

Item 3.1: Synthetic biology and Biosafety

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September 24

11.30 am – 12.15 pm

Central and Eastern European Training Course on Risk
Assessment of Living Modified Organisms

24.-28.9.2018

Minsk, Belarus

Synthetic Biology and Biosafety (1)

Definitions:

“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.”

(CBD/COP/DEC/XIII/17 - 2016)

Synthetic Biology and Biosafety (2)

“Synthetic Biology is the application of science, technology and engineering to facilitate and accelerate the design, manufacture and/or modification of genetic materials in living organisms”.

(European Commission, Scientific Committees, 2014-2015)

Synthetic Biology and Biosafety (3)

- Three documents by the EU CION Scientific Committees:
 - I Definition
 - II Risk assessment methodologies and safety aspects
 - III Risks to the environment and biodiversity related to synthetic biology and research priorities in the field of synthetic biology



Synthetic Biology and Biosafety (4)

- Document II
 - The framework for risk assessment
 - Possible new approaches may be necessary, including risks pertaining to
 - Routes of exposure, adverse effects from integration of protocells into living organisms
 - New xenobiological variants
 - DNA synthesis and direct genome editing of zygotes
 - New multiplexed genetic modifications

Synthetic Biology and Biosafety (5)

- Document III
 - How may the objectives of the CBD be affected?
 - Bioenergy, agricultural and chemical industry applications -> significant land use changes, decrease soil fertility
 - Accidental releases
 - Production of varieties of organisms -> future de-extincted species and products -> could destabilise conservation efforts -> diminish support to conservation due to reduced focus on species and habitat preservation



Synthetic Biology and Biosafety (6)

Additional publications:

- CBD: Technical Series 82 (2015)
- European Commission: Science for Environment Policy, Future Brief: Synthetic biology and Biodiversity (2016)
- OECD: Emerging Policy Issues in Synthetic Biology (2014)

Synthetic Biology and Biosafety (7)

CBD: Technical Series 82

- Definitions
- Techniques
- Possible negative impacts:
 - SynBio organisms and products: novel type of micro-organisms, gene drive -systems (niche-substitution), toxic effects, transfer of genetic material
 - Large-scale increase in the utilization of biomass
 - Depend on the level of exposure of the SynBio organisms and products

Synthetic Biology and Biosafety (8)

CBD: Technical Series 82 (continues)

- Release vs contained use
- Possible major economic shifts (with positive and negative impacts)
- Risk assessment frameworks sufficient for now – with new developments this may have to be revisited
- Health and societal perspective
- Ethical issues
- Intellectual property rights



Synthetic Biology and Biosafety (9)

What has happened under the CBD?

- Decision X/13 (2010) on New and emerging issues (NEI)
- Considered by the SBSTTA 16 (April-May 2012)
- Decision XI/11 (2012) on NEI: the precautionary approach, the need to consider the potential positive and negative impacts of components, organisms and products resulting from synthetic biology techniques
- Considered by SBSTTA 18 (June 2014)
- Decision XII/24 (2014) on NEI – Synthetic Biology
 - Ad Hoc Technical Expert Group (AHTEG), a moderated open-ended online forum to support the work of the AHTEG

Synthetic Biology and Biosafety (10)

- Considered by SBSTTA 20 (April 2016)
- Decision XIII/17 (2016) on Synthetic Biology: welcomed the operational definition, extended the mandate of the AHTEG and the online forum
- Considered by SBSTTA 22 (July 2018)
Recommendations to the COP-MOP 14 include:
 - Horizon scanning, monitoring and assessing new developments
 - Information on potential positive and potential negative impacts
 - Analysis of SynBio being a NEI to be finalized
 - Organisms containing engineered gene drives
 - Genome editing
 - AHTEG, online forum to continue