

Cartagena Protocol on Biosafety (CPB)

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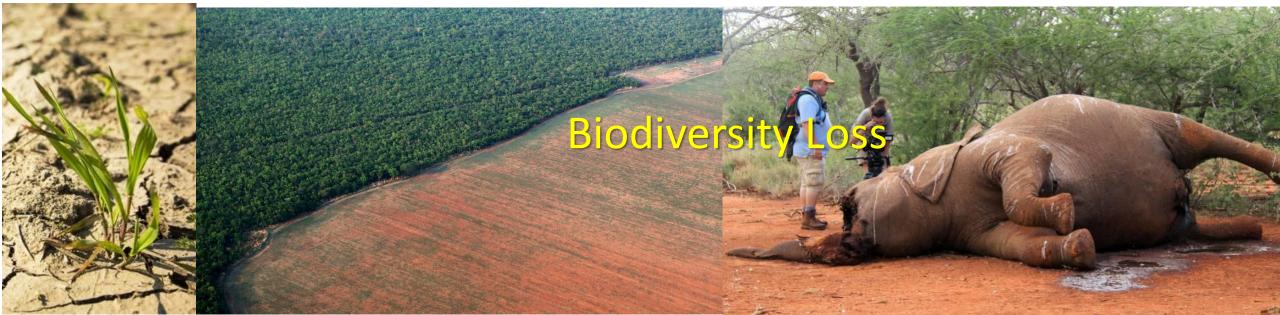
International Specialist in Biotechnology and Biosafety

Session 4: Concepts in biotech regulatory approaches 4th International Workshop on Regulatory Approaches for Agricultural Applications of Animal Biotechnologies Sao Paulo, Brazil, 13 September, 2022

Environmental Concerns



Desertification



United Nations Conference on Environment and Development (Río, 1992)



The United Nations Framework Convention on Climate Change (UNFCCC)

COP27-(6-18 Nov., Egypt)



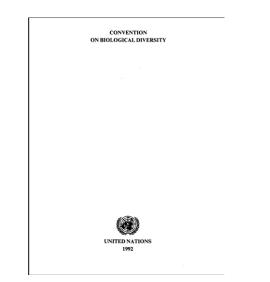
Convention to Combat Desertification and Drought (UNCCD)



The Convention on Biological Diversity (UNCBD)

COP15-(3-19 Dec., Canada)

The Convention on Biological Diversity



✓ Approved: 22 May 1992
✓ In force: 29 December 1993
✓ Parties: 196 countries
✓ <u>http://www.cbd.int/</u>

• Objectives:

- Conservation of biological diversity,
- Sustainable use of its components and
- Sharing benefits from genetic resources, including access and technology transfer

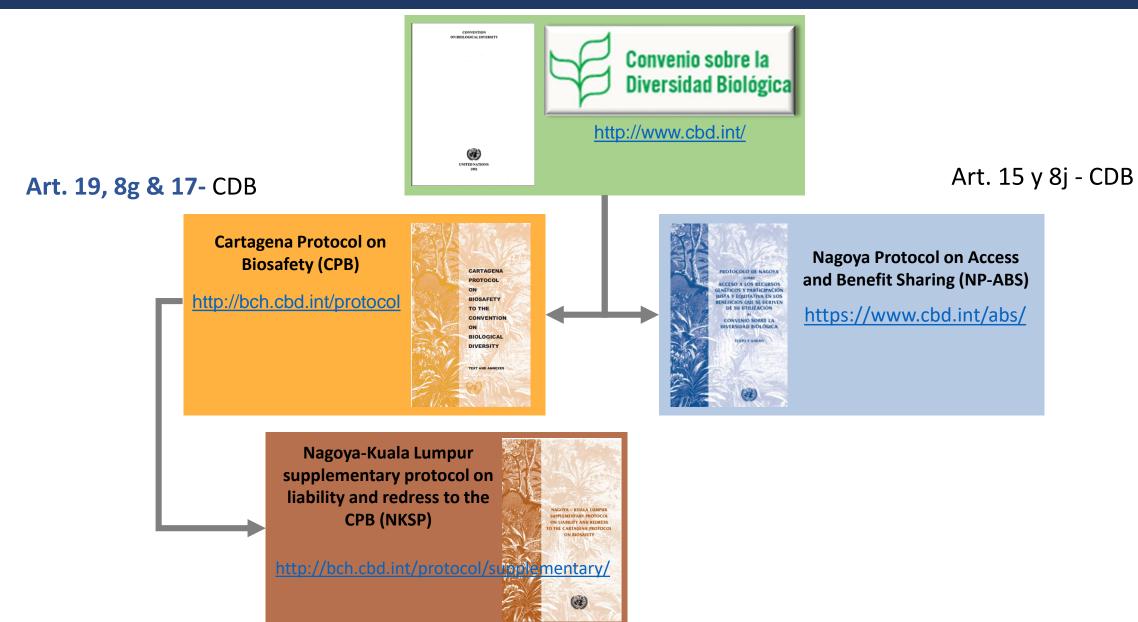
• Biotechnology in the CBD:

