**template for Peer Review comments**

**Technical series on synthetic biology**

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| **Comments on the Technical Series on Synthetic Biology** |
| **Page #** | **Line #** | **Comment** |
| 0 | 0 | As highlighted in the document, there are numerous typos that need to be fixed, these will not be mentioned further as requested.  |
| 0 | 0 | After reading the entire document in detail, it was apparent that there was a notable amount of repetition between sections, either when examples were highlighted or when specific content from Conventions and Protocols were mentioned. It is understandable that there will be some degree of repetition which will be unavoidable but this could potentially be minimised by re-organising the flow of some of the sections. This would also make the document less dense and more reader-friendly.  |
| 0 | 0 | Throughout the document, it is emphasised that there is a need to engage with local people (indigenous or otherwise) in order to highlight concerns for new synthetic biology technologies and to gauge their acceptance for implementation of developed technologies. This was highlighted by Trump et al. (2020 – this reference was cited in the document for other reasons) who noted that an essential component for acceptance of synthetic biology technologies will have to involve co-operation between biosecurity experts, social scientists and practitioners. These authors termed this the “building of bridges” between the role players early in the technology development and forecasting stages. These authors demonstrated in another study (Trump et al. 2019), what they termed the value of the co-evolution of physical and social sciences in the development of synthetic biology over a 16 year period. It is recommended that this aspect needs to be expanded upon in the document as it is mentioned in very general terms.  |
| 0 | 0 | While reviewing the literature on regulation of synthetic biology under the CBD, an interesting review article by Keiper and Atanassova (2020) was noted (this was cited numerous times in the document). These authors concluded that the CBD discussions on synthetic biology were seen as a longer version of the Asilomar conference as the decision making process has been in progress for an extended period of time. These authors also highlighted the general lack of participation of practitioners in the CBD decision making process. The authors further advocated for more active involvement by the scientific community in order to drive efficient, science-based regulation.  |
| 0 | 0 | It is recommended that more emphasis be placed on international co-operation in terms of regulation and implementation of new technologies, for example, gene drives which have the potential for transboundary movement. This is highlighted by Reynolds (2020 – cited in the document) in terms of international governance of gene drives.  |
| 0 | 0 | The document is very comprehensive and seeks to provide useful information on synthetic biology as it relates to the Convention and its Protocols. However, most sections seem to be repeating information from the text of the Convention and its Protocol, mostly as background and to provide context, but in some cases seem irrelevant or lack a link to synthetic biology. We propose that background information be reduced and only keep as far as possible shorter paragraphs that provide context to the aspects of synthetic biology discussed in the different sections.  |
| 3 | 6 | OPCW full description not provided |
| 8 | 10 | We propose that the word “sector” be qualified. As it currently stands, it is not clear which sector is being referred to. |
| 8 | 24-27 | It is proposed that the document maintains consistency when referring to the broader issues other than the scientific assessments, that is socio-economic, political, moral, cultural, legal, and ethical, ethical, socio-cultural, epidemiological, ecological and economic considerations social justice consistent with the Convention language?While acknowledging that these broader dimensions will vary depending on national circumstances, it would be useful to have these dimensions defined or expanded on in the context of synthetic biology. |
| 8 | 32-33 | We proposed that the term “classical genetic engineering” be defined in a footnote |
| 12 | 23 | Incomplete sentence “of those countries form the basis of discussions aimed at reaching a consensus at the international level.” |
| 12 | 34-38 | While socio-economic considerations as outlined in Article 26 of the Biosafety Protocol are not mandatory, most Parties have specific approaches or requirements that facilitate how socio-economic considerations should be taken into account in decision-making with regard to living modified organisms. South Africa’s NBF for example, has a holistic approach that considers both biosafety aspects and socio-economic consideration in decision-making. As such, organism resulting from synthetic biology techniques considered as LMOs would be accommodated.  |
| 12-13 | 49-50 and 1-2 | It would be useful to put into context “regulatory mechanisms/frameworks” referred to as at not having been developed with the necessary scope and scale, especially given that it is implied that there are others beyond the Convention and its Protocols.It would be useful to gather information on regulatory frameworks under which synbio applications have been considered by parties thus far to get an idea of the extent to which they accommodate synthetic biology. This can assist other parties in assessing the appropriateness of their regulatory frameworks and whether there would be a need to update based on national circumstances |
| 13 | 40 | It is recommended that Table 1 be moved closer to where it is first cited (i.e. page 10) for ease of reference. Currently, there are a number of other sections that appear before Table 1. |
| 15 | 13 and 14 | The lack of an international agreed-upon definition of ‘’Synthetic Biology’’ is a great concern. Without progress made on an agreed-upon definition, the content of the document is merely a suggestion according to the proposed definition suggested in lines 13 and 14 of page 15.It is suggested that the document be updated again after a clear definition is agreed upon internationally for Synthetic Biology.  |
| 18 | 28-29 | No clarity if all synthetic biology product will be seen as GMO’s or LMO’s, the document refers to gene-editing technology that most countries have indicated, when used, will lead to products that will be a non-GMO product such as technologies mentioned in line 28-29 of page 18. If synthetic biology will be regarded as a GMO/LMO then the inclusion of these methods in the Technical Series should be reviewed.  |
| 31 | 13 | There is also reference made to “Synthetic biology applications in semi-managed, managed, or urban settings” on page 31, line 13, which includes various examples of gene-edited crops without mentioning the method used to genome edit these crops, which lead to the conclusion that all genome-edited crops fall under the scope of Synthetic-Biology. Before a definition of synthetic biology is not agreed upon this cannot be concluded.  |
| 42 | 8, 28 | The reference list need to be checked. It was noted that the reference for Reynolds (2020) was incorrectly cited and referenced as Reynolds 2021 when it should be Reynolds (2020). This same reference was also cited as Reynolds 2021b which does not appear in the reference list. This error was found by co-incidence, therefore, it is recommended that the entire reference list be checked for errors.  |
| 54 | 27-28 | The potential use of synthetic biology for bioterrorism, biological warfare and the construction of novel organisms designed to be hostile to human highlights the need to bring on board ministries responsible for this in the regulatory system |
| 66 | 34-38 | South Africa does not yet have a policy/guidance describing which genome-edited applications are not required to follow as indicated in the document. The decision-making body supported a scientific committee is considering different views from a experts and a range of stakeholders, including scientific experts, and reports such as “The Regulatory Implications Of New Breeding Techniques” developed by the Academy of Science of South Africa (ASSAf) (2016) to formulate a country position on how genome edited organisms will be regulated. |
| 81 | 31 | This section should appear earlier on in the document and summarised |
| 90 | 6 | This section seems to be repeating information from the text of the Protocol without linking it to synthetic biology. Therefore, we propose deletion.  |
| 131 | 36-44 | Regulation of Synthetic Biology at national levels should consider a synergistic approach between government and institutions, and alternatively a governance system that depend on an independent authority can be utilized especially for those products and/or technologies that do not fall within the scope of existing regulatory frameworks. Miller and Selgelid (2007) suggested this approach.Synthetic biology is also anticipated to increase the amount of genetically engineered organisms to be reviewed and the use of an independent authority will also be useful to curb the influx and unburden the existing regulatory systems. |

**References:**

Trump B.D et al. 2019. Review: Co-evolution of physical and social sciences in synthetic biology. Critical Reviews in Biotechnology 39(3): 351-365

Miller S, Selgelid MJ. 2007. Ethical and philosophical consideration of the dual-use dilemma in the biological sciences. Sci Eng Ethics 13:523–580

Please submit your comments to secretariat@cbd.int.