









Update on the outcomes of modern biotechnology discussions under the Convention on Biological Diversity and its Protocol





PRESENTATION OVERVIEW

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- Outcomes of CBD discussion on Synthetic biology
- Outcomes of key Agenda Items of Biosafety protocol:
 - Risk assessment and Management
 - ii. Socio-economic
 - iii. Post-2020 framework
- Outcomes of the relevant discussion under the Nagoya protocol (digital sequencing of genetic resources).

Background

South Africa is the 3rd most biodiverse country in the world



7% of the world's reptiles, birds and mammals



10% of the world's plants



2% of the world's land area

15% of the world's coastal marine species

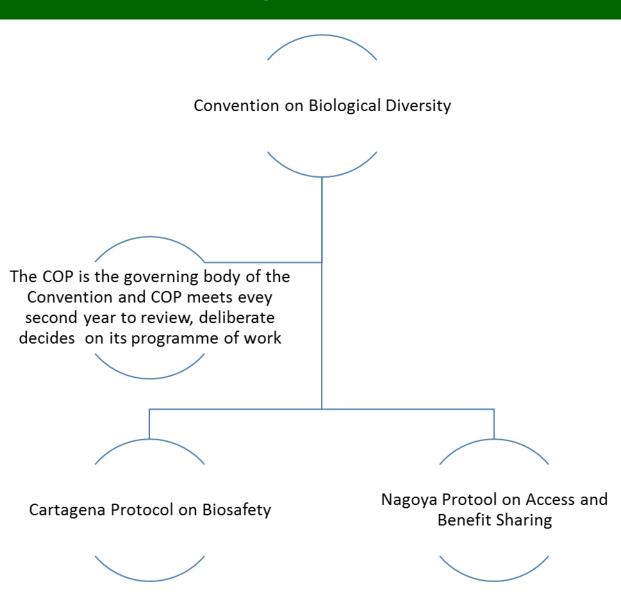








Background Cont...



Outcomes of CBD discussion on Synthetic biology

BACKGROUND

- Synthetic biology is a rapidly developing and cross-cutting issue, with potential benefits and potential adverse effects vis-à-vis the three objectives of the Convention;
- Developments arising from research and development in the field of synthetic biology may pose challenges to the ability of some countries to assess the full range of applications and their potential impacts.
- Due to its cross-cutting nature, synthetic biology is being discussed under the Convention and the Cartagena Protocol on Biosafety;

Key issues:

- The AHTEG on synthetic biology had, during the intercessional period concluded that:
 - ✓ living organisms developed through current and near future applications of synthetic biology are similar to living modified organisms (LMOs) as defined in the Cartagena Protocol on Biosafety.
 - ✓it is not clear at the current stage whether or not some organisms of synthetic biology, which are currently in the early stages of research and development, would fall under the Cartagena Protocol's definition of LMOs.

Outcomes of CBD discussion on Synthetic biology

Final decision

- The COP agrees that broad and regular horizon scanning, monitoring, and assessing of the
 most recent technological developments is needed for reviewing new information on the
 potential positive and potential negative impacts of synthetic biology vis-à-vis the three
 objectives of the Convention and those of the Cartagena and Nagoya Protocols;
 - ✓ It called upon parties and others, taking into account the current uncertainties regarding engineered gene drives:
 - ✓ to apply a precautionary approach,
 - ✓ to only consider introducing organisms containing engineered gene drives into the environment, when scientifically-sound case-by-case risk assessments have been carried out, risk management measures are in place to avoid or minimize potential adverse effects, as appropriate,
 - ✓ and where appropriate, the "prior and informed consent," the "free PIC," or "approval and involvement" of potentially affected IPLCs is sought or obtained, in accordance with national circumstances and legislation.
- The COP also decides to extend the AHTEG on synthetic biology and the open-ended online forum;
- The annexed ToR for the AHTEG on synthetic biology include taking stock of new technological developments in synthetic biology since the last meeting of the AHTEG, including the consideration, among other things, of concrete applications of genome editing if they relate to synthetic biology, in order to support a broad and regular horizon scanning process.

Outcomes of key Agenda Items of Biosafety protocol:

i. Risk Assessment

Background:

- COP MOP8 acknowledged the work of the AHTEG on Risk Assessment and Risk Management;
- They also acknowledged other guidance and national approaches, and requested Parties to share an assessment of their applicability and usefulness through the Biosafety Clearing-House (decision VIII/12, paras. 3 and 4);
- SBSTTA noted availability of numerous guidance documents and other resources to support the process of risk assessment, but recognizes the gaps and needs identified by some Parties.

