**Peer review of the outcomes of the process in response to decision XII/24 on synthetic biology**

To Braulio Ferreira de Souza Dias

Executive Secretary

Secretariat of the Convention on Biological Diversity

ETC Group welcomes the opportunity to provide Peer Review comments to the following reports prepared by the Secretariat and the AHTEG on Synthetic Biology:

(a)           Updated report and synthesis of views in response to paragraph 7(b) of decision XII/24; and

(b)           Report of the meeting of the Ad Hoc Technical Expert Group on Synthetic Biology.

ETC Group participated extensively in the online forum and Jim Thomas was a participant in the AHTEG on Synthetic Biology. We appreciate the high level of work and care put into these two documents by the Secretariat and by all participants in the process and believe these documents are a useful basis for decisions to be made at the upcoming SBSTTA 20 meeting.

For this submission we have confined our comments to the report of the Ad Hoc Technical Expert Group on Synthetic Biology.

Your Sincerely,

Jim Thomas

Programme Director

On behalf of ETC Group – Action Group on Erosion, Technology and Concentration

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**Comments on the Report of the meeting of the Ad Hoc Technical Expert Group on Synthetic Biology.**

**Overall comments:**

This is useful report providing a fair summary of the discussions. ETC Group commend the secretariat on managing a process with such a large and diverse number of AHTEG members over short timescales. We would like to draw attention to the point 68 on page 12 where the AHTEG noted with regret the absence of indigenous peoples and local communities at this meeting. Since the mandate for the AHTEG as agreed under decisions XII/24 explicitly requested that the AHTEG “include representation of indigenous and local communities” this is indeed regretful and the parties may wish to consider a further and separately structured process of engagement with indigenous and local communities. (eg. through the Working group on 8j) as proposed at point 66(k).

**On the operational definition of synthetic biology comprising inclusion and exclusion criteria:**

ETC Group believes that the operational definition provided at paragraph 24 is a useful definition. We particularly draw attention to the ways in which this definition expands upon and improves the European Union definition by also including the notion of ‘redesign’ of genetic materials and living organisms. Redesign is a common and consistent feature of Synthetic biology definitions and practice and this notion of ‘redesign’ adequately encompasses the gene-editing approaches used within synthetic biology as well as ‘refactoring’ of genomes, creation of minimal genomes and redesign and optimization of metabolic pathways within an organism. It is also important that the definition expresses continuity within the field of ‘modern biotechnology’ which is already well defined in legal terms within the convention and for example through CODEX Alimentarius.

It was our recollection from the discussion in the AHTEG that the CBD Secretariat had agreed to append an illustrative list of approaches , techniques and hallmarks by way of examples of what may be covered by this definition – eg as an annexe. The proposal had been to list the approaches and techniques already referenced in the already peer-reviewed CBD Technical Series 82 sections C2 and C3. We feel this would still be useful as guidance to parties.

Drawing on Technical Series 82, such a list would include:

DNA based genetic circuits, Synthetic Metabolic Pathway Engineering, Synthetic Genomics, Genome-level Engineering, Refactoring of Genomes, Minimal Genomes, Standard Modular DNA ‘parts’, Protocell Construction, Xenobiology, Expanded Genetic Alphabets, DNA Synthesis and Assembly, Gibson Assembly, Directed Evolution, Oligonucleotide Directed Mutagenesis, Genome Shuffling, Multiplex Automated Genome Engineering, Genome Editing, Zinc Finger Nucleases(ZFN), Transcription-Activator-like Effector Nucleases (TALEN), Clustered Regularly Interspersed Short Palindomic Repeats (CRISPR), Epigenetic Modifications, RNA-Directed DNA Methylation (RDDM).

This is not an exhaustive or exclusive list and should be only for illustrative purposes.

**On 3.2 - Relationship between Synthetic Biology and Biological Diversity**

ETC Group very much welcomes the approach taken throughout the AHTEG of keeping in mind all three objectives of the convention and agrees with the opinion expressed by the AHTEG at para 28 that the use of both living organisms and non-living products and components can affect the achievement of the 3 objectives. Also very important is the recognition that indirect effects of the use of organisms ,products and components will need to be taken into account in order to ensure sustainable use of biodiversity is maintained (para 30) We also welcome the reference to the importance of the precautionary approach (in para 29) that has already been so well established in decisions on Synthetic Biology under the CBD.

 In our view these 4 observations should help guide parties in their deliberations at SBSTTA 20 and in future deliberations on this topic within the CBD ( The four observations are: 1- consideration of all three objectives, 2- relevance of both living and non-living, 3- consideration of Indirect as well as direct effects and 4 – the importance of the precautionary approach)

ETC Group feels there is a discrepancy between the call in paragraph 27 for evidence-based information and peer-reviewed data to undergird decision-making and the presently unsupportable assumptions expressed at paragraph 29 that Synthetic Biology research and development may lead to more predictability in the characteristsics of the organisms, thereby facilitating risk assessment processes and reducing uncertainty. No data was provided at the AHTEG or through the online forum to support this assumption which seems very speculative. We have not seen evidence that the the ‘predictability’ claims of synthetic biology in regards to engineering the functioning of organisms and genetic systems has resulted in more reliable control of risks and unexpected outcomes. A similar claim is made at paragraph 45 but is more properly balanced.

**On 3.3 - Similarities between living modified organisms as defined in the Cartagena Protocol and organisms, components and Products of Synthetic Biology Techniques**

In ETC Group’s view paragraph 34 could be stated more baldly: It is our memory that the AHTEG group felt not only that living organisms developed through synthetic Biology currently and in the near term are merely ‘similar to’ LMO’s but that in fact they ought to be considered as LMO’s.