- Biotechnology essential to attain the CBD objectives (Artt. 16 & 19)
- Need to establish and maintain biosafety systems (Artt. 8 and 19)

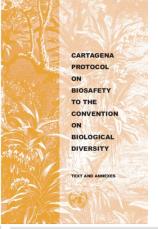
• Protocols:

- The Cartagena Protocol on Biosafety (CPB, in force in 2003)
- The Nagoya Protocol on Access and Benefit-Sharing (NP-ABS, 2014)
- The Nagoya/Kuala Lumpur Suppl. Prot. on Liability and Redress (NP/KL-SPL&R, 2018)

Convention on Biological Diversity



Cartagena Protocol on Biosafethy



Activities and Documentation

Meetings and Documents $_{ar{n}}$

Notifications

Reports of the Executive Secretary

Resources

The Biosafety Clearing-House 🕀

Frequently Asked Questions

Media and Outreach

A video on the Cartagena Protocol

Search the ${\rm BIRC}_{\rm OD}$

Publications

Protocols and decisions

Fact Sheets and Banners

Newsletter

Biosafety Technical Series

Other Publications

- Objectives:

- to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.
- Based on the precautionary principle.
 - Approved: 29 January 2000
 - In force: 11 September 2003
 - Parties: 173 countries
 - No-parties from the Americas: ARG, CAN, CHI, HAI, USA
 - ✓ <u>http://www.cbd.int/protocolo</u>

COP-MOP (Governing Body)

COP-MOP Bureau

COP-MOP Meetings

COP-MOP Decisions

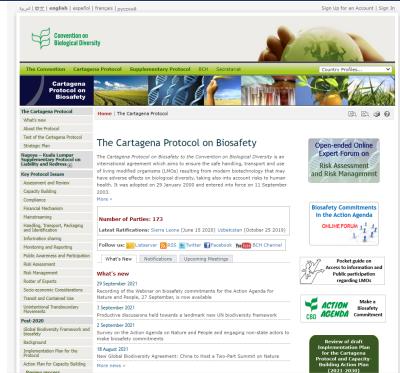
Key Protocol Issues Assessment and Review Capacity Building Compliance Financial Mechanism Mainstreaming Handling, Transport, Packaging and Identification Information sharing Monitoring and Reporting Public Awareness and Participation Risk Assessment **Risk Management** Roster of Experts Sampling, Detection and Identification Socio-economic Considerations Transit and Contained Use

Unintentional Transboundary Movements

CPB and Biotech

• **Provides the definitions** of "Living Modified Organism" and "modern biotechnology" – the first one relevant for GnEd regulatory development –

- Establishes procedures for transboundary movement of LMOs in the absence of national regulations.
- Recognizes the importance and need for agreed principles and methodology for **risk assessment**.
- Proposes the creation and use of the **Biosafety Clearinghouse** mechanism
- Allows for diverse interpretations.