Key issues:

- Resolving the square brackets on text referring to LMOs produced through genome editing;
- Establishment of a stepwise process for the identification and prioritization of specific issues of risk assessment of LMOs for consideration by COP-MOP, for the development of further guidance on risk assessment.
- Establishment of the AHTEG.

Outcomes of key Agenda Items of Biosafety protocol Cont....

Final Decision:

- COP/MOP recognizes that, as there could be potential adverse effects arising from organisms containing engineered gene drives, before these organisms are considered for release into the environment, research and analysis are needed, and specific guidance may be useful, to support case-by-case risk assessment;
- COP MOP also decides to:
 - ✓ Establish a process for the identification and prioritization of specific issues regarding LMO risk assessment for consideration by the Cartagena Protocol COP/MOP with a view to developing further guidance on risk assessment on the specific issues identified in an annex;
 - ✓ Consider at COP/MOP 10 whether additional guidance materials on risk assessment are needed for LMOs containing engineered gene drives, and living modified fish;
 - ✓ Establish an AHTEG on risk assessment in accordance with the annexed terms of reference; and
 - ✓ Extend the online forum on risk assessment and risk management to assist the AHTEG.

Socio-economic

Background:

- The Cartagena Protocol on Biosafety establishes the right of Parties to take into account socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biodiversity, especially with regard to the value of biodiversity to indigenous and local communities, in reaching a decision on whether to import LMOs.
- The inclusion of socio-economic considerations in Parties' decision-making on the import of LMOs must be consistent with their other international obligations.
- The Protocol also encourages Parties to cooperate on research and information exchange on any socio-economic impacts of LMOs, especially on indigenous and local communities.
- Outcome under the strategic plan objective addressing socio-economic considerations
 - By 2020 guidelines regarding socio-economic considerations of living modified organisms developed and used by Parties

Key Issues:

- "Take note or adopt and make use" of guidance document
- Underscored the voluntary character of the guidance.
- The continuation of the AHTEG.
- Testing the guidance vs the process of gathering information on the usefulness of the guidance.

Socio-economic cont...

Final decision

- The COP-MOP took note of the "Guidance on the Assessment of Socio-Economic Considerations in the Context of Article 26 of the Cartagena Protocol on Biosafety".
- It invited for the submission of preliminary experience using the Guidance as well as examples of methodologies and applications of socio-economic considerations in light of the elements of the Guidance.
- It requested the Executive Secretary to compile the information and organize moderated online discussions of the online forum on socio-economic considerations to comment on and add views to review the compilation.
- The COP-MOP extended the Ad Hoc Technical Expert Group on Socioeconomic Considerations to review the outcomes of the online forum and requested the Executive Secretary to convene a face-to-face meeting of the Group.
- The COP-MOP decided to consider the outcomes of the process at its tenth meeting

Specific post-2020 implementation plan for the Cartagena Protocol

Background:

- In 2010, the Conference of the Parties adopted the Strategic Plan for Biodiversity 2011-2020, with its Aichi Biodiversity Targets (decision X/2) and the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety adopted the Strategic Plan of the Cartagena Protocol on Biosafety for the period 2011-2020 and its multi-year programme of work (decision BS-V/16);
- In decision XIII/1, paragraph 34, the Conference of the Parties recognized the need for a comprehensive and participatory process to develop proposals for the follow-up to the Strategic Plan for Biodiversity 2011-2020.

Key issues:

 Development a specific post-2020 implementation plan for the Cartagena Protocol that is anchored in, and complementary to, the post-2020 framework.

Specific post-2020 implementation plan for the Cartagena Protocol Cont...

Final decision:

- The COP/MOP further decides to expand the scope of the Liaison Group on Capacity Building for Biosafety, and rename it the Liaison Group on the Cartagena Protocol on Biosafety.
- On the development of the biosafety element of the post-2020 framework, it requests the Secretariat to:
 - ✓ Convene dedicated biosafety sessions during global and regional consultation workshops;
 - ✓ Compile submissions by parties and others regarding potential structure and content;
 - ✓ Convene meetings of the Liaison Group; and
 - ✓ Prepare, and facilitate peer-review of, a draft post-2020 implementation plan for consideration by the next COP/MOP.