**On 3.4 Adequacy of other existing national , regional or international instruments to regulate the organisms, components or products derived from synthetic Biology techniques.**

It is our view that the insight of the AHTEG under paragraph 38 is correct and extremely important to parties when deliberating at SBSTTA 20 and so should be considered a key message. This Paragraph addresses a key gap in oversight that needs to be addressed by the parties and the conclusion of this paragraph should be highlighted:

The observation that “living organisms, components and products of Synthetic Biology fall under the scope of the convention and its three objectives” is exactly correct and it may be useful here to reference article 8g of the Convention which is the operative article in this case (as well as article 19). Article 8g of the CBD directs parties to:

“Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health”

It should be noted that 8g covers adverse effects of the “use” and not just the “release” of organisms resulting from biotechnology – thereby making no distinction between the “use” of such organisms in closed or open systems and implicitly including products and components (Which are “associated with the use” of engineered organisms).

It should be noted that 8g concerns adverse environmental effects impacting the first two objectives of the convention (both conservation AND ALSO sustainable use) – thereby also covering indirect effects such as socio-economic effects). Article 19 directly addresses the third aim of the convention.

In order to fulfil the requirements of 8g Parties are required to “establish or maintain means to regulate, manage or control the risks”.

Article 8g therefore, when applied to Synthetic Biology, clearly directs parties to have in place regulations or other means to manage the risks (including indirect risks and risks to sustainable use) that the ‘use ‘ of synthetic biology (including in closed systems) may have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health . As summarized by paragraph 38 – this charge given under Article 8g of the convention is only partly met by the protocols to the CBD. The question of regulating the impacts on sustainable use from use of components and products are left as orphans with in the CBD.

For example there is no clear place within the CBD for a party to address the socio-economic and indirect impacts of the products of Synthetic Biology even where those effects adversely affect their forests or agrobiodiversity. For example if the introduction of Syn Bio-derived vanillin to the market place under a ‘natural’ label or commercial use of synbio-derived vetiver replacement for perfumery lead to a shift in agriculture in Madagascar or Haiti that may be environmentally damaging or increase the take of sugar and other biomass while impacting human wellbeing (including health) via livelihood loss however neither of the two protocols would be appropriate to address or resolve this.

In fact this scenario was raised explicitly by Madagascar in their intervention in the Online Forum when John Roger Rakotoarijaona of the Madagascan National Office of the Environment pointed out that

“The texts in force and the structures in place at national level do not protect us enough against biopiracy. So that our wealth in genetic resources are regularly looted and all data to synthesize our plants are in the hands of multinational companies that allow them to make biological copy legally.

Internationally, although the Convention on Biological Diversity recognizes the risk of unfair trade (UNEP/CBD/SBSTTA/18/10 para 22), there is no arrangement under which intellectual property on genetic resource is protected and right to copy and market synthetic products is framed. This is very detrimental for poor countries as demonstrated by several studies. Risk assessments done in the biotechnologically-advanced countries do not take into account the impact of their technologies on the developing countries which constitute the original source of raw materials. It is not only a matter of livelihoods of cash crop dependent people but the survival of the economy is at stake.”

We would point out that Article 10c of the convention may in effect place on countries a requirement to act to protect Madagascar’s vanilla growers from threats of synthetic replacements since it requires parties to “Protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements;”. Once again this is a clear basis to act in response to the use of synthetic biology that is not being met by decisions within the CBD. It points to the gap between the theoretical governance and oversight obligations of the CBD and the lack of actual institutions or processes to enact that. This is exactly the sort of gap the AHTEG was tasked to find.

**Regarding 3.5 on Potential benefits and risks**

It is helpful that potential benefits and risks are presented with reference to the three aims of the convention. This approach can help highlight applications that may warrant closer scrutiny.

 ETC Group would draw particular attention to the recurrent concern about gene drives which appear to be relevant across all 3 of the aims of the convention – identified on the benefit side as potentially benefitting sustainable use through elimination of agricultural and other pests but also identified on the risks side as having adverse effects on ecosystems and vis a vis the other two objectives of the convention. The first working gene drive, enabled by CRISPR-CAS9, was demonstrated in 2015 and this is exactly the sort of high-impact new and emerging issue that the convention would do well to assess and evaluate to aid parties in their obligations under Article 14 and 8g of the convention. Parties may consider the topic of gene drives an appropriate urgent object of study for further work on this topic.

**Regarding 3.7 on the degree to which existing arrangements constitute a comprehensive framework**

Once again the stated importance of a comprehensive framework addressing all 3 objectives of the convention as well as covering organisms, components and products (and not just organisms alone) is welcome and it is appropriate that was universally recognized by the AHTEG. ETC Group would share the view of those who felt that socio-economic considerations are not sufficiently expressed by existing framework and remind that the scio-economic effects if products and components is not at all addressed.. It is unclear what is meant at paras 62 and 63 by ‘assessment of the added value of synthetic biology application’ - it may be clearer to say simply ‘in the assessment of synthetic biology applications’ (the ‘added value to society’ would be only one part of an assessment)

**Regarding item 4 – Conclusions and Ways forward**

ETC Group agrees with all of the parts of this item and draws particular attention to para 66C as a key recommendation for establishing a way forward.

For 66b it may better reflect the discussion in the AHTEG if the sentence was bolder in establishing that living organisms developed through current and near future applications of Synthetic Biology should be regarded as LMO’s ( and not just ‘similar to’ ).