European Commission

Workshop on Synthetic Biology
From science to policy and societal challenges
Luxembourg, 10/12/15

Potential impacts of synthetic biology on biological diversity

Anne Teller, Senior Expert, DG ENV.B2

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History

- **New research area** associated with an expansion of the scope and scale and complexity of genetic modification;

- Potential to provide for **opportunities** for new benefits for health, the environment, resources management and the economy;

- **Scientific uncertainties** associated with the development of synthetic life, cells or genomes and their potential impact on the environment, the conservation and sustainable use of biological diversity and human health;

- **Need to be addressed consistently within the Convention on Biological Diversity and its Protocols (Cartagena/Biosafety and Nagoya/Access and Benefit-Sharing).**

New and emerging issue (NEI)*

2012	• **Proposal for consideration as "New and Emerging Issue"** - SBSTTA XVI/12 • **Precautionary approach:** COP Decision XI/11
2014	• **Relevance to the Convention**: SBSTTA XVIII/7 calling Executive Secretary (ES) to update documents for CBD COP12 and Biosafety (BS) COP-MOP 7. Recommendation to COP mostly bracketed! • **Coordinated approach**: Decision BS-VII/12 • **Establishment of a Process:** Decision XII/24 calling ES 1) to call for additional information, 2) convene a moderated open-ended online forum to support the work of 3) an (expanded) Ad Hoc Technical Expert Group on synbio Reference to Article 14 on Impact Assessment and Minimizing Adverse Impacts and Decision X/37 on precautionary approach

COP Decision XII/24 follow-up

1. **Additional information**: 27 submissions in total provided by Parties (15), other Governments (1) and relevant organisations (11) made available through the Biosafety-Clearing House (BCH) of the Convention

2. **Moderated Open-ended online forum:** 235 nominated experts (146 Parties, 9 non-Party, 80 organisations) through BCH (402 interventions from April to July)

3. **AHTEG:** Meeting on 21-25 September in Montreal, 40 nominated experts (29 Parties, 1 non-Party, 10 organisations)

Highlights of the meeting of the AHTEG on Synthetic Biology

21 - 25 September 2015 - Montreal, Canada

1. **Operational** definition of synthetic biology

2. Relationship between synthetic biology and biological diversity

3. Similarities and differences between living modified organisms (as defined in the Cartagena Protocol) and organisms from synthetic biology

4. Potential benefits and risks of organisms, components and products of synthetic biology

5. Adequacy of existing national, regional and/or international instruments to regulate and address impacts the organisms, components or products of synthetic biology

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.”

Relationship between synthetic biology and biological diversity

The conservation and sustainable use of biodiversity, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources may be affected, **both positively and negatively**, by living organisms resulting from synthetic biology, as well as by non-living products or components.

Similarities and differences between living modified organisms (as defined in the Cartagena Protocol) and organisms from synthetic biology

- **Living organisms** developed through current and near future applications of synthetic biology **are similar to LMOs** as defined in the Cartagena Protocol.

- However, it is not clear whether **some organisms of synthetic biology**, which are currently in the early stages of research and development, fall under the definition of LMOs under the Cartagena Protocol.

Potential benefits and risks of organisms, components and products of synthetic biology

- In comparison with classical genetic engineering, a distinctive quality of synthetic biology is its **rate and depth of intervention**, which may lead to decreased familiarity of the organisms developed through synthetic biology in comparison with non-modified organisms.

- From an engineering perspective, synthetic biology aims at achieving **more predictability in the characteristics of the resulting organism**. However, the **level of uncertainty in risk assessment may increase** with regard to the impacts on biodiversity and human health as well as the time needed to complete the risk assessment.

Adequacy of existing national, regional and/or international instruments to regulate and address impacts the organisms, components or products of synthetic biology

- Living organisms, components and products of synthetic biology **fall within the scope of the Convention and its three objectives**. However, **only living organisms of synthetic biology fall under the scope of the Cartagena Protocol and the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress**.

- **Risk assessment practices** currently in place to evaluate LMOs may need to be **modified and adapted to accommodate** new specific considerations related to synthetic biology.

Adequacy of existing national, regional and/or international instruments to regulate and address impacts the organisms, components or products of synthetic biology

The Nagoya Protocol and synthetic biology

- The Nagoya Protocol provides a framework for the **fair and equitable sharing of the benefits** arising from the utilization of genetic resources, including in synthetic biology.
- So far there is very **little practical experience** with application of the Protocol (entry into force in October 2014). Its **scope** of application remains contested in some respects.
- The AHTEG recommended setting up **mechanisms for clarifying the issue of digital genetic resource information** as it relates to access and benefit-sharing, and assessing potential gaps in oversight under the Convention and its Protocols with regard to components and products of synthetic biology.

Next steps

- Peer-review of the outcomes of the CBD process: deadline for submission of comments **31 January 2016**;

- **SBSTTA 20 (April 2016):** background document prepared by the SCBD, including draft recommendations. Information documents: report of the AHTEG, updated report by the Secretariat and peer-review comments;

- **COP13, BS COP-MOP8 & NP COP-MOP2 (December 2016):** Possible decisions could include: adoption of the operational definition; noting the relationship between synbio organisms and LMOs; process to adapt risk assessment methodologies to synbio organisms and provide clarity on how access and benefit-sharing apply to the use of digital genetic resource information… ???

Thank you for your attention!

More information on http://bch.cbd.int/synbio/