Governing bodies of the Convention and its Protocols





- CBD: Conference of the Parties (COP).
- **CPB, NP-ABS, NKL-SPL&R:** Conference of the Parties (COP) serving as the Meeting of the Parties (MOP), '**COPMOP**' or 'MOP'.
- Since 2016, COPs and MOPs meet in an integrated fashion: the **UN Biodiversity Conference.**

COP & COP-MOP main duties

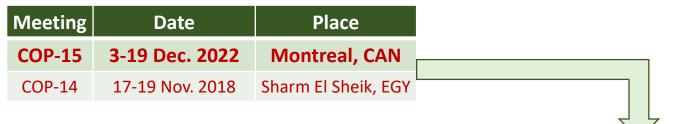
- To promote the implementation of the Convention and its protocols through the decisions they take at their periodic meetings.
- CBD/COP: Establishes thematic programs that set objectives and strategies for conserving genetic resources in each of the main types of ecosystems: marine and coastal areas, inland waterways, forests, mountainous areas, agricultural areas, and dry and subhumid lands
- CPB/COP-MOP: Reviews implementation, discuss topics related to risk assessment, communication, capacity building, financial mechanism, emerging issues.

Meetings COP & COP-MOPs

Meeting	Date	Place
COP-15	3-19 Dec. 2022	Montreal, CAN
COP-14	17-19 Nov. 2018	Sharm El Sheik, EGY
COP-13	4-17 Dic. 2016	Cancún, MEX
COP-12	6-17 Oct. 2014	Pyeongchang, KOR
COP-11	8-19 Oct. 2012	Hyderabad, IND
COP-10	18-19 Oct. 2010	Nagoya, Aichi , JAP
COP-9	19-30 May. 2008	Bonn, GER
COP-8	20-31 Mar. 2006	Curitiba, BRA
COP-7	9-20 Feb. 2004	Kuala Lumpur, MAL
COP-6	7-19 Abr. 2002	The Hage, NET
COP-5	15-26 May. 2000	Nairobi, KEN
ExCOP 1	23-23 Feb. 1999 & 24-28 Ene. 2000	Cartagena, COL & Montreal, CAN
COP-4	4-15 May. 1998	Bratislava, SLO
COP-3	4-15 Nov. 1996	Buenos Aires, ARG
COP-2	6-17 Nov. 1995	Jakarta, INS
COP-1	28 Nov9 Dic. 1994	Nassau, BAH

COP, COP-MOP, SBSTTA, SBI, and more...

Meetings COP & COP-MOPs



• Between COPs & COP-MOPs:

- Governments and organizations submit formal comments

- Open ended on-line fora

- AHTEG (Ad Hoc Technical Expert Groups)

> AHTEGs on LMO Risk Assessment, SynBio, DSI, Socioeconomic considerations,

- SBSTTA (Subsidiary Body on Scientific, Technical and Technological Advice)
- SBI (Subsidiary Body of Implementation)

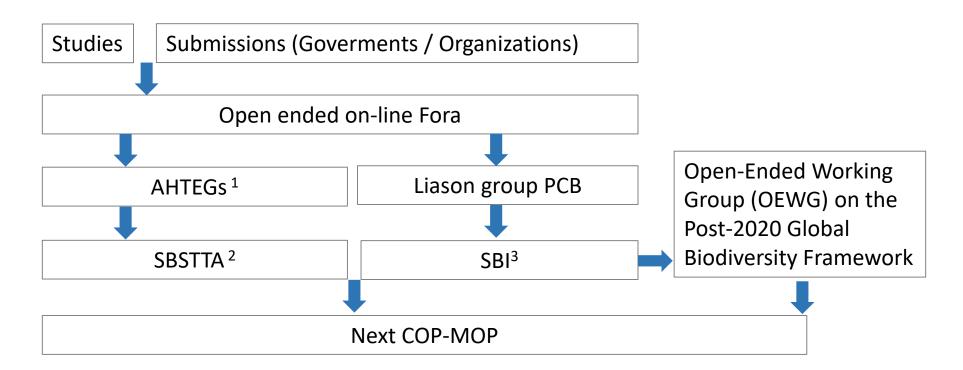
Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA)

