview of the three topics with links to relevant documents/websites.

SYNTHETIC BIOLOGY

Synthetic biology was proposed as a "new and emerging issue (NEI)" in the deliberations of the CBD at the Tenth Meeting of the Conference of Parties (COP10) held in 2010. Since 2010, the subject has been intensely debated at all the COPs (COP10, COP11, COP12, COP13, and COP14), and several intersessional activities have also been undertaken, aiming to:

- Define synthetic biology.
- Determine if synthetic biology qualifies as an NEI.
  - Examine potential positive and negative implications for the objectives of the CBD and its protocols.
  - Examine the applicability of the provisions of the CBD, its protocols, and other relevant instruments, and identify any "gaps."
  - Identify organisms developed through synthetic biology techniques that may not be within the definition of "Living Modified Organisms."
- Establish a process for monitoring and assessing developments in the field.

At COP13, an operational definition of synthetic biology was developed by an Ad Hoc Technical Expert Group, which states: "synthetic biology is a further development and new dimension of modern

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BACKGROUND

Convention on Biological Diversity (CBD) and Its Protocols

Adopted at the Earth Summit in Rio de Janeiro in 1992, the Convention on Biological Diversity (CBD) is the first global agreement covering all aspects relating to biodiversity. The three objectives of the Convention are: conservation of biodiversity, sustainable use of its components, and fair and equitable sharing of benefits arising out of the use of these resources. With 196 Parties, the Convention has near universal membership.

Thus far, two protocols have been adopted under the aegis of the CBD: the Cartagena Protocol on Biosafety in 2000 and the Nagoya Protocol on Access and Benefit Sharing (ABS) in 2010.

The Cartagena Protocol on Biosafety, which entered into force on 11 September 2003, seeks to protect biodiversity from the potential risks posed by living modified organisms resulting from modern biotechnology. To date, 173 Parties have ratified the Cartagena Protocol.

The Nagoya Protocol on ABS aims to share the benefits arising from the utilization of genetic resources in a fair and equitable way, including through appropriate access to genetic resources and appropriate transfer of relevant technologies. It entered into force on 12 October 2014 and has been ratified by 135 Parties.

The Conference of Parties (COP), which consists of representatives of all governments that have ratified the treaty, is the governing body of CBD. The COP regularly reviews progress under the CBD, identifies new priorities, and sets work plans for members.

biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems." Though not agreed upon by the Parties, the definition is considered useful as a starting point for the purpose of facilitating scientific and technical deliberations under the Convention and its protocols.

At COP15 held in December 2022, a process for broad and regular horizon scanning, monitoring, and assessment of the most recent technological developments in synthetic biology was established, to be undertaken by a multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology (multidisciplinary AHTEG). The outcomes of the horizon scanning process contained in the report of the multidisciplinary AHTEG, as well as the report on the effectiveness of the horizon scanning process, will be considered in COP16.

The *Portal on Synthetic Biology* provides all relevant information related to discussions on the topic in the CBD:
https://www.cbd.int/synbio

Digital sequence information (DSI) on genetic resources is a placeholder term being used for data obtained from dematerialization of genetic resources, such as genetic sequence data.

GENE DRIVES

The issue of organisms containing engineered gene drives was initially discussed at the CBD under the topic of synthetic biology. As LMOs containing engineered gene drives fall within the scope and objective of the Cartagena Protocol on Biosafety, the topic will be deliberated by CP-MOP 11. Though existing risk assessment methodology may be applicable for LMOs containing engineered gene drives, the need for additional guidance, in view of some methodological considerations, has been agreed to. The scope of these guidelines and how they will be developed is still under discussion.

More information and the documents can be accessed at:
https://bch.cbd.int/en/portals/risk-assessment

DIGITAL SEQUENCE INFORMATION

Digital sequence information (DSI) on genetic resources is a placeholder term being used for data obtained from dematerialization of genetic resources, such as genetic sequence data. The discussion on DSI brought a new dimension to the scope of provisions on access and benefit sharing, as whether or not DSI should fall within the scope of the

Nilgai in mustard field in India © Saji Kamalasanan | Dreamstime.com

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CBD was debated. After a series of discussions since COP13, it was agreed in Target 13 of the Kunming Montreal Global Biodiversity Framework adopted at COP15 that effective legal, policy, administrative, and capacity building measures are to be taken by Parties at all levels to ensure fair and equitable sharing of benefits that arise from the utilization of genetic resources, DSI, and traditional knowledge. Based on a series of studies and deliberations, it was also decided in COP15 that a "Global Multilateral Benefit-Sharing Mechanism (GMBSM)," including a global fund, may be set up, in view of the complexities of the track and trace mechanism in using DSI. During COP16, issues related to operationalizing the GMBSM will be discussed. These include:

- Contributions to the fund.
- Disbursement from the fund.
- Non-monetary benefit sharing.
- Governance.
- Relation to other approaches and systems.

