

# Synthetic Biology, Genome Editing and Gene Drives

## Briefing for Delegates to the Convention on Biological Diversity

### COP 14 and Cartagena Protocol on Biosafety COP-MOP 9

Sharm el-Sheikh, Egypt, 17 - 29 November 2018

Over the past 25 years, the UN Convention on Biological Diversity (CBD) has established a system of global oversight for living (a.k.a. genetically) modified organisms (LMOs) based on the **principles of precaution, fairness (equitable sharing of benefits) and prior informed consent.**

COP 14 and COP-MOP 9 will be key to upholding those principles and ensuring they are extended to the governance of next-generation genetic engineering technologies: i.e., synthetic biology, which increasingly encompasses genome editing and gene drive technologies.

**Negotiations in Sharm el-Sheikh will explicitly address three broad and interconnected topics relevant for the oversight of these new and emerging genetic engineering technologies:**

- **Synthetic Biology** – The explicit focus of the CBD COP’s Agenda Item 27 is synthetic biology. Parties aim to agree a series of decisions arising from recommendations (22/2 and 22/3) of the CBD’s Subsidiary Scientific Body (SBSTTA), which met in July 2018. The COP’s decisions should: include precautionary measures to govern engineered gene drives, including stringent standards for their contained use and to prevent their environmental release; protect the free, prior and informed consent of Indigenous Peoples and local communities; prioritize methods to detect, identify, monitor and track new synthetic biology components, organisms and products; and establish capacity for horizon scanning of new technological developments.
- **Biosafety of LMOs** – The Cartagena Protocol’s Agenda Item 15 also stems from SBSTTA’s recommendation (22/2). It asks Parties to agree a path for developing timely risk assessment and risk management guidance for organisms arising from genetic engineering – including an explicit focus on living modified fish and LMOs containing engineered gene drives. This work should also be extended to include genome-edited organisms.
- **Digital Sequence Information** – The CBD COP’s Agenda Item 18 (arising from SBSTTA recommendation 22/1) asks Parties to agree on a process, which may include the establishment of a working group, that aims to ensure that the transfer of digital (genetic) sequence information does not “facilitate misappropriation” (i.e., permit biopiracy), undermine the sovereign right to control access to biodiversity or compromise the fair and equitable sharing of benefits arising from the use of biodiversity.



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*This briefing introduces the terms and technologies under discussion and the key decisions facing Parties to the CBD and Cartagena Protocol.*

## Synthetic Biology (Agenda Item 27):

### 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-à-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.

## Synthetic Biology: Key Decisions for COP 14

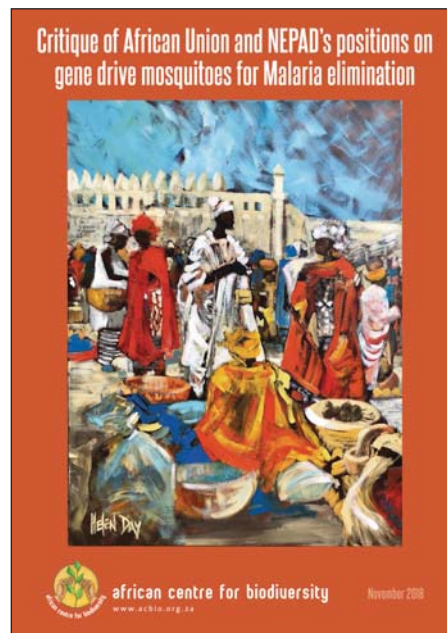
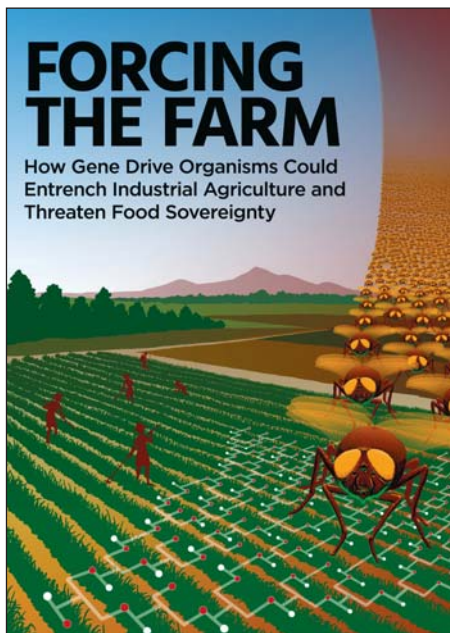
### Engineered Gene Drives

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 (GDOs, see box below). 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 GURT’s (“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.

### 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 (e.g., mosquitos 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.



*Two recent 2018 reports on the dangers of Gene Drive organisms.  
Download PDFs for free from: [www.etcgroup.org](http://www.etcgroup.org) and [www.acbio.org.za](http://www.acbio.org.za)*

## 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.**

## 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.

## Risk Assessment / Risk Management of LMOs – Parties to the Cartagena Protocol on Biosafety (COP-MOP 9), Agenda Item 15: The Story so Far 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.



## Risk Assessment and Risk Management: Key Decisions for COP 14 /COP-MOP 9

### 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.**

## Ad Hoc Technical Expert Group on Risk Assessment and Risk Management (AHTEG on RA/RM)

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.

## For Further Information

Information documents on Synthetic Biology, Gene Drives and Digital Sequence Information — as well as regional overviews for Africa, Asia-Pacific and Latin America and the Caribbean — are available in three languages from the **BICSBAG Project (Building International Capacity in Synthetic Biology Assessment and Governance)** at:

[www.synbiogovernance.org](http://www.synbiogovernance.org)



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