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Four Steps Forward, One Leap Back on Global Governance of Synthetic Biology

UN Biodiversity Convention grapples with threats posed by extreme biotech industry

CANCUN, MEXICO — This week, 196 countries meeting at the 2016 UN Convention on Biodiversity (CBD) Conference of the Parties made progress on the global governance and oversight of synthetic biology. Synthetic biology (syn bio) has become one of the most fiercely debated topics at the Biodiversity Convention, almost 7 years after civil society first brought the need for precaution and regulation of the new set of biotechnologies to this UN body.

During the 13th Conference of the Parties (COP 13) to the CBD, countries agreed to investigate how digital genetic sequences may be used to commit biopiracy and warned against a risky new genetic extinction technology called gene drives. They also agreed on a working definition of synthetic biology (2) and to support an ongoing expert group to move forward international discussions on the topic. However, this progress was undermined by a significant 'move backwards' in safety oversight and risk assessment when a key standing expert group expected to issue risk assessment guidelines for synthetic biology was dissolved.

"Syn bio was among the hottest topics on the negotiating table," explains **Jim Thomas** of ETC Group, who sits on the CBD's expert group on Synthetic Biology. "Governments now get it: they need to urgently grapple with how synthetic biology and other fast moving, risky technologies are threatening biodiversity, local economies and the rights of farmers and Indigenous Peoples."

Parties took a big step forward in addressing the controversial issue of **digital biopiracy**, a fast-emerging loophole in the Biodiversity Convention through which companies and others can access gene sequences of plants and seeds on the internet and then use them, including by recreating physical DNA via synthetic biology techniques, without the agreement of (or any benefit to) biodiverse countries or communities from whom the genes originated. While some rich countries with large biotech industries (e.g. Canada) tried to take the topic of digital biopiracy off the table, eventually all agreed the topic needed further examination at future meetings.

"We are pleased that there is a specific and agreed plan to address piracy of gene sequences over the next two years," said **Edward Hammond** of Third World Network who is another member of the CBD expert group on syn bio. "Wealthy countries can no longer plead that they are unprepared to discuss this loophole. Fast-moving technology demands an equally fast decision, and there can be no more pretending that understandings of genetic resources based on the biotechnology of the 1990s suffice to regulate the field today."

Civil society at the CBD also urged governments to apply strong precaution on **gene drives**, a new gene-editing technology that enables species-wide genetic engineering by aggressively spreading genetic changes through the wild. The issue was brought to the negotiating table

after more than 170 civil society organizations called on governments at the Biodiversity Convention to place [a moratorium](#) on the development and release of gene drives because of their potential for unpredictable, and possibly uncontrollable, impacts on biodiversity, wildlife and ecosystems.

Many governments were very alarmed about this new technology. Countries agreed to approach gene drives with precaution and to establish risk assessment and regulation (4), even though Australia, Canada, New Zealand and Brazil, countries with close ties to the biotech industry, bluntly opposed even mentioning the issue. A global meeting of governments and civil society at IUCN (International Union for Conservation of Nature) in September 2016 had already adopted highly precautionary language on gene drives.

“The explicit mention of gene drives in the decision is an alert to all governments that they need to pay close attention to this new high-risk technology that is intentionally designed to aggressively spread into wild species and the environment, with potential serious transboundary effects,” added **Silvia Ribeiro** from ETC Group.

“Gene drives are a false solution to the real problem of biodiversity loss,” said **Dana Perls**, with Friends of the Earth International. “We should not release dangerous gene drives into our environment without robust systems to evaluate the risks and without an international governance mechanism in place. We want to see real, sustainable, community-based conservation efforts, not a live testing-zone that could allow new destructive agricultural practices or cause permanent damage to ecosystems.”

Unfortunately, the positive decisions addressing definitions, future work, digital sequences and gene drives were accompanied by a slide backwards following a decision on risk assessment of genetically modified organisms under the CBD’s Cartagena Protocol on Biosafety.

