

Hungarian Comment on the

"REPORT OF THE AD HOC TECHNICAL EXPERT GROUP ON SYNTHETIC BIOLOGY"

Introduction

1-8: Hungary agrees with establishing and *permanent existence* of the Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology, and moderating an open-ended online forum to support the work of the AHTEG and with all its activities, although Hungary has not submitted a report nor has it nominated experts to AHTEG.

3. SUBSTANTIVE ISSUES

3.1.

24: Hungary agrees with the working definition of synthetic biology as is defined in "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."

3.2. Relationship between synthetic biology and biological diversity

25-26: Hungary agrees with the conclusion that synthetic biology may have both positive and negative impacts on biological diversity at different levels, and (29:) welcomes the notion that "there is a potentially higher level of uncertainty due to the increased depth of intervention of synthetic biology in living organisms and biological systems, and emphasized, in accordance with paragraph 3 of decision XII/24, the need for Governments to take *a precautionary approach* when addressing threats of significant reduction or loss of biological diversity posed by organisms, components and products resulting from synthetic biology". However, Hungarian experts disagree with those AHTEG members who noted that the nature of synthetic biology research and development may lead to more predictability in the characteristics of the resulting organism", thinking rather the opposite, the more unpredictable nature of the interactions and making the risk assessment process less certain.

30: Aspects of the relationship between synthetic biology and biological diversity are more unpredictable when one wants to judge the potential positive-, and negative indirect effects.

3.3. Similarities and differences exist between living modified organisms (as defined in the Cartagena Protocol) and organisms, components and products of synthetic biology techniques.

33-34: Hungarian opinion concur with that of AHTEG that living organisms developed through current-, and near future applications of synthetic biology are similar to LMOs as defined in the Cartagena Protocol and should be considered as LMOs.

35: According to Hungarian experts all living products of synthetic biology should be considered, by definition, as LMOs, although they agree that (36:) there might be cases in which there may be no consensus on whether the result of a synthetic biology application is “living” or not (for example, protocells).

3.4. Adequacy of other existing national, regional and/or international instruments to regulate the organisms, components or products derived from synthetic biology techniques are of essential importance for Hungary, as well as the international-, and interboundary movement of such products.

39-41: Hungary fully agrees with these points.

42: Hungary notes that its existing national legislation might not be adequate for regulating the non-living components of synthetic biology.

3.5. Potential benefits and risks of organisms, components and products arising from synthetic biology techniques might possibly impact the conservation and sustainable use of biodiversity, although they might have disadvantages in connection to human health and might have undesirably socioeconomic implications, which are absolutely relevant to the mandate of the Convention and its Protocols.

44-45: Hungary fully agrees with, and would like to put special emphasis on that “in line with the agreed operational definition of synthetic biology.., components and products of synthetic biology are expected to have similar positive and negative impacts on biological diversity as those of classical genetic engineering. However, *the potential positive and negative impacts of synthetic biology may be broader and more wide-ranging* due to the potential of synthetic biology to engineer more complex organisms and biological systems for use in a varied range of applications” and notes that 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, and have therefore more unpredictable effects. Since the level of uncertainty in risk assessment may increase with regard to the impacts on biodiversity and human health, more time is needed to complete any risk assessment in connection with LMOs produced by synthetic biology.

3.6. Best practices on risk assessment and monitoring regimes currently used by Parties to the Convention and other Governments

3.7. Degree to which the existing arrangements constitute a comprehensive framework in order to address impacts of organisms, components and products resulting from synthetic biology, in particular threats of significant reduction or loss of biological diversity

59: Hungary is of the opinion that current risk assessment approaches and methodologies must be adapted to address matters that are of particular relevance to synthetic biology, especially the challenges in establishing meaningful comparators, the higher levels of uncertainty in assessing the environmental/health impacts of organisms of synthetic biology.

