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Biosafety in Danger - How industry, researchers and negotiators collaborate to undermine the UN Biodiversity Convention

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A new batch of emails released by the Dutch authorities following a freedom of information request reveals how industry, researchers and a small group of negotiators are collaborating to undercut UN biosafety talks of the CBD and Cartagena Protocol. Through dedicated email lists, the sharing of political intelligence, the mobilization of groups of students as well as attempts to influence the outcome of online consultations, the Public Research and Regulation Initiative (PRRI) coordinated efforts aimed at skewing decisions on the Guidance on risk assessment, Synthetic Biology and gene drives.

Implicated in these activities is also a Dutch negotiator who chaired talks on the EU endorsement of the UN Guidance for risk assessment and discussed these closed-door talks within the network. Just before COP13 in Cancún, PRRI encouraged the network to actively share negotiation positions from other countries with her.

A meeting was convened of this network in February 2016 at the headquarters of the International Life Sciences Institute in Washington DC, financed with a grant from the USDA, aimed at discussing the UN Guidance. The Dutch official attended this meeting as well as a representative from the European Food Safety Authority (EFSA) even though this agency once decided to ban too close ties between their experts and ILSI.

At COP13-MOP8 in Cancún in 2016, under pressure of some of the delegations active within PRRI circles, the AHTEG on risk assessment was dissolved and therefore new topics like syn-bio or gene editing could not be addressed. Also, the tone of debate had become more aggressive, and several side events had been disturbed.

Focus was also placed on influencing the outcome of CBD online consultations. This was brought to another level in 2017 when the lobby firm Emerging Ag was paid 1.6 million dollars by the Gates Foundation to skew a consultation on Synthetic Biology, as shown by the *Gene Drive Files*. Gene editing techniques are also at the center of attention in the EU, as the European Court of Justice is expected to issue a ruling on the legal status of these techniques on 25 July.

Following the Gene Drive Files, civil society organizations called on Executive Secretary Dr. Cristiana Paşca Palmer to take urgent measures to address conflicts of interest in the CBD, its subsidiary bodies and processes. The CBD Secretariat has taken an important and welcome step by proposing procedures to avoid and manage conflicts of interest.

Officials whose job is to regulate certain products in order to protect the environment and food safety should not be closely collaborating with companies that have a commercial stake in such products. With the rapid pace of development of new genetic engineering techniques including syn-bio and gene drives, it is of crucial importance to have international agreements in place to help avoid any potential damage to biodiversity or risk for food safety.

You can find the full text at: https://corporateeurope.org/food-and-agriculture/2018/06/biosafety-danger

Sequence Information: A Key Topic for the Biodiversity Convention

Third World Network (TWN)

Sequence information will be on the agenda at the 14th Conference of the Parties (COP) to the Convention on Biological Diversity (CBD) in November 2018 in Egypt, and it is a topic that governments cannot afford to ignore. New applications of sequence information are transforming how genetic resources are used, and have major long-term implications for the CBD, particularly for the objective of fair and equitable benefit sharing.

"Free" sequence information of a wide variety of biodiversity is increasingly becoming available, and is reducing the need for physical access to plants, microbes, animals and other living things in a growing number of research and commercial applications. As the drivers of this phenomenon- which include cheap digital sequencing - gene editing, and other biotechnological and synthetic biology approaches, continue to develop, the trend will accelerate. More and more sequences will be generated "in the field" and shared electronically, potentially without proper prior informed consent (PIC) and mutually agreed terms (MAT).

These rapidly advancing technologies are upending traditional approaches to access and benefit-sharing under the CBD and extend across the realm of biodiversity from the smallest organisms, such as viral pathogens, to the large and complex genomes of many crops. A situation is quickly arising in which biopiracy is allowed to occur because legal frameworks have not caught up with technical realities. Sharing of sequence information is now central to many aspects of research, but so long as that information is generated and shared without applying benefit-sharing obligations, the developing countries´ governments, farmers, and indigenous peoples which created and nurtured that diversity will lose out. National genetic resources and Indigenous Peoples' plants will be privately "mined" for profitable sequences with little or no recompense.

This impending change promises to be so stark that failing to address sequence information could undermine the entire Convention by upsetting application of its third objective, the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, and the substantial efforts put forth by the CBD to date to implement it, not least the Nagoya Protocol on Access and Benefit Sharing.

Governments should recognize that it is unrealistic to expect results from the CBD's discussion on digital sequence information (DSI) if they do not make it a high priority in their preparation for the COP. That is because the status quo is highly beneficial to the interests of user countries and the biotechnology industry, and the North will not move on its own to effectively address this threat to the CBD, as it would rather continue to benefit from free access to genetic resources in the form of a massive and growing cloud of DSI.

To stop the unfolding free-for-all on sequence information, Parties to the CBD must make the Convention current by finding a way to apply benefit sharing rules to access and use of sequences. Otherwise, as ex-situ collections move to sequence their collections, researchers deploy small (even hand-held) sequencers, and online databases continue to mass-publish sequences without regard for benefit sharing and without placing any restrictions on patent claims, Parties will find that the access and benefit sharing (ABS) foundation on which the CBD was built has been washed away by a sea of big data.

