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In this issue

Agenda item 17

Synthetic Biology: Key Decisions for COP 14

BICSBAG Project (Building International Capacity in Synthetic Biology Assessment and Governance)

Engineered gene drives

In light of the significant potential for adverse effects on biodiversity and the associated high level of uncertainty, both the AHTEG on Synthetic Biology and SBSTTA have articulated the need for a strict precautionary approach to environmental releases of gene drive organisms. For the first time, a genetic engineering technology has been overtly designed to aggressively spread throughout the natural environment, thereby impacting - by design - not only targeted organisms and species, but also entire ecosystems. There is not yet a framework to evaluate the associated risks, much less a way to minimize or eliminate the risks. Governments should insist on further research and assessment before GDOs could be released. Following on calls by hundreds of civil society, indigenous, science and farmer organizations, **COP 14 is the moment for the CBD to agree to a moratorium on the release of engineered gene drives** in line with previous decisions related to untested, high-risk technologies, such as Decision V/5 on GURTs ("terminator" technologies).

Parties should additionally affirm that moving ahead with experimental work on gene drives is not warranted until a **global, transparent regulatory framework** is agreed, including specific rules on **contained use, guidance for risk assessment and risk management** (including ensuring that commercial and military interests are not driving developments) and a clear mechanism to protect the **free, prior and informed consent (FPIC)** of all affected Indigenous Peoples and local communities. Given that agricultural and other environmental applications are envisioned for gene drive technologies, an explicit focus on farmers, peasants, fisherfolk and traditional livestock keepers within local communities is important, as is considering the potential impacts on their traditional knowledge, innovation, practices, livelihood and use of land and water.

Gene Editing

Several new genome editing technologies - including techniques known as CRISPR/Cas9, TALENs and Zinc Finger Nucleases (ZFNs) - are being used to create LMOs; they fall squarely within the operational definition of synthetic biology already agreed by COP 13. **Genome Editing should therefore be explicitly referenced in decisions on synthetic biology at COP 14.**

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What are Gene Drives?

Gene Drives (also known as genetic forcing technologies) are artificial genetic systems inserted into sexually reproducing organisms, which are designed to always (or almost always) pass on a specific, engineered trait to offspring - and all subsequent generations of offspring.

The effect of a functioning gene drive inserted into an organism is that the genetically engineered trait will quickly spread, by design, throughout a population in order to alter the population or cause it to crash. Over time - and in accelerated way - GDOs could theoretically modify or eradicate entire species.

Envisioned applications range from livestock breeding (in order to increase 'genetic gain') to industrial agriculture (to increase herbicide sensitivity or to eliminate weeds or insect 'pests') to biowarfare agent production, and even to targeted disease-vector eradication (for example mosquitoes that carry malaria).

Gene drive technologies are highly speculative; their efficacy is unproven; and evolutionary resistance is expected to develop, especially when the insertion of the gene drive reduces the genetic fitness of the organism.

Horizon Scanning

Given the fast-moving nature of synthetic biology developments, an important outcome of the AHTEG on Synthetic Biology was the proposal for **"regular horizon scanning, monitoring and assessment of new developments in the field of synthetic biology"** — including tracking the adaptation of risk assessment and risk management of synthetic biology organisms — which could inform the work of the SBSTTA and the COP.Detection, Identification, Monitoring, Tracking and Testing

Because organisms, biological components and products created using synthetic biology are now entering the commercial market (and the environment), there is an **urgent need to establish the means to detect, identify, monitor, track and test them.** Existing means of tracking, testing and monitoring LMOs may be of limited use when considering genome-edited organisms and the movement of synthetic biology 'parts' such as 'biobricks.'

Monitoring and testing is especially important for biosynthesized (i.e. synthetic biology-derived) compounds used as food flavourings, sweeteners, cosmetic ingredients or essential oils, which may also disrupt and displace the sustainable production and use of naturally-derived ingredients.

