**CBD Notification No. 2015-013**

MALAYSIA – SUBMISSION OF INFORMATION ON SYNTHETIC BIOLOGY

Malaysia would like to submit the following information that can be served as a basis for the deliberations of the online forum and the AHTEG on synthetic biology.

**a) Information that may relevant to the work of the AHTEG:**

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| *Issues* | *Malaysia’s submissions* |
| i. | How to address the **relationship** between synthetic biology and biological diversity | Synthetic Biology is an "accelerated and intensified" form of classical genetic engineering. By default, both classical genetic engineering and synthetic biology are designed to push biological systems to produce the maximum output in minimum time. Synthetic Biology is expected to have produce similar, but wider and more intense, impacts as classical genetic engineering on biological diversity.It may be considered as a strategy, that if responsibly managed could support enrichment and exploitation of biological diversity, for the well-being of humankind as well as biological diversity. Unlike classical genetic engineering, synthetic biology can possibly increase biological diversity especially when in involves *de novo* LMO. The artificial traits introduced into the new LMO may be too invasive that will diminish the biological diversity.  |
| ii. | The **similarities and differences** between **living modified organisms** (as defined in the Cartagena Protocol) and organisms, components and products of **synthetic biology** techniques | **Similarities:** To a certain extent, synthetic biology still relies on classical genetic engineering. Both types of products involve combination of genes from different sources using modern biotechnology methods. In the case of synthetic biology products, these are enhanced by computational studies and engineering concepts. The underlying technology makes synthetic biology and classical genetic engineering products basically the same. Some of the impacts of synthetic biology products can be inferred from that of similar products or combination of products made using classical genetic engineering. However it does involve new elements that can produce *de novo* elements and this requires further discussions. **Differences:** Although both classical genetic engineering and synthetic biology introduces novel traits, LMOs with multiple traits from genetic material across a wide genome range may be so unique and give rise to “new genetic materials” such as XDNA which may defer from the “modern biotechnology”. This xeno-genetic materials are not naturally found and hence may or may not be readily classified like DNA and RNA. Synthetic biology allows us to create biological systems with a higher degree of complexity, and using a more complex mix of building materials. By adapting engineering design principles and concepts, synthetic biology attempts to bring in a higher degree of predictability and control. This is however is only possible if the exact specifications of the 'parts' and all operating parameters for the 'system' is known. Unknown parameters or novel combination of known parameters can give rise to novel traits and unpredictable effects.As synthetic biology products grow in complexity and have such unique traits, the need for a natural parent organism to serve as a comparator in current risk assessment will be difficult to meet. |
| iii. | Adequacy of existing national, regional and/or international instruments to **regulate** the organisms, components or products derived from synthetic biology techniques | There is an inadequate basis on which to assess risks associated with synthetic biology at the moment. Existing instruments for regulating LMOs can be adapted to deal with synthetic biology products. Products of synthetic biology are likely to be more complex, thus there is a need to fully characterize additional risks posed and to collect data on biosafety issues. The existing approaches of risk assessment, mitigation and communication can be used for synthetic biology products, provided that guidelines and methods are made available to address the additional uncertainties and knowledge gaps. |
| iv. | An **operational definition** of synthetic biology, comprising inclusion and exclusion criteria | Synthetic biology employs modern biotechnology to produce a transgenic LMO, by amplifying, synthesizing, and putting back into the original organism modified/engineered genetic material(s) with novel traits or capable of producing unique components or products that are not naturally designable in the original organism itself. Synthetic Biology is an "accelerated and intensified" form of classical genetic engineering.  |
| v. | 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 | Benefits similar to classic LMOs, with a wider spectrum and higher impacts due to the ability to engineer more complex systems and more building materials and is applicable in the bio-industries. Concomitantly, the potential risks also increased. This is because the net outcome of LMO/SB technology is unpredictable. Furthermore, mutation rates are expected to be high given that the genetic material is foreign and novel and has not had time to stabilize. Lateral/horizontal gene flow could also be far more extensive than that which has recently been reported to have indeed taken place naturally between humans, vertebrates and invertebrates (Crisp et al. Genome (2015); doi: 10.1186/s13059-015-0607-3). |
| vi. | Best practices on **risk assessment** and **monitoring regimes** currently used by Parties to the Convention and other Governments, including transboundary movement, to inform those who do not have national risk assessment or monitoring regimes, or are in the process of reviewing their current risk assessment or monitoring regimes | Existing risk assessment and monitoring regimes can be adapted with specific guidelines to address the additional and heightened risks posed by synthetic biology products. Urgently required as modern biotechnology is an extremely fast developing and highly sophisticated area of biological sciences.  |
| vii. | The degree to which the existing arrangements constitute a comprehensive framework in order to address impacts of organisms, components and products resulting from synthetic biology relevant to the objectives of the Convention on Biological Diversity and its Protocols, in particular threats of significant reduction or loss of biological diversity | Existing framework is probably inadequate for sophisticated applications of synthetic biology, especially in microorganisms engineered to produce novel components and products which were originally designed for animals or crop plants. We propose that the current risk assessment framework be reviewed and/or adaptation be made and/or a new framework be provided if necessary as a guidance to assess organisms produced via synthetic biology. The assessment should be robust enough to assess not only work that involves incorporation of genes but also work of building organisms where there are no parent organisms as comparators. |

**b) Information on measures undertaken in accordance with paragraph 3 of the decision, including the identification of needs for guidance:**

*Malaysia’s submission*

There is a need for a revised risk assessment framework to address the possible novel risks posed by products of synthetic biology whereby no parent organisms can be used as comparators.

**c) Further information on the components, organisms and products resulting from synthetic biology techniques that may have impacts on the conservation and sustainable use of biological diversity and associated social, economic and cultural considerations:**

*Malaysia’s submission*

No further information available as for now.