Information that is relevant to the work of the AHTEG, including views on:

1. **How to address the relationship between synthetic biology and biological diversity**;

The Convention on Biological Diversity (CBD) already covers the conservation, sustainable use and fair and equitable sharing of the benefits arising out of the utilization of genetic resources. CBD should also be used to address the relationship between Synthetic Biology and Biological diversity and there is several articles, including article 7, 8, 10, 13, 14, 17, that seems very relevant for products arising from synthetic biology processes.

1. **The similarities and differences between living modified organisms (as defined in the Cartagena Protocol) and organisms, components and products of synthetic biology techniques;**

Synbio products arise from techniques that currently fall within the definitions laid out in CBD and the Cartagena Protocol on biosafety to the CBD (CP), thus they should be considered LMOs. Upstream and downstream supporting technologies, like cell transformation methods and regeneration methods are no different in the synbio products than in the products currently regarded as LMOs. Most of the LMOs today consist of a novel combination of genes and DNA sequences that does not occur in nature (i.e. virus promoters coupled to bacterial proteins etc) and is constructed synthetically before inserted into the genome. There is therefore a strong link between current LMOs and synthetic biology already.

Many new biotechnology techniques like nuclease directed mutagenesis (including CAS9/CRISPR), oligo-directed mutagenesis and other genome editing techniques falls under the definition of modern biotechnology in CP and products made by these techniques would therefore meet the criteria of a LMO.

Synbio products would not only constitute living modified organisms, but also products made from Synbio living organisms or separate in vitro techniques from synthetic constructs or processes. Synthetic biology would therefore be wider than living organism and also wider than the aspects covered by CP.

1. **Adequacy of existing national, regional and/or international instruments to regulate the organisms, components or products derived from synthetic biology techniques;**

As products of Synthetic biology processes are not covered fully by CP, there is a need to reach adequate national, regional and international agreements on how to implement regulation of these products. It is also unclear if and to what extent these products could be regulated under the existing regulatory bodies or if new regulatory systems needs to be developed.

1. **An operational definition of synthetic biology, comprising inclusion and exclusion criteria;**

Although we are unable to suggest a satisfying operational definition on synthetic biology at the current time, the definition agreed upon should encompass not only techniques in which the utilization of nucleic acids and *de novo* genetic constructs are produced, but also take into account direct genome editing techniques in which changes are made in the genetic make up of the organism. This could be for instance, changes in methylation patterns. It is also important that the definition is not only restricted to living organisms but also to products thereof.

1. **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 socioeconomic impacts relevant to the mandate of the Convention and its Protocols;**

Release of organisms into a new environment is always connected to risks to the conservation of biodiversity, and many of the synthetic biological organisms are intended for release into the environment Particularly in areas of bioremediation and in suppression of insect populations (i.e. daughterless technology and overcoming plant pests). New techniques with synthetic constructs, like RNAi, has been suggested to be used for combating plant pest populations and while the benefits to this is obvious, the risks and knowledge gaps are huge, as stated by the report from a scientific workshop on issues related to risk assessment of RNAi-based GM plants (doi: 10.1111/pbi.12305). There is a general lack of understanding how biological processes interact with synthetic constructs, particular for new technologies like synthetic biology.

1. **Best practices on risk assessment and monitoring regimes currently used by Parties to the Convention and other Governments, including transboundary movement, to inform those who do not have national risk assessment or monitoring regimes, or are in the process of reviewing their current risk assessment or monitoring regimes;**

The guidance for risk assessment developed by two ad-hoc technical comities also includes a road map for risk assessment of LMOs, that although not currently sufficiently covers synthetic biology products and organisms, could be extended to address these as well. Special care should be taken to also address products arising from Synthetic biological processes or organism and direct genome editing techniques that do not currently falls under the definition of LMOs.

1. **The degree to which the existing arrangements constitute a comprehensive framework in order to address impacts of organisms, components and products resulting from synthetic biology relevant to the objectives of the Convention on Biological Diversity and its Protocols, in particular threats of significant reduction or loss of biological diversity;**
2. **Information on measures undertaken in accordance with paragraph 3 of the decision, including the identification of needs for guidance**

In accordance with paragraph 3 of the decision, GenOk – Centre for Biosafety is planning to coordinate two capacity building workshops together with partners in Norway, Africa and Asia on the biosafety connected to Synthetic Biology, where the questions addressed in paragraph 3 will be discussed and reported on.

1. **Further information on the components, organisms and products resulting from synthetic biology techniques that may have impacts on the conservation and sustainable use of biological diversity and associated social, economic and cultural considerations.**