“Given the rapid advances in technological developments, it is crucial to understand the risks that each of these holds for the environment or human health,” said **Dr. Ricarda Steinbrecher**, representing the Federation of German Scientists. “Guidance on risk assessment is very much needed, yet parties failed their duty. They not only blocked the development of new risk assessment guidance for synthetic biology, gene drives or genetically modified fish, but they also closed down the expert group that could have developed such guidance in the future.”

The next Conference of the Parties will convene in 2018 in Egypt, and the expert group on synthetic biology will meet again before that.

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More information on synthetic biology and gene drives at:

<http://www.synbiowatch.org/>

<http://www.foei.org/news/greater-regulation-needed-synthetic-biology-cop-13>

<http://www.etcgroup.org/>

Notes to editors:

1. The full text of the decisions on Synthetic Biology and Digital Sequence Information on Genetic resources from CBD COP 13 are available at <https://www.cbd.int/conferences/2016/cop-13/documents>. The relevant decisions are:

UNEP/CBD/COP/13/L34

UNEP/CBD/COP/13/L29

UNEP/CBD/NP/COP-MOP/2/L11 (available at <https://www.cbd.int/conferences/2016/np-mop-2/documents>)

2. Synthetic biology is an emerging biotechnology industry expected to reach almost \$40 billion by 2020. The definition of Synthetic Biology now agreed under the Biodiversity Convention is: **“Synthetic biology is a further development and new dimension of modern 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.”**
3. Civil society has been calling on countries to assess synthetic biology in light of possible impacts on people, communities and the environment for over a decade and first raised the topic of synthetic biology at the CBD in 2010. The topic was taken up as a new and emerging issue under the CBD following submissions of information by the International Civil Society Working Group on Synthetic Biology – a network of international organizations that currently includes Friends of the Earth, ETC Group, Third World Network, Heinrich Boell Foundation, Ecoropa, Econexus and the Federation of German Scientists.

4. **The text of the decision on gene drives:**

2. *Reiterates* paragraph 3 of decision XII/24 and *notes* that it can also apply to some living modified organisms containing gene drives;

Paragraph 3 of decision XII/24:

3. *Urges* Parties and *invites* other Governments to take a precautionary approach, in accordance with paragraph 4 of decision XI/11 and:

(a) To establish, or have in place, **effective risk assessment and management procedures and/or regulatory systems to regulate environmental release of any organisms, components or products resulting from synthetic biology techniques**, consistent with Article 3 of the Convention;

(b) To approve organisms resulting from synthetic biology techniques for field trials **only after appropriate risk assessments have been carried out** in accordance with national, regional and/or international frameworks, as appropriate;

(c) **To carry out scientific assessments concerning organisms, components and products resulting from synthetic biology techniques with regard to potential effects on the conservation and sustainable use of biodiversity, taking into account risks to human health** and addressing, as appropriate, and according to national and/or regional legislation, **other issues such as food security and socioeconomic considerations with, where appropriate, the full participation of indigenous and local communities**;

(d) To encourage the provision of funding for **research into synthetic biology risk assessment methodologies** and into the positive and negative impacts of synthetic biology on the conservation and sustainable use of biodiversity, and to promote interdisciplinary research that includes related socioeconomic considerations;

(e) To cooperate in the development and/or strengthening of human resources and institutional capacities, including on methodologies for risk assessments in synthetic biology and its potential impacts on biodiversity, in developing countries, in particular the least developed countries and small island developing States, and countries with economies in transition, including through existing global, regional and national institutions and organizations and, as appropriate, by facilitating civil society involvement. The needs of developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, for financial resources; access to and transfer of technology consistent with Article 16 of the Convention; establishing or strengthening regulatory frameworks; and the management of risks related to the release of organisms, components and products resulting from synthetic biology techniques, should be taken fully into account in this regard;