MALAYSIA - COMMENTS ON SYNTHETIC BIOLOGY AND BIOLOGICAL DIVERSITY

CBD NOTIFICATION 2016-008 - PEER REVIEW OF THE OUTCOMES OF THE PROCESS IN RESPONSE TO DECISION XII/24 ON SYNTHETIC BIOLOGY

1. Malaysia takes notes of the following reports provided by the Secretariat of the Convention of Biological Diversity as follows:

    (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.

2. Based on the Report of the AHTEG, some specific views are given as below based on the broad areas of discussion:

NO.	TOPIC	DOC REF (REPORT OF THE AHTEG)	VIEW/COMMENTS
1	TOWARDS AN OPERATIONAL DEFINITION OF SYNTHETIC BIOLOGY COMPRISING INCLUSION AND EXCLUSION CRITERIA	Item 24 page 4	The operational definition for synthetic biology (SynBio) proposed is acceptable and can be adopted.
2	RELATIONSHIP BETWEEN SYNTHETIC BIOLOGY AND BIOLOGICAL DIVERSITY	Item 29 page 5	The existing risk assessment for LMOs has the mechanism to be used to address the issue of SynBio and biological diversity. Precautionary principle in the Cartagena Protocol is still relevant concept, and in fact, the key concept for SynBio LMOs.
3	SIMILARITIES AND DIFFERENCES BETWEEN LIVING MODIFIED ORGANISMS (AS DEFINED IN THE CARTAGENA PROTOCOL) AND ORGANISMS, COMPONENTS AND PRODUCTS OF SYNTHETIC BIOLOGY TECHNIQUES	Item 32 page 5	"Organisms from SynBio" needs to be clearly defined. If it involves gene transfers or genetic modifications at any point in the process of synthesis then these would be treated as LMOs requiring the risk assessment and risk management procedures already in place as per biosafety requirements of Cartagena Protocol on Biosafety. It needs to be emphasised that one should not confuse the terms namely "products" with the meaning of "products" as in Cartagena Protocol (eg. "living modified organism or products thereof…" (Annex I, para. (i)). In the SynBio document, it is stated that "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". In item 32, it went on to say "components" would refer to parts used in a synthetic biology process (for example, a DNA molecule)", while this is acceptable to have "component" added to facilitate the feature of SynBio. In Cartagena Protocol, it is clearly stated that "LMOs and its products thereof..." is within the scope of the Protocol, but the SynBio document seems to remove this product of SynBio from the Protocol, not only is

			this incorrect, it is very confusing to understand "product" within the ambit of SynBio and "product" within the ambit of the Cartagena Protocol. It is strongly advised not to create such confusion.
		Item 34 page 5	It is agreed that living organisms developed through current and near future applications of synthetic biology are similar to LMOs as defined in the Cartagena Protocol.
		Item 36 page 5	It is agreed that there are cases in which there may be no consensus on whether the result of a synthetic biology application is "living" or not (for example, protocells). These cases need to be carefully handled. When in doubt treat as LMOs for the present at least.
4	ADEQUACY OF OTHER EXISTING NATIONAL, REGIONAL AND/OR INTERNATIONAL INSTRUMENTS TO REGULATE THE ORGANISMS, COMPONENTS OR PRODUCTS DERIVED FROM SYNTHETIC BIOLOGY TECHNIQUES	Item 38 page 6	Item 38 stated "within the scope of the Convention and its three objectives. However, only living organisms of synthetic biology would fall under the scope of the Cartagena Protocol and the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress." which is not agreeable. It is difficult to understand and confusing why there is a distinction of product under SynBio and Cartagena Protocol. In Cartagena Protocol, both the LMOs and its products thereof, are regulated by the protocol. The document seems to conflict with the Protocol. It is best if current biosafety frameworks are expanded to incorporate components and products of SynBio. Definitions have to harmonise with Cartagena Protocol on Biosafety for ease of usage.
		Item 41 page 6	Needs with regard to international regimes: (a) provisions to address the socioeconomic impacts of the components and products of synthetic biology; (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. The views expressed do not differ from what is conventionally applied for LMOs under the Cartagena Protocol on Biosafety. It is best therefore to treat these new products and components in a similar manner.
5	POTENTIAL BENEFITS AND RISKS OF ORGANISMS, COMPONENTS AND PRODUCTS ARISING FROM SYNTHETIC BIOLOGY TECHNIQUES TO THE CONSERVATION AND SUSTAINABLE USE OF BIODIVERSITY AND RELATED HUMAN HEALTH AND SOCIOECONOMIC IMPACTS RELEVANT TO THE MANDATE OF THE CONVENTION AND ITS PROTOCOLS	Item 52 pages 7,8,9,10	The list provided seems to be quite comprehensive. However, it should be clearly stated that it is not an exhaustive list.
6	BEST PRACTICES ON RISK ASSESSMENT AND MONITORING REGIMES CURRENTLY USED BY PARTIES TO THE CONVENTION AND OTHER GOVERNMENTS	Item 55 page 10	It is agreed 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.
7	DEGREE TO WHICH THE EXISTING ARRANGEMENTS CONSTITUTE A COMPREHENSIVE	Items 60, 61, 62,63, 64, 65 page 11	In brief, the current methodologies need to be expanded and further improved on to enable fair treatment of SynBio's output.

	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		Integrating ethical values that are relevant to society in the assessment is not relevant to risk assessment per se. It is proposed to put it within the scope of socio-economical consideration to avoid diversion of attention away from biosafety. It is strongly agreed that there is a need for coordination with current processes under the Cartagena Protocol on Biosafety in particular with the AHTEG on Socio-economic Considerations and the AHTEG on Risk Assessment and Risk Management.