**Possible considerations during the environmental risk assessment of LMOs developed or created through approaches commonly referred to as “synthetic biology”**

As per the conclusions and recommendations of the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology, the AHTEG on Risk Assessment and Risk Management of living modified organisms (LMOs), and the Subsidiary Body on Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA), living organisms developed through current and near-future techniques of synthetic biology are similar to LMOs as per definition of the Cartagena Protocol.

The AHTEG on Synthetic Biology also recognized that synthetic biology shares both aspects of novelty as well as of continuity in relation to modern biotechnology and agreed on the following definition: “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”.

Although the boundary between synthetic biology and modern biotechnology is not well-defined, approaches that are commonly referred to as synthetic biology include, but are not limit to, genome editing, gene drive, and metabolic pathway engineering. However other branches of modern biotechnology also use gene editing.

While the risk assessment principles as per Annex III to the Cartagena Protocol are also applicable to the risk assessment of LMOs developed through synthetic biology, the two AHTEGs and SBSTTA concluded that risk assessment methodologies may need to be updated and adapted for LMOs developed through synthetic biology.

This document was prepared by the Secretariat, with input from members of one of the AHTEG subgroups, on the basis of views shared through various relevant processes under the Convention on Biological Diversity and the Cartagena Protocol on Biosafety.[[1]](#footnote-1) The purpose of this document is to highlight a set of elements which may require particular consideration when assessing the risk of LMOs developed through synthetic biology, in accordance with Annex III of the Protocol, with a view to assisting the COP-MOP at its eighth meeting in its deliberation on whether or not further guidance is needed on this topic.

The views expressed in this document do not reflect consensus or the majority of views. Instead this document attempts to compile views on which considerations could be particularly relevant during the risk assessment of organisms developed through synthetic biology.

It is noted that ~~many~~ **some** experts in the various fora that contributed to this process were also of the view that the current methodologies for environmental risk assessment of LMOs are fully adequate to assess the risks of organisms developed through synthetic biology and, therefore, no further guidance is needed.

The following are considerations were brought forward by some experts as particularly relevant during the evaluation of LMOs developed through synthetic biology and as indication that current assessment methodologies may need to be adapted to assess the risk and safety of such LMOs:

*Comparative approach*

Synthetic biology approaches may lead to the development or creation of LMOs containing new features that are significantly different from those in the original organism or from organisms existing in nature. The lack of suitable comparators will present a challenge in risk assessments based on a comparative approach.

*LMOs containing an increased number of modified traits*

While synthetic biology aim at increasing the precision of the changes in the organisms produced through such approaches, it will also lead to an increased number and complexity of changes and novel traits. The possibility that unintended and unexpected adverse effects emerging as a result of an interaction between the changes as well as interactions between the changes and the environment cannot be ruled out and will make the evaluation of the overall risk of such LMOs more complex.

*Potential to alter entire wild populations*

Modified traits built into LMOs though mechanisms called “gene drives” can cause the traits to be passed on to entire wild populations, instead of only to some members of the population. Gene drive systems may be able to address serious threats to health and ecosystems by, for example, eliminating diseases and eradicating invasive alien species, but gene drives also have the potential to cause irreversible adverse effects on beneficial organisms and ecosystems. Robust methods are called for in order to assess the risk of gene drives being transferred to non-target species. These methods must rely, among other things, on in-depth knowledge of the ecology of target and non-target species.

*Increased accessibility to techniques of synthetic biology*

Synthetic biology approaches will become more accessible and easy to use by the general public through “do-it-yourself” projects. The increased number of LMOs developed outside of formally established laboratory facilities will likely change the way in which risk assessment and risk management methodologies are used to assess, avoid or minimize the potential adverse impacts of such LMOs. For example, the likely potential receiving environment, as one of the key elements of a case-by-case risk assessment, will no longer be relevant when assessing the risks of LMOs produced by the general public.

*Detection and characterization of changes at the genome level*

Challenges may arise in applying the methodology of Annex III of the Protocol with regard to the genotypic characterization of LMOs developed using synthetic biology approaches. For example, genome editing creates small changes at the DNA level (e.g. single nucleotide changes) both in target as well as off-target sites across the genome, and the resulting LMOs will not be easily characterized through methods that are currently in use. Likewise, it will be difficult to assess the rate of outcrossing of LMOs containing small off-target changes at the DNA level and to detect such LMOs during environmental monitoring.

***Speed of development***

**The speed of new developments is going to rise, which leads to challenges to current risk assessment structures. Means to encounter these challenges and to foster capacity building should be discussed.**

1. These processes include: the Online Forum and AHTEG on Synthetic Biology (established in COP decision XII/24) and the Online Forum and AHTEG on Risk Assessment and Risk Management of Living Modified Organisms (COP-MOP decision BS-VII/12). [↑](#footnote-ref-1)