Meeting	Date	Place
SBSTTA 24	14-29 Mar. 2022	Geneve, SWI
SBSTTA 24	3 May 2021	virtual
SBSTTA 23	20-22 Nov. 2019	Montreal, CAN
SBSTTA 22	2-7 Jul. 2018	Montreal, CAN
SBSTTA 21	11-14 Dic. 2017	Montreal, CAN
SBSTTA 20	25-30 Abr. 2016	Montreal, CAN
SBSTTA 19	2-5 Nov. 2015	Montreal, CAN
SBSTTA 18	23-28 Jun 2014	Montreal, CAN
SBSTTA 17	14-18 Oct 2013	Montreal, CAN
SBSTTA 16	30Abr-5May 2010	Montreal, CAN
SBSTTA 15	7-11 Nov. 2011	Montreal, CAN
SBSTTA 14	10-21 May. 2010	Nairobi, KEN
SBSTTA 13	18-22 Feb. 2008	Roma, ITA
SBSTTA 12	2-6 Jul. 2007	Paris, FRA
SBSTTA 11	28Nov2Dic 2005	Montreal, CAN
SBSTTA 10	7-11 Feb. 2005	Bangkok, THA
SBSTTA 9	10-14 Nov. 2003	Montreal, CAN
SBSTTA 8	10-14 Mar. 2003	Montreal, CAN
SBSTTA 7	12-16 Nov. 2001	Montreal, CAN
SBSTTA 6	12-16 Mar. 2001	Montreal, CAN
SBSTTA 5	31Ene4Feb. 2000	Montreal, CAN
SBSTTA 4	21-25 Jun. 1999	Montreal, CAN
SBSTTA 3	1-5 Sep. 1997	Montreal, CAN
SBSTTA 2	2-6 Sep. 1996	Montreal, CAN
SBSTTA 1	4-8 Sep. 1995	Paris, FRA

- Established in response to Art. 25 of the CBD
- Reports to the COP
- Seeks open and multidisciplinary participation of all parties.
- It is a kind of pre-COP/COP-MOP
- Functions:
 - Provide assessments of the status of biological diversity.
 - Provide assessments of the types of measures taken in accordance with the provisions of the Convention.
 - Respond to queries that the COP may put to the agency.
 - Prepare the final reports to COP.

Process leading up to COPs and MOPs

COP-MOP identifies topics to be discussed at the next COP-MOP



¹ Ad Hoc Technical Expert Group (AHTEGs)

² Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA)

³ Subsidiary Body on Implementation (SBI)

Functioning of COPs & COP-MOPs

- Participants are officially delegated by the Parties.
- Observers can assist and express their ideas, but in plenary sessions, they must be supported by the Parties)
- Different types of meetings in COPMOPs and subsidiary bodies - *E.g.* Plenary, Working Groups, Contact Groups, 'Friends of the Chair'
- Different categories of documents
 - E.g. Official, Plenary, Statements, Information, Notification, Other
- Access to oficial documents

http://cbd.int/conferences/2021-2022/insession

Participación en COP & COP-MOP

- Participation in the COP and COP-MOP process is important, also for those who do not attend, as **silence implies acceptance**.
 - Incorporation of the results of the COPs and COP-MOPs into national systems.
- It is important to have a thorough understanding of the terms and definitions, as they become key elements for interpretation at the national and global levels.
- IICA Monthly Preparatory Meetings for COP-MOPs
 - From March 2020



<u>https://sites.google.com/iica.int/biotecnologia-y-bioseguridad/actividades-tecnicas/seminarios-virtuales/pre-cop-mop15</u>

Contact



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https://sites.google.com/iica.int/biotecnologia-y-bioseguridad/actividades-tecnicas

GnEd products are not LMOs

 (g) "Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

 (h) "Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

- (i) "Modern biotechnology" means the application of:
 - In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
 - b. Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;



"4.6. NEW COMBINATION OF GENETIC MATERIAL. For the purposes of these regulations, a new combination of genetic material is understood as a stable insertion in the genome of one or more genes or DNA sequences encoding double-stranded DNA, RNA, proteins, or regulatory sequences that could not be obtained by conventional breeding or are not found in nature".