Third World Network

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Braulio Ferreira de Souza Dias
Executive Secretary
Convention on Biological Diversity

30 January 2016

Re: Peer review of the outcomes of the process in response to decision XII/24 on synthetic biology (Ref: SCBD/BS/CG/MPM/DA/85140)

Dear Sir,

Thank you for the opportunity to peer review the following documents:

(a) Updated report and synthesis of views in response to paragraph 7(b) of decision XII/24 (UNEP/CBD/SYNBIO/AHTEG/2015/2); and
(b) Report of the meeting of the Ad Hoc Technical Expert Group on Synthetic Biology (UNEP/CBD/SYNBIO/AHTEG/2015/3).

We are pleased to participate in this process and attach herewith Third World Network's submission.

Please note that our comments refer to both documents (hereinafter referred to as the synthesis report and AHTEG report), given the considerable overlap in their substantive content. Where necessary, we have provided reference to particular paragraphs and text.

Thank you for your kind consideration.

Yours sincerely

Chee Yoke Ling
Director of Programmes

Please note new email address for TWN: twn@twnetwork.org

Peer review of the outcomes of the process in response to decision XII/24 on synthetic biology: Submission by Third World Network (TWN)

1. A **precautionary approach** needs to be adopted and put into operation in relation to synthetic biology, as highlighted in paragraphs 18 and 57(c) of the synthesis report and paragraph 29 of the AHTEG report.

The precautionary approach is in conformity with the Convention on Biological Diversity and its Protocols (Cartagena Protocol on Biosafety, Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization and Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress). Numerous decisions of the Conference of Parties to the CBD in relation to synthetic biology have also been adopted that call for a precautionary approach, the latest being Decision XII/24.

2. There is also a need for a **multi-pronged yet coordinated approach** between the Convention and its Protocols, as highlighted in paragraphs 57(e) of the synthesis report and 66(d) of the AHTEG report.

In this respect, living organisms, components and products of synthetic biology fall within the scope of the CBD and its three objectives, synthetically modified organisms that are also living modified organisms are clearly regulated by the Cartagena Protocol, while the Nagoya Protocol and its provisions on access and benefit sharing are relevant to the issues of gene synthesis, gene editing and synthetic biopiracy.

For example, the obligations for impact assessment and risk assessment under the CBD (Article 14) and Cartagena Protocol (Article 15) respectively, are extremely relevant to the assessment of the organisms, components and products of synthetic biology and their impacts on biological diversity and human health. At the same time, socio-economic considerations are under the purview of the CBD, Cartagena Protocol and Nagoya Protocol, with different levels of attention and focus areas.

However, while the issue of synthetic biology is relevant to several areas of the Convention and its Protocol, it must be ensured that how synthetic biology is addressed is not just divided into constituent pieces at the expense of an oversight of the whole. The CBD therefore needs to maintain an **oversight body** that is able to conduct stock-taking and adopt cross-cutting decisions. In this respect, the monitoring and assessment process recommended in paragraph 66(c) of the AHTEG report is welcomed.

In addition, some synthetic biology applications present grave implications for biological diversity that demand rapid high-level attention, for example **gene-drive systems** (also identified specifically in paragraph 38 of the synthesis report as deserving close attention), for which we recommend a specific CBD decision.

At the same time, because the Cartagena Protocol and its Supplementary Protocol on Liability and Redress are largely (but not exclusively) restricted to living modified organisms, there could be potential gaps with regard to components and products of

synthetic biology, as highlighted by the AHTEG report in paragraph 66 (j). **Special attention therefore needs to be paid to the issue of the non-living components and products**, in light of their potential risks to the conservation and sustainable use of biological diversity, taking also into account risks to human health. This need is heightened by the possibility that **it may not be clear if some synthetic biology constructs should be considered living or not**, a situation the Convention's approach should take into account.

Therefore we agree that there is a need to develop an **international framework** to cover the organisms, components or products of synthetic biology techniques, which also provides for an assessment of the cultural and socioeconomic impacts, primarily the impacts on small-scale farmers, and also on biodiversity, and in particular wild relatives, as highlighted in paragraph 57(h) of the synthesis report. The issue of **socio-economic considerations** also deserves special attention.

3. Paragraph 66(k) of the AHTEG report urges the Convention to promote the full engagement of indigenous peoples and local communities in future activities relating to synthetic biology.

It is regrettable that the AHTEG membership did not reflect this. Specific mechanisms and processes need to be put into place, including through the Working Group on Article 8(j), to ensure the **meaningful participation of indigenous and local communities** in the discussions on synthetic biology.

4. The risk assessment of the organisms, components and products of synthetic biology raises specific challenges, given the added complexity and uncertainties related to synthetic biology.

