TITLE: PEER REVIEW OF THE OUTCOMES OF THE REPORTS IN RELATION TO SYNTHETIC BIOLOGY

REPORT OF THE MEETING OF THE AD HOC TECHNICAL EXPERT GROUP ON SYNTHETIC BIOLOGY

Item.	Content	Comments / Inputs
3.1. **Page 4** **Para 24**	**Towards an operational definition of synthetic biology comprising inclusion and exclusion criteria** The following is the outcome of the deliberations of the Group on an operational definition of synthetic biology: "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."	**The definition is considered and it shall assist Parties for the implementation of the provisions of the Convention but it is not a prerequisite for the discussion on the potential regulatory and risk assessment challenges of synthetic biology.**
3.2. **Page 4** **Para 27**	**Relationship between synthetic biology and biological diversity** In addressing the relationship between synthetic biology and biological diversity, the Group worked within the context of the operational definition agreed on and each of the specific three objectives of the Convention. It was noted that, in order to facilitate discussions on the relationship between synthetic biology and biological diversity, an appropriate baseline for measuring the potential positive and negative impacts of synthetic biology on each of the objectives of the Convention needs to be considered or developed and, where possible, supported by evidence-based information, including peer-reviewed data, as well as specialized knowledge, indigenous and traditional knowledge.	**Agreed to the addressing point stated and due to the increasingly complex and wide range of synthetic biology tools and techniques, it may be harder to predict the impacts of synthetic biology.**

3.3. **Page 5** **Para 32.**	**Similarities and differences between living modified organisms (as defined in the Cartagena Protocol) and organisms, components and products of synthetic biology techniques** In considering the agenda item, the AHTEG arrived at a common understanding that the term "components" would refer to parts used in a synthetic biology process (for example, a DNA molecule), and the term "products" would refer to the resulting output of a synthetic biology process (for example, a chemical substance). Both terms were considered as referring to non-living entities. On the basis of that understanding, the Group agreed that those non-living components and products of synthetic biology do not fall under the scope of the Cartagena Protocol on Biosafety.	**Agreed**
Para 34.	The AHTEG agreed that living organisms developed through current and near future applications of synthetic biology are similar to LMOs as defined in the Cartagena Protocol.	**Agreed**
Para 35.	The AHTEG noted, however, that it is not clear at the current stage whether or not some organisms of synthetic biology, which are currently in the early stages of research and development, would fall under the definition of LMOs under the Cartagena Protocol.	**If these newly introduced organisms do not fall within the scope of Cartagena Protocol, it is necessary to introduce new approaches to the regulations especially on its biosafety.**
3.4. **Page 6** **Para 41.**	**Adequancy of other existing national, regional and / or international instruments to regulate the organisms, components or products derived from synthetic biology techniques** Some members of the AHTEG noted the following needs with regard to international regimes: (a) provisions to address the socioeconomic impacts of the components and products of synthetic biology;	**Agree for these issues to be addressed by countries lacking of operational**

	(b)measures to minimize the likelihood of unintentional transboundary movements of organisms of synthetic biology after their release into the environment; and (c) traceability tools to ensure the fair and equitable sharing of the benefits arising from the utilization of genetic resources in synthetic biology.	**provisions in order to adequately control and regulate especially for the exchange, distribution and commercialization of products derived from synthetic biology techniques.**
3.6 **Page 10** **Para 55.**	**Best practices on risk assessment and monitoring regimes currently used by Parties to the Convention and other Governments** The AHTEG concluded that it would be useful to compile the existing body of knowledge on relevant best practices on risk assessment and monitoring in a single and easily accessible online portal under, for example, the Biosafety-Clearing House of the Cartagena Protocol or the clearing-house mechanism of the Convention.	**Indeed, and although there is a robust rick assessment practices already in place (primarily based on experiences with LMO risk assessment), there is still a need for specific guidelines and capacity building opportunities to be made available for the development of synthetic biology concerning their safety and protocols.**
3.7. **Page 10** **Para 58.**	**Degree to which the existing arrangements constitute a comprehensive framework in order to address impacts of organisms, components and products resulting from synthetic biology, in particular threats of significant reduction or loss of biological diversity** In considering the degree to which existing risk assessment principles and methodologies constitute a comprehensive framework to address the impact of organisms of synthetic biology, some members of the AHTEG noted that risk assessment practices currently in place to evaluate LMOs are sufficient and appropriate to evaluate organisms of synthetic biology, and could be modified to accommodate new specific considerations	**Because synthetic biology techniques are and will becoming increasingly complex, modifying the currently in place LMOs may not be sufficient at times of developing organisms that differ fundamentally from the naturally**

Page 11 **Para 60.**	related to synthetic biology should the need arise. The views of the members of the AHTEG diverged with regard to whether or not current methodologies to address the environmental impacts of the components and products of synthetic biology are adequate or even needed.	**occurring ones in the future.** **Hence it is important to revise and continue to further develop risk assessment methodologies in order to fully address the potential environmental and societal impacts of synthetic biology as well as to address the additional complexity and risks posed by synthetic biology organisms.**