The bottom line on synthetic biology:

To put precautionary governance ahead of this fast-moving and disruptive field, Parties should:

- urgently agree to not release gene drive organisms;
- implement stringent contained-use standards to prevent accidental releases;
- put in place the means to detect, identify, monitor, track and test for the presence of synthetic biology components, organisms and products; and,
- establish the means for rapid horizon scanning of new developments.
- Synthetic Biology could also be formally identified as "a new and emerging issue," reflecting its substantive and recurrent presence in the CBD's programme of work.

Synbio: The story so far at CBD

At CBD, the term Synthetic Biology describes the next generation of genetic engineering tools and techniques enabling interventions beyond 'transgenic' organisms.
The CBD's operational definition of synthetic biology highlights *"a new dimension of modern biotechnology"* that facilitates and accelerates the *"design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems."*
This includes building DNA from scratch (i.e., DNA synthesis), designing and fabricating biological components or 'parts' and altering genetic sequences directly with new technological tools such as CRISPR/Cas9 (i.e., genome editing).
The CBD is the first and only international body addressing governance of the rapidly emerging field of synthetic biology, which has played a role in the Convention's formal discussions over the last eight years.

In earlier decisions, the CBD has emphasized the need for precaution, regulatory systems and risk assessments of socio-economic impacts vis-á-vis the Convention's three objectives. There have been extensive inter-sessional discussions at meetings of SBSTTA as well as two meetings of the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology.
In *CBD Technical Series* no. 82 (2015), the CBD Secretariat, with input from the SBSTTA, explored the potential impacts of synthetic biology on biodiversity as well as the place of synthetic biology in the Convention's programme of work.
Against the wishes of most Parties, a handful of delegates from heavily-invested, biotech-rich countries have sought to block discussions on procedural grounds, insisting that synthetic biology has not been formally deemed a "new and emerging issue," despite that COP 14 will be the fifth consecutive COP to engage in substantive discussions of the topic.

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The CBD Alliance thanks USC Canada for their support for the ECO.

***Submissions** are welcome from all civil society groups.*
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Indigenous and local knowledge and actions are key to addressing the biodiversity crisis

Tom Dixon (Forest Peoples Programme)

From the Arctic North, to the Pacific Island South, to the Tropical Forests of Latin America, *Local Biodiversity Outlooks online* highlights how indigenous peoples and local communities are rising to the challenge to counter the effects of some of the most pressing threats to our planet. The outlooks, provided by indigenous peoples and local communities, outline issues they face including deforestation, and pressures on cultures and languages. They also describe solutions including indigenous-led conservation, and community-based monitoring.

Local Biodiversity Outlooks (LBO) is a key resource for the review of progress in the implementation of the strategic plan for biodiversity 2011-2020, as referenced in agenda Item 8 of the CBD COP14 draft decisions (see box)

> *"For Target 18, increase efforts in the protection of and respect for traditional knowledge and make use of information contained in the Local Biodiversity Outlooks, inter alia, on the customary sustainable use by indigenous peoples and local communities to contribute to updated reporting on progress in the implementation of the Aichi Biodiversity Targets"*

This online 'living' site will serve to build on the key messages from the current edition of the Outlooks, while making the information much more readily available to governments, media, and the indigenous peoples and local communities who contributed. It shows the cross-cutting contributions of the collective actions to all the twenty Aichi Targets.

The case studies are searchable by their connections with each Aichi Biodiversity Target (both primary target, and other relevant targets), Strategic Goal, by map, or by area of interest (for example, 'community-based monitoring' or 'climate change').

LBO online enables more detailed case studies including video and audio materials. It allows new case studies and materials to be uploaded in real time, prior to release of the print publication. This format also allows anyone to download materials, for example for use in educational curricula, or as evidence cases for policy briefings.

Finally, LBO online will set the standard for the second round of the Local Biodiversity Outlooks (LBO-2), complementing the fifth edition of the Global Biodiversity Outlooks (GBO-5), both due for release in 2020, and serve as a linkage to other related global agreements such as the Sustainable Development Goals (SDGs) and the Paris Agreement.