In particular, we agree that while there is a basis to begin to approach these challenges in experiences garnered in the risk assessment of LMOs, there is a need to **adapt and/or expand existing frameworks** for risk assessment of LMOs and to develop **specific regulations and risk assessment guidelines** to address the additional complexity and risks posed by synthetic biology organisms, including for when no parent organisms can be used as comparators. In this respect, we welcome the current work of the AHTEG on Risk Assessment that will develop further guidance on risk assessment of LMOs developed through techniques of synthetic biology, as a starting point.

These needs are recognized in paragraphs 44, 53-56 and 57(g) of the synthesis report, as well as paragraphs 59 of the AHTEG report.

In addition, because current detection techniques might be insufficient when applied to the organisms, components and products of synthetic biology, specific arrangements need to be made to address issues related to their **detection, identification and traceability**. This is necessary to enable subsequent functions such as meaningful labeling, monitoring, risk assessment, risk management, and liability and redress.

5. In relation to the fair and equitable sharing of benefits arising from the utilization of genetic resources, within the context of the objectives of the CBD, and the Nagoya

Protocol, the issue of **misappropriation in the form of *synthetic biopiracy*[1]** should be clearly acknowledged.

Therefore in paragraph 31 of the AHTEG report, it should be clearly stated that synthetic biology enables misappropriation in new ways. Similarly, in paragraph 62 of the AHTEG report, it is the detrimental effects of synthetic biology on the fair and equitable sharing of the benefits that must be assessed.

In should be noted that the notion of an assessment of "added value" of synthetic biology, as spelt out in paragraphs 62 and 63 of the AHTEG report, is something that we disagree with. In the context of Article 14 of the CBD and Article 15 of the Cartagena Protocol, impact and risk assessments are with regard to **adverse effects and risks**, not added value.

6. With respect to an operational definition of synthetic biology, we proposed, and continue to believe, that a material-based definition of synthetic biology is of most use, specifically, one stating that synthetic biology encompasses all organisms, products, and processes that involve use of **synthesized nucleic acids** (including DNA and RNA in all forms, as well as modified or novel nucleic acids), and the products and progeny created therefrom.

Nonetheless, with the AHTEG-proposed operational definition (paragraph 24 of the AHTEG report), it is important to clarify that this definition **encompasses important emerging technologies** with implications for biodiversity, human health and society, such as CRISPR, gene-drive systems and other gene/genome-editing techniques including TALEN, ZFN and ODM.

7. While the greater uncertainties associated with synthetic biology are important to acknowledge, we are not convinced that "depth of intervention" as articulated in paragraphs 29 and 45 of the AHTEG report is useful to consider a distinctive quality of synthetic biology. The number of genetic changes to an organism is not necessarily indicative of the technique used to create it, nor of the potential biodiversity impacts of the construct and its product(s).

For example, expression of synthesized pathogenicity-related genes in a new nucleic acid background may pose severe biodiversity risks yet not involve significant "depth of intervention" because genes are expressed in a new context rather being altered. Similarly, efforts such as use of synthetic biology to revive extinct species pose potentially profound biological diversity, health and/or societal effects, but the "depth of intervention" of such efforts is not clear, since the goal is to replicate what existed before, rather than novel alterations.

8. While the attention to contained use in paragraph 38(g) of the synthesis report is welcome, this is somewhat negated by paragraph 55(a) which calls for focus on organisms that are being developed for intentional introduction into the environment.

[1] That is, transfer and use of genetic sequence data (GSD), and synthesis and use of nucleic acids therefrom in the absence of access and benefit sharing procedures required by the Convention, the Nagoya Protocol, and national implementing legislation.

With the novel capabilities of synthetic biology, and their potentially increased impacts on biodiversity, a **new assessment of risks stemming from contained use** is merited. Experiments such as synthetic biology gain of function studies with animal pathogens have potentially great impacts on biological diversity and human health, and a series of recent incidents at high containment laboratories, including repeated accidental releases by labs regarded as being highly professional and secure,[2] draw attention to the inevitability of containment failure.

Other applications described as contained use, for example, large-scale biofuels production, can involve cultures of tens of thousands of liters of organisms and carry greater risks than envisaged in the documents. Therefore, synthetic biology applications in contained use present novel risks upon unintentional release and this also needs to be properly assessed and regulated by the Convention and its Protocols, as appropriate.

[2] These recently include accidental distribution of potentially pandemic influenza viruses by the US Centers for Disease Control, the discovery of improperly stored and forgotten samples of viable smallpox virus at the US National Institutes of Health, and numerous incidents of accidental distribution of viable anthrax bacteria by the US Army's Dugway Proving Ground.