**India’s submission on information that is relevant to the work of the**

**AHTEG on synthetic biology**

 **(i) How to address the relationship between synthetic biology and biological diversity**

As we continue to document biological diversity using modern methods such as environmental metagenomics, we become aware of new previously undescribed classes of organisms, primarily microbes, as well as their genetic repertoires. Today’s synthetic biology makes use of natural genes and proteins as its basic building blocks and makes changes in these as needed using tools of modern biology and mathematical analysis. The larger the base of known diversity, the greater the chance of novel building blocks being put to novel environmentally-sound uses.

Synthetic Biology has multiple application scenarios, including those given below:

1. origin from *ab initio* synthesized genes, which when contained in a secure environment for industrial applications has no consequence for biological diversity. For example, engineered **organisms** like *E.coli* and Yeast (and maybe other hosts) with recombinant proteins for production of specific compounds, when used in contained environment, would have no effect on biological diversity.
2. New hosts that have been discovered are used for industrial applications and or used in environment for applications like bioremediation etc.  In the first case, there may be issues relating to intellectual property from the application perspective. In the second case, a more detailed study is carried out on its impact on the environment including the effect on the ecosystem.
3. Engineered hosts being released to environment for applications in environment, food etc.

Synthetic biology can also be used to simulate biological diversity in the laboratory to study the evolution of the organism or to understand evolution of certain traits.

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

 Handling, exposure and release of components and products of synthetic biology techniques that are not living may be governed more by environmental chemistry safety regulations (as these are non-living and hence, chemical in nature).

  Living modified organisms (LMOs) are genetically modified organisms that are constructed by modern biological methods incorporating a single or fewer gene(s) of interest. On the other hand, organisms constructed by means of synthetic biology techniques are likely to have larger chunks of modified DNA representing multiple genes, regulatory elements and/or metabolic pathway inserted in the genome, or even complete reconstruction of the genome of a given organism. Synthetic biology techniques have commonly been used to design metabolic on/off switches to generate favorable environment for production of desirable products. With the help of bioinformatics and synthetic biology, scientists can design and construct pathways for producing completely novel products that were never synthesized biologically before. For example, it has been shown that chemically synthesized/modified bases can also be incorporated in synthesized DNA fragments, thus producing artificial amino acids.

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

Synthetic biology can offer benefit to the mankind in terms of constructing organisms for producing useful products as well as making models for understanding human diseases. While regulation is in place for addressing LMOs, there is a need to put adequate systems in place in consultation with scientists from synthetic and systems biology fields. The general principles of containment of LMOs are applicable to regulate organisms, components or products derived from synthetic biology techniques as well. In certain cases, and if there is reason to believe that the introduction of the new genes/ pathways poses an increased safety hazard , the synthetic biology-derived organisms may be put at one level above the base organism in the Biosafety Level (BSL) criteria, e.g., a synthetic biology derived organism derived from a BSL-1 organism may be put under BSL-2. It is also important that centralized facilities be created to characterize these organisms at metabolomic (to ensure no harmful product is synthesized inadvertently) and at genomic level (to ensure that the unintended affects at the genome level are properly characterized).

**(iv)   An operational definition of synthetic biology, comprising inclusion and exclusion criteria;**

Operational definition of Synthetic Biology: Synthetic Biology is a science of constructing biological parts, pathways and organisms towards useful social outcomes.

**Inclusion criteria**:

* Engineering (i.e., design and assembly) of novel biological components and organisms. Biological components include biomolecules (DNA, RNA, Protein), modules (e.g., operon, transcription factor complex), pathways and networks.
* Synthesis of novel DNA, RNA and Protein parts (includes both naturally and non-naturally derived materials)
* Long DNA synthesis technology Protein Synthesis technology
Input / output data that describes behavior of biological components in a range of conditions.
* BioCAD and other similar tools that offer design and assembly of biological components and organisms

**Exclusion Criteria**

1. Study on naturally synthesized biological components (molecules to networks)
2. Standard recombinant DNA methods
3. Standard bioinformatics and computational biology tools
4. Approaches that do not lead towards engineering of biological components and

organisms

Synthetic biology is an extension of conventional molecular biology, which utilizes modern tools and understanding of genetic engineering, electric engineering and systems biology. An overall goal of synthetic biology is to design and build engineered biological systems that process information, produce green chemicals, provide energy and assist in enhancing human nutrition and health. A simple recombinant protein expression cannot be considered as synthetic biology. Rather a complex engineering of genome, typically targeting multiple genes, or introducing multiple heterologous or artificial genes, may be considered in the inclusion criteria.

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

The potential benefits relate to health, food, environment materials and fuel. Essentially, it is about designing a product that will generate a socially useful outcome faster, in a more environment friendly way that will in time be also less expensive. Examples include biofuels, green chemicals, therapeutic molecules and so on. Towards this, a system is needed that not only encourages innovation, but also fosters an open legal framework and transparency, leading to awareness by the public and oversight by an informed collection of governments worldwide, for environmentally sound uses of synthetic biology techniques.

The use of synthetic biology techniques can lead to replacing non-eco friendly chemical processes with biological production processes, by deploying recombinant bacteria, fungi, cell cultures and on occasions, plants and other higher organisms.   This has the potential of not only reducing carbon foot-prints but also dramatically reducing the environmental hazards of industrial chemical processes.  This may also contribute to reduction of damage to the environment by not using toxic chemicals and processes. Thus, the cost of health and socioeconomic impacts of processes originating from synthetic biology may be assessed and evaluated in relation to its potential to replace hazardous and polluting chemical (especially petrochemical) processes.

Biodiversity may tend to be negatively impacted in the absence of demonstrating its usefulness and contribution to the economic progress of society.

The science of synthetic biology is new. To be able to identify and demarcate safe zones with warning signs at various points in the design process would requires generation of sufficient data and experience.

**(vi)      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**;

In India, robust risk assessment practices (BSL level 1-4) are already in place. However, separate funding avenues and guidelines for including novel synthetic organisms in one of these four levels would be required in future.

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