

## Hungarian Comment on the

### " UPDATED REPORT AND SYNTHESIS OF VIEWS IN RESPONSE TO PARAGRAPH 7(b) OF DECISION XII/24 ON NEW AND EMERGING ISSUES: SYNTHETIC BIOLOGY"

#### I. Background

#### II. RELATIONSHIP BETWEEN SYNTHETIC BIOLOGY AND BIOLOGICAL DIVERSITY

16: Hungary would agree with the view that discussion on the relationship between synthetic biology and biodiversity should focus on all components of synthetic biology.

17: According to Hungarian experts an increase in the complexity and range of synthetic biology tools and techniques may also lead to an increase in the uncertainty and unpredictability of their outcomes, making it harder to predict their effects on biodiversity, leading to the need for stricter measures to prevent damage to biodiversity.

18: Hungary would call for the application of the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development.

19: Hungarian experts agree that the changes in some of the organisms and products may not be easily detectable and an assessment of the impacts on biodiversity can only be performed if the process is taken only as a starting point. Hungarian experts are of the opinion that as with LMOs/GMOs the process of production should have been also evaluated because of unexpected effects, (such as insertional mutagenesis, etc. in case of some LMOs) in addition to evaluating the product, and supports the idea of focusing future debate on the relationship between synthetic biology and biodiversity on both the outputs and the process in a mutually supportive rather than competing elements of assessment.

21: Hungary support the conclusion that since no one fully understands the risks posed by synthetic organisms to the environment (and also to health), there are challenges as to what kinds of information is needed to support rigorous risk assessments, or who should collect such data.

22: Hungarian expert agree that the potential damage resulting from organisms, components and products of synthetic biology techniques also needs to be addressed through a liability and redress regime.

#### III. SIMILARITIES AND DIFFERENCES BETWEEN LIVING MODIFIED ORGANISMS (AS DEFINED IN THE CARTAGENA PROTOCOL) AND ORGANISMS, COMPONENTS AND PRODUCTS OF SYNTHETIC BIOLOGY TECHNIQUES

26.(a,b) Hungarian experts disagree with the statements “LMOs are organisms developed by incorporating a single or a few gene(s) of interest, whereas organisms constructed by means of synthetic biology techniques are likely to have larger segments of modified DNA or even complete novel genomes”. According to their view there is no defined number or limit of genes incorporated to LMOs. Stacked GMOs with 10 or more genes exist and are defined as LMOs. In addition there are LMOs in which gene have been silenced and not added, and they are still defined as LMOs. According to Hungarian experts any living organisms in which the genome has been modified by laboratory means, are termed as LMOs (GMOs), including living products of synthetic biology.

27. Hungarian experts share the view that “current techniques of synthetic biology do not develop organisms that are entirely synthetic. Rather, they create artificial genetic material, which is then inserted into bacterial cells from which the original genetic material has been removed.” Therefore, it is important to highlight that such organisms are LMOs obtained through modern biotechnology as per the Cartagena Protocol on Biosafety.

#### IV. OPERATIONAL DEFINITION OF SYNTHETIC BIOLOGY, COMPRISING INCLUSION AND EXCLUSION CRITERIA

28-34: Hungary agrees with the definition of the AHTEG, but suggests that the LMO definition also covers living organisms produced by synthetic biology. May be the definition in the protocol should be changed by adding a clarification to that effect that LMOs are also those living organisms, in which the genetic material has been modified by laboratory methods using natural, modified and/or synthetic genetic material.

#### V. POTENTIAL BENEFITS AND RISKS OF ORGANISMS, COMPONENTS AND PRODUCTS ARISING FROM SYNTHETIC BIOLOGY TECHNIQUES TO THE CONSERVATION AND SUSTAINABLE USE OF BIODIVERSITY AND RELATED HUMAN HEALTH AND

35: Hungarian experts would suggest that the components, organisms and products of synthetic biology are expected to produce similar, broader and more intense impacts, both positive and negative, as classical genetic engineering on biological diversity.

36: Based on the experience with GMOs it is believed that the benefits of synthetic biology if any, will come with a higher environmental cost, especially in case of (b: by producing synthetic e.g. flavours, scents, dyes), (d:) and (e: remembering synthetic chemicals, plastics), while all disadvantages listed in 37 are likely to occur.

#### VI. BEST PRACTICES REGARDING RISK ASSESSMENT AND MONITORING REGIMES CURRENTLY USED BY PARTIES TO THE CONVENTION AND OTHER GOVERNMENTS

40: It was seen by herbicide-tolerant GMOs how the best practice of risk assessment had been carried out and applied with a science-based approach, the results were the emergence of herbicide resistant weeds all over the World, and massive environmental damage. All this could happen because there were no scientific data to show that this sort of damage have occurred earlier. According to Hungarian experts the risk assessment of synthetic biology should consider and be based upon the precautionary principle.

41: Taking again the example of GMOs, monitoring as it is carried at present has never identified any harmful effect of a GMO, and it is unlikely that it ever will.

#### VII. ADEQUACY OF EXISTING NATIONAL, REGIONAL AND/OR INTERNATIONAL INSTRUMENTS TO REGULATE THE ORGANISMS, COMPONENTS OR PRODUCTS DERIVED FROM SYNTHETIC BIOLOGY TECHNIQUES

#### VIII. DEGREE TO WHICH THE EXISTING ARRANGEMENTS CONSTITUTE A COMPREHENSIVE FRAMEWORK IN ORDER TO ADDRESS THE IMPACTS OF SYNTHETIC BIOLOGY, IN PARTICULAR THREATS OF SIGNIFICANT REDUCTION OR LOSS OF BIOLOGICAL DIVERSITY

52: Hungarian experts have the opinion that the principles and methodologies of risk assessment and risk management measures established for LMOs can serve as a basis for addressing potential adverse effects associated with organisms developed through synthetic biology. However, they want to emphasise the importance of the precautionary principle and a cautious approach in connection with potential adverse effects associated with organisms developed through synthetic biology.

#### IX. OUTLOOK AND POSSIBLE ELEMENTS OF A WAY FORWARD

57: Hungary fully agrees with 57, especially with (a), (g (i), (ii)) and (h).