**template for Peer Review comments**

**Technical series on synthetic biology**

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| **Contact information** |
| **Surname:** | Durham |
|  |  |
| **Given Name:** | Ben |
|  |  |
| **Government** | Republic of South Africa |
| **(if applicable):** |  |
|  |  |
| **Organization:** | National Department of Science & Innovation |
|  |  |
| **E-mail:** | Ben.durham@dst.gov.za |
|  |  |
| **Comments on the Technical Series on Synthetic Biology** |
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| 0 | 0 | A significant challenge to resolving CBD guidance and advice on Synthetic biology is the current ‘operational definition’ of Synthetic biology which states: “*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*”. This is a very broad definition, which potentially covers all aspects of genetic engineering ranging from genetic modification (already well considered under the Cartagena Protocol on Biosafety) through to the ***de novo*** creation of synthetic life (hereafter termed ***novel*** life).The definition therefore prevents Synthetic Biology being a useful term for defining regulatory scope, as it covers large parts which are already defined and extensively dealt with under the CPB (including, potential future modification technologies), but also areas that will need new considerations, and will require different approaches (from genetic modification) to risk assessment and risk mitigation. This then causes confusion when the question is asked (such as during the recent SBSTTA) whether Synthetic Biology is a “New and Emerging Issue”, as – on the one hand - genetic modification is well covered, and therefore clearly not a new and emerging issue, while other aspects of Synthetic biology are indeed new and emerging, - as per the criteria provided in Decision IX/29.There are two possible solutions. Firstly, it would be to redefine Synthetic Biology as “*A new dimension of modern biotechnology that combines science, technology and engineering with the objective of creating life/living organisms with limited or no resemblance to existing or extinct organisms”.* This would then clearly differentiate Synthetic Biology from genetic modification (which generally has substantial equivalence to existing, unmodified organisms), and allow the CBD to proceed with new considerations beyond living modified organisms (i.e. Novel life), for which there is no existing comparator organism.The availability of a relevant comparator is a critical distinguishing issue, as it forms the basis for the existing risk assessment process as defined under the CPB. The modified organism is compared with the existing organism, taking into account the modification. A ***novel*** organism has no directly equivalent comparator, and therefore the risk assessment process is necessarily different.The alternative solution – albeit eroding its functional utility - is to retain the term Synthetic biology as an all-encompassing term, but recognize that is includes two substantial sub-classes – living modified organisms, and ***novel*** organisms. The distinction would be whether there is substantial equivalence to an existing organism (which would form the basis for deciding what risk assessment approach can be used). Synthetic biology could then not be identified as a ‘new and emerging issue’, but the ***novel*** category (or sub categories of these) could be. It further needs to be recognised that issues like Genome editing and Gene drives are genetic engineering techniques that could be applied either to modifying LMOs, or to ***novel*** organisms, and the risk assessment process for either category (although not yet developed for novel organisms) would still hold. |
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