28.02.2018

**Peer review of the report of the Ad Hoc Technical Expert Group on Synthetic Biology**

Ref FOEN: R093-1643 / BN

Ref CBD.: SCBD/SPS/DC/MPM/MW/87112

Dear Executive Secretary

With regard to notification SCBD/SPS/DC/MPM/MW/87112, dated 18 January 2018 Switzerland would like to make the following comments:

Switzerland thanks the COP MOP for the opportunity to peer review the report of the face-to-face meeting of the AHTEG on Synthetic Biology, convened in Montreal, Canada, from 5 to 8 December 2017.

Switzerland thanks the secretariat for the excellent work done since 2017 in accordance with decision XIII/17 from the 16 December 2016.

Switzerland thanks the ATHEG on Synthetic Biology for its excellent work in accordance with the terms of references contained in the annex of the above-mentioned decision.

Switzerland would like to transmit few specific comments and general comments and views on the report given for peer review.

**Specific comments from Switzerland:**

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| **Page #** | **Para #** | **Comment** |
| **3-4** | **Ch. 3.1** | Under §15: We would have liked to have a more structured list of the recent technological development of syn. Bio. according to problematics such as: Definition or models of the syn. bio. technologies / Risk assessment / Risk management / Purposes of the development (biosecurity concern, conservation, health, industrial etc.)/ questions related to access to the technology and benefit (and risk) sharing/ problems related to the rate, complexity and broadness of development |
| **5** | **Ch. 3.3** | Under § 28: we would have liked to find a comment from the ATHEG in the report on the criteria used to deliberate that: ” **most** living organisms…  |
| **5** | **Ch. 3.4** | We see the chapter 3.4 as a part of the risk management problematics. We would like to hear from ATHEG the reasons why it is presented as a separate issue.  |

**General comments from Switzerland:**

In its report, the ATHEG acknowledged in the report that technological development within the field of synthetic biology were advancing at an accelerated rate, resulting in increasing number of organisms that are engineered by various tools and techniques.

It recalled the conclusion reached at previous meeting that Benefits and adverse effects of Synthetic biology vis-à-vis the three objectives of the convention are expected to be similar to those of classical engineering. Although it considered that potential positive and negative impacts might be broader and wider ranging due to the potential for synthetic biology to produce organisms and biological systems with higher level of complexity and range of applications. It noted as well that the experience gained from LMO, management of pests and alien species, as well as biological control might be useful in exploring positive and negative impacts of synthetic biology.

Coming back to the upon mentionned substantive issues of the report, Switzerland would like to remind that although there are examples of organisms developed through techniques of synthetic biology that are in a grey area (not fully compliant to the definition of LMO), many actual development of synthetic biology organisms that are LMO are available. In particular, in the context of LMO containing a gene drive mechanisms and particularly where the goal of the release of such LMO is the extinction of populations or species, respectively, many relevant issues, ranging from risks to the environment to authorisation criteria, need to be discussed and properly assessed to safeguard the CBD and Cartagena protection goals. Such gene drive systems are actually in development or ready for release in many areas (e.g., public health, agriculture) to control vector, pest populations, or host competence, therefore Switzerland sees an urgent need for a discussion on risk assessment and risk management measures /or obligations for the use of synthetic biology organisms or products, which can be considered as LMO, with potentially irreversible damages vis à vis the three objectives of the convention.

Switzerland reiterates its view point that organisms that are engineered by various tools and techniques of synthetic biology are to be considered on a case by case basis using a robust risk assessment methodology and implementing sound risk management procedures as required by Cartagena Protocol.

In order to achieve an international harmonization, international guidelines (e.g., regarding justifiable reasons for a release or mandatory integration of safety mechanisms) are of particular importance because synthetic biology organisms, in particular those LMO containing a gene drive mechanisms, might easily spread across boarders into areas, where a control of the target is not desirable or acceptable, respectively.

Lately, as submitted at the online Forum on Synthetic Biology, Switzerland strongly supports the development of guidelines and methodologies under the Cartagena Protocol, on how to conduct environmental risk assessment in situations where risk scenarios drafted on the basis of data on existing biological processes or based on scientifically sound knowledge are unavailable.

Finally, we would recommend that the discussion and developments on synthetic biology develop in line or even synergies with other similar developments and discussions such as the ongoing CITES discussion on specimen produced from synthetic or cultures DNA (notification 2018/013 dated 29 January 2018) or the discussion on gene editing on the basis of digital sequence information on genetic resources (International Treaty on Plant Genetic Resources for Food and Agriculture, CBD, Pandemic Influenza Preparedness (PIP) Framework etc.) .

Please accept, Madam, Sir, the assurances of our highest consideration

On behalf of Switzerland

Norbert Bärlocher

Focal Point CBD