Outcomes of the relevant discussion under the Nagoya protocol (digital sequencing of genetic resources)

Background:

- The Convention has a long history in addressing a broad range of emerging technologies and their potential impact on biodiversity, including living modified organisms, genetic use restriction technologies, biofuels, and geoengineering;
- NP defines the term utilisation of genetic resources as the conduct of research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention
- Gene sequences are increasingly replacing the need to access biological samples of genetic resources, creating major implications for the Convention's architecture on ABS.
- However, some countries are taking the position that sequence information should be or even is covered by the Protocol, leading to an uncertain legal position.

Key issues:

- Whether or not DSI falls within the scope of the Convention and its Protocols, and benefit sharing should arise from its use;
- The use of digital sequence information is not covered by the term utilisation of genetic resources of Art. 2;
- Identical genetic sequence is synthesised and assembled de novo by artificial means (artificial gene synthesis or 'DNA printing'), which is subsequently found in nature; or
- Genetic sequences are synthesised, which, while not identical, lead to an identical protein sequence;
- Genetic sequence may occur naturally as the same across several species, and/or the same species across disparate geographical locations.

Outcomes of the relevant discussion under the Nagoya protocol (digital sequencing of genetic resources)

Final Decision:

- The COP recognizes that access to and use of DSI contributes to scientific research, and that further capacity to access, use, generate, and analyze DSI is needed in many countries;
- It notes that some parties have adopted domestic measures that regulate the access to and use of DSI as part of their ABS frameworks, and that there is a divergence of views among parties regarding benefit-sharing from the use of DSI;
- The COP further decides to establish a science and policy-based process, which involves:
 - ✓ inviting governments, IPLCs, and others to submit their views and information to clarify the concept, including relevant terminology and scope, and if and how domestic ABS measures consider DSI, and on benefit-sharing arrangements from commercial and non-commercial use of DSI;
 - ✓ inviting governments, IPLCs, and others to submit information on capacity-building needs; and
 - ✓ establishing an extended AHTEG, including participation of IPLCs.
- The COP also requested the Secretariat to synthesize submissions, and commission studies on:
 - ✓ the concept and scope of DSI, ongoing developments in the field of traceability, public and, to the extent possible, private databases of DSI; and
 - ✓ how domestic ABS measures address benefit-sharing arising from commercial and noncommercial use of DSI.

intercessional period Activities

| Programme of work | Activities | Meetings |
|-------------------|---|---|
| Risk Assessment | a) Experience in undertaking risk assessment of living modified organisms containing engineered gene drives and living modified fish (detailing how and for which cases); or else, lack of experience in doing so; b) Challenges experienced or foreseen in undertaking risk assessment of living modified organisms containing engineered gene drives and living modified fish; c) Specific needs (if any) to properly undertake risk assessment of living modified organisms containing engineered gene drives. | Online forum: 4 th quarter 2019 AHTEG December 2019/ Jan 2020 |

intercessional period Activities Cont...

| Programme of work | Activities | Meetings |
|-------------------|--|---|
| Post-2020 | Submit information (1) the structure and content of the Implementation Plan for the Cartagena Protocol on Biosafety post-2020; (2) possible elements of a specific action plan for capacity-building on biosafety, covering the Cartagena Protocol and its Supplementary Protocol; and (3) relevant elements of the biosafety component of the post-2020 global biodiversity framework. | Regional consultations are underway Africa: 2-5 April 2019, Ethiopia, Addis Ababa Meeting of the open-ended intersessional working group on the post-2020 global biodiversity framework: July 2020 |

intercessional period Activities Cont...

| Socio-economic consideration | (i) preliminary experiences using the voluntary Guidance, (ii) examples of methodologies and applications of socio-economic considerations, in the light of the elements of the voluntary Guidance, | AHTEG will take place in the first half of December 2019. |
|------------------------------|---|--|
| Synthetic Biology | a) The relationship between synthetic biology and the criteria set out in decision IX/29, paragraph 12; b) New technological developments in synthetic biology since the last meeting of AHTEG; c) The current state of knowledge on the potential positive and negative environmental impacts, taking into account human health, cultural and socioeconomic impacts, d) Living organisms developed thus far through new developments in synthetic biology that may fall outside the definition of LMOs as per the Cartagena Protocol. | Online forum is currently underway AHTEG: 4 to 7 June 2019 |

intercessional period Activities Cont...

| Digital Piracy | Submit views due 1 June 2019: 1. To clarify the concept, including relevant terminology and scope, of digital sequence information on genetic resources and if and how domestic measures on access and benefit-sharing consider digital sequence information on genetic resources; | AHTEG February/March 2020 |
|----------------|---|---------------------------|
| | 2. On benefit-sharing arrangements from commercial and non-commercial use of digital sequence information on genetic resources. | |