Relevant information and documents regarding DSI are available at:
https://www.cbd.int/dsi-gr

RESOURCE SPOTLIGHT

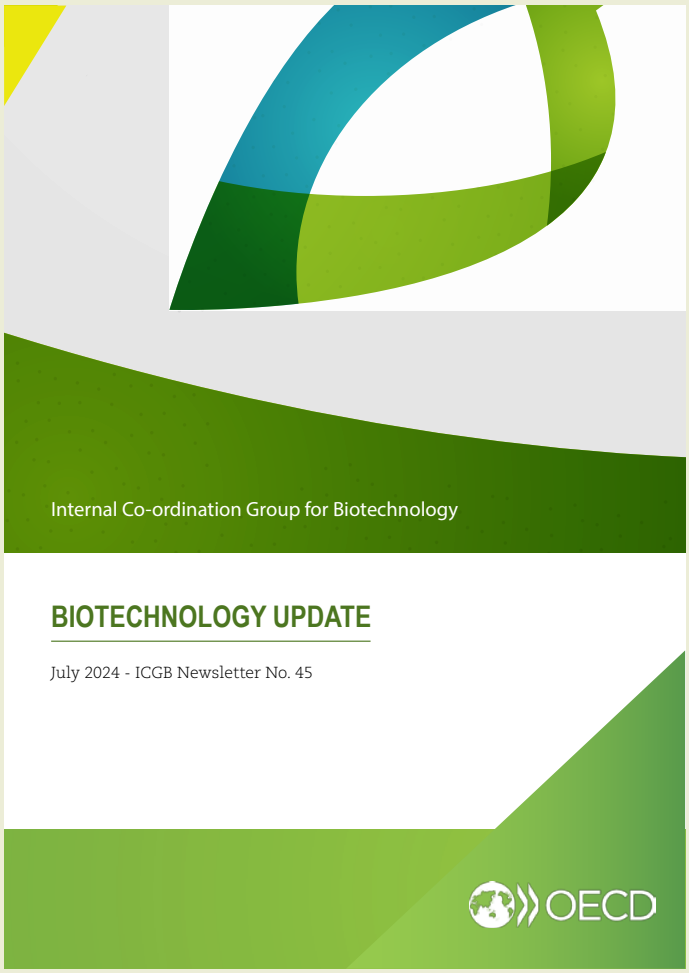
OECD Internal Co-ordination Group for Biotechnology (ICGB) Newsletter No. 45 – Biotechnology Update July 2024

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

The 45th issue of the OECD Internal Co-ordination Group for Biotechnology's Newsletter, *Biotechnology Update*, was released by the OECD. This resource provides up-to-date information on biotechnology-related OECD activities in several directorates–Environment, Trade & Agriculture, and Science, Technology & Innovation–and the International Energy Agency/Renewable Energy Division.

The document provides an overview of the publications, work under development, and upcoming events on topics relevant to biosafety and biotechnology regulation. These include:

- Harmonisation of Regulatory Oversight in Biotechnology
- Safety of Novel Foods and Feeds
- BioTrack Online
- Regulation of externally applied dsRNA-based products for pest management
- Expert Group on Biopesticides Seminar on Problem Formulation for the Risk Assessment of Biopesticides
- Policy issues and opportunities for next generation biotechnologies
- Framework for anticipatory governance of emerging technologies



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ICGB Newsletter No. 45, July 2024

The newsletter can be accessed at:
https://www.oecd.org/en/topics/biosafety-novel-food-and-feed-safety.html

CALENDAR OF EVENTS

EVENT	ORGANIZED BY	DATE	WEBSITE
INDIA			
Training on Market-Driven Breeding in Crops for Commercial Success	Federation of Seed Industry of India (FSII), The Foundation for Advanced Training in Plant Breeding (ATPBR)	21-23 August 2024 Aurangabad	https://www.linkedin.com/posts/advanced-training-in-plant-breeding_training-on-market-driven-breeding-in-crops-activity-7225064018959302656-AVVh
International Conference on Precision Horticulture: Advancing Technologies for Sustainable Production, Food, and Environment (ICPH 2024)	Horticultural College and Research Institute , Tamil Nadu Agricultural University and the	22-24 August 2024 Coimbatore	https://icph2024.com
Brainstorming on Insect Genomics and its Prospects in Pest Management	ICAR-National Bureau of Agricultural Insect Resources	23 August 2024 Bengaluru	https://iims.icar.gov.in/Institute_Details.aspx?Inst=BaPDE2CW+tM=
Global Conference on Nano Connect 2024	Centre for Agricultural Nanotechnology, Directorate of Natural Resource Management, Tamil Nadu Agricultural University	5-6 September 2024 Coimbatore	https://drive.google.com/file/d/1WL2kuUhrudsTut21Cj_MpFKI4MO8gLKj/view
ThinkAg Harvesting Tomorrow Summit 2024	ThinkAg	24-26 September 2024 Goa	https://thinkag.co.in/harvesting-tomorrow-summit/
INTERNATIONAL			
5th International Workshop on Regulatory Approaches for Agricultural Applications of Animal Biotechnologies	International Service for the Acquisition of Agri-biotech Applications (ISAAA)	19-22 & 26-29 August 2024 Virtual	https://na.eventscloud.com/799102
7th Asian Short Course on Agribiotechnology, Biosafety Regulation, and Communication	ISAAA and Malaysian Biotechnology Information Centre (MABIC)	2-6 September 2024 Bangkok, Thailand	https://docs.google.com/forms/d/e/1FAIpQLSfdHEkDsPC-yWHo1p6WRDu5aguR1hPLv9SiQbD7LOyhXQzlyA/viewform
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/
Global Capacity-Building Workshop on Operationalizing Access and Benefit-Sharing National Frameworks under the Nagoya Protocol	CBD Secretariat	30 September-3 October 2024 Bonn, Germany	https://www.cbd.int/meetings/NP-CB-WS-2024-01

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.

SOUTH ASIA BIOSAFETY PROGRAM

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