Local Biodiversity Outlook key findings include:

- Collective actions of indigenous peoples and local communities (IPLCs) are advancing the Strategic Plan for Biodiversity and all 20 Aichi Biodiversity Targets.
- IPLCs' lands hold much of the world's biodiversity; supporting their actions can be one of the most effective ways to secure biodiversity conservation and sustainable use.
- Biological and cultural diversity together increase resilience to social, environmental and climate changes.
- Policy commitments on traditional knowledge and customary sustainable use must be translated into programmes and projects in partnerships with IPLCs.
- Recognising customary land tenure and traditional occupations, and protecting human rights secure social well-being, and ecosystem and climate benefits.
- Community-based mapping and monitoring complements wider data and reporting systems and promotes accountability for social, biodiversity, development and climate commitments.

Links:

- www.localbiodiversityoutlooks.net
- "Indigenous and Local Knowledge(s) and Science(s)" ECO 55(5) cbd-alliance.org/en/cbd/eco/2017/eco-55

Risk Assessment / Risk Management of LMOs

BICSBAG Project (Building International Capacity inSynthetic Biology Assessmentand Governance)

Genome Editing

Genome-editing technologies such as CRISPR/Cas9, TALENs and Zinc Finger Nucleases (ZFNs) are rapidly becoming the dominant platform for genetically engineering organisms, yet they appear to give rise to novel, unintended effects such as mutations to off-target DNA. **There is an urgent need to develop guidance on how to assess the biosafety of genome-edited organisms and how to manage, minimise or eliminate risks.**

Gene Drives

Engineered gene drives pose a novel set of ecological risks since, by design, they aim to spread through entire populations and ecosystems. Gene Drive Organisms (GDOs) are poorly understood — especially over subsequent generations — and appear to give rise to a phenomenon of 'gene drive resistance,' particularly in cases where an organism's fitness has been reduced by the insertion of the gene drive. Claims that it is possible to design controllable, 'local' gene drives have yet to be tested — rightly so — but a theoretical control cannot be considered a reliable mitigation strategy in the event of adverse effects. Given the uncertainties, it is not clear whether or how gene drives are subject to risk assessment and risk management measures.

There is an urgent need to explore the possibility of a framework for robust risk assessment of gene drive technologies. In the absence of such a framework and the free, prior and informed consent of Indigenous Peoples and local communities in line with international agreements, the release of gene drives must be prohibited.

AHTEG on Risk Assessment and Risk Management

In 2008, at COP-MOP 4 in Bonn, an Ad Hoc Technical Expert Group on Risk Assessment and Risk Management was formed to develop guidance on LMOs; however, COP-MOP 8 (2016) failed to endorse the AHTEG's guidance document that had been developed, reviewed, revised and improved in the intervening years. It also terminated the AHTEG. **At COP-MOP 9, the AHTEG on Risk Assessment should be re-established in order to move forward work on genome editing, gene drives and living modified fish.**

The current draft decision related to (re)convening the AHTEG on Risk Assessment proposes a protracted process involving back-and-forth reporting between multiple CBD bodies and Parties before actual work on risk assessment guidance documents can get underway. Recognizing the urgent need to develop precautionary and robust risk assessment and risk management guidelines for LMOs, **Parties should streamline the work toward producing such risk assessments rather than wasting further resources on labyrinthine processes.**

Finally, the **AHTEG on Socio-Economic Considerations should be mandated to continue its work** as outlined in the Executive Secretary's Note on Socio-Economic Considerations in preparation for COP-MOP 9, including work on cross cutting issues that relate to synthetic biology.

BICSBAG includes members of Third World Network, ETC Group and ACBio.

More information: www.synbiogovernance.org

Biosafety of LMOs

The Cartagena Protocol on Biosafety recognises the necessity of both biosafety assessments and the means to regulate, manage and control identified risks arising from LMOs, in advance of transboundary exchange or their release to the environment.

To this end - and after an eight-year process by experts appointed by Parties to the Protocol - an initial set of Risk Assessment and Risk Management guidance documents for LMOs was developed but subsequently sidelined by the actions of a small group of biotech-rich countries at COP-MOP 8 in Cancun.

In an effort to put the process of developing guidance back on track, Parties at SBSTTA 22 proposed moving forward with work that could lead to new guidance documents related to organisms containing engineered gene drives and living modified fish, and, possibly, guidance documents on genome-edited organisms.