You can read the full briefing at: www.synbiogovernance.org

Synthetic Biology and AI-enabled Biosynthesis – The Implications for Biodiversity and Farmer Livelihoods

African Center for Biodiversity (ACB)

It is now almost a decade since the Convention on Biological Diversity first began tracking developments in synthetic biology (syn-bio). At the time, prominent synthetic biologists boasted that any compound that was produced by a plant could now be synthesized in a vat of engineered microbes. While that was theoretically true a decade ago, it is now becoming truer: the field of synthetic biosynthesis has become more significant because of capabilities in artificial intelligence and automation are rapidly converging. These developments have serious implications for the conservation and sustainable use of biodiversity.

In the face of ever-increasing numbers of syn-bio derived organisms and compounds, there is now an urgent need for governments to better get a handle on an emerging 'biosynthesis' industry and to address the disruption that may be felt by millions of traditional farm producers and pickers and the biodiversity that they steward.

Key Points:

> Socio Economic harms must be addressed:

Addressing the potential social, economic and indirect harms to biodiversity from replacement of natural products by biosynthesis should be a high priority for the CBD. In its recent report, the AHTEG highlighted "the importance of addressing the potential socio-economic impacts of the commercialization of products of synthetic biology that replaced naturally occurring products" [para 57] as well as "the need to take into account the socio-economic impacts, perspectives, rights and lands of indigenous peoples and local communities when considering the possible release of organisms developed through synthetic biology into the lands and territories of indigenous peoples and local communities" [para 53].

> Safety, traceability, recall, liability:

Public and private entities are accelerating the pace of organism design and proposing to release syn-bio synthesized ingredients into the market. They must ensure means to test their products for safety, to ensure traceability for integrity in the marketplace and the ability to recall their products and remediate if necessary. Products of synthetic biology differ from those produced through chemical synthesis and should be labelled, regulated and carefully tested. As a way forward, the AHTEG offers that those commercializing "products and organisms resulting from synthetic biology...could be made responsible for providing validated tools, relevant sequence data and reference materials, in an accessible manner, that would facilitate the detection, identification and monitoring of such organisms and products" [para 38].

> No false natural claims:

Biosynthesized products also should not be obscured by misleading marketing claims: While the technologies involved may "hijack" natural processes for production, the products of synthetic biology are not naturally produced. Claims of "natural" are not justified and they are misleading to government regulators as well as consumers. The CBD SBSTTA should explicitly reject the "natural" label for the biosynthesized products of synthetic biology.

You can read the full briefing at: www.synbiogovernance.org

Synthetic Gene Drives – Genetic Engineering Gone Wild

ETC Group

Gene Drives are a technique to engineer the genetics of entire populations. A gene drive is a genetic sequence that is meant to advantageously force itself (via sexual reproduction) through a population of organisms, passing on a particular trait to all or most offspring until the trait takes over.

There are now rapidly-advancing proposals to use synthetic gene drive organisms (GDO's) to alter wild and domestic populations of insects, mammals, nematodes, fish and other species, which may impact ecosystems and biodiversity as well as agriculture, human security and conservation practice. Proponents of gene drives, bankrolled largely by the US military and wealthy tech billionaires, have spent millions of dollars in trying to hype one or two theoretical 'best case' scenarios for gene drives (such as anti malarial mosquitos)
while obscuring the military and agribusiness interests that will benefit most from the technology.

Governance gaps: The case for a moratorium

International Civil Society organizations are recommending that the UN Convention on Biological Diversity place an immediate moratorium on the release of genetically engineered gene drives (including field trials) and slow down the rush to develop applications.They argue that some serious governance gaps must be addressed:

Inability to regulate the transboundary movement: Unlike previous GMO's a GDO is designed to spread in the wild. There is no internationally agreed process for the effective governance of transboundary effects arising from the release of a gene drive. Since gene drives are likely to eventually spread across political boundaries, this is a very significant governance gap. If a gene drive was proposed for release in one country, it follows that all potentially affected countries would need to be taken into a process of advance joint consideration under new procedures that do not yet exist.

Containment: Gene drives are designed to persist and spread. While gene drive developers claim there may in the future be technical and geographical means to effectively contain gene drive organisms (so called 'local drives'), these hypothetical techniques do not yet exist and claims and assumptions need to be rigorously examined and tested. Strict laboratory handling and containment rules for all gene drive research should be internationally agreed upon and put into practice before further research can proceed even in the lab.

Monitoring, assessment and liability: Critical to any release proposal would be the development of internationally accepted procedures for not only monitoring and assessing impacts, but also tracking the spread of gene-drive constructs in the wild. This would involve developing practical means to detect gene drive constructs in wild populations, obtaining agreement on the scope of effects that should be monitored and importantly, the methodologies to be used. Until it is agreed how to do this it is irresponsible to allow release of GDO's.

Free, Prior and Informed consent: Besides the provisions of the Cartagena Protocol that require that parties should obtain prior informed consent before transboundary movement of a living modified organism which is released into the wild, there are additional duties placed upon states that could impact the invasion of gene drive organisms into the land and territories of Indigenous Peoples and local communities or onto land that is designated organic, GM-free, agro-ecological or traditional production.

You can read the full briefing at: www.synbiogovernance.org