Comments from 'Indian Council of Forestry Research and Education', Dehradun (India)

Sub: Submission of Information on Synthetic Biology (action required by 30 April 2015)

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

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

The relationship between biological diversity and synthetic biology has not been systematically analysed, hence, elaborate analysis on this aspect is needed.

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

Synthetic biology refers to a) the design and fabrication of biological components and systems that do not already exist in the natural world. It uses unnatural molecules to mimic natural molecules with the goal of creating artificial life; and b) the redesign and fabrication of existing biological systems. It uses natural molecules and assembles them into a system that acts unnaturally.

Living modified organism means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

Products of both the technologies do not occur naturally.

LMOs are developed through recombinant DNA technology whereas products of synthetic biology are developed through combination of techniques/technologies of chemistry, biology, engineering, biotechnology etc.

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

There are a number of issues and concerns raised about synthetic biology, such as biosafety concerns from unintended release, which may or may not be similar to those associated with LMOs developed through 'conventional' genetic engineering; matters relating to risk assessment, monitoring, recall and liability; socioeconomic issues including potential threats to livelihoods and sustainable use of biodiversity because of introduction of synthetic versions of natural products; possibility of misuse of technology for bio-weapons; and human health concerns etc. Hence, the existing national, regional and/or international instruments to regulate the organisms, components or products derived from synthetic biology techniques are inadequate.

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

Synthetic Biology may include design and fabrication of biological components and systems that do not exist in the natural world and redesign and fabrication of existing biological systems. This may exclude the LMOs and GMOs as they are thoroughly elaborated in focused manner in Cartagena and Nagoya- Kuala Lumpur Protocols.

(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;

Benefits- The goal of synthetic biology is to solve problems that are not easily understood through analysis and observation alone and it is only achieved by the manifestation of new models.

Risks- Accidental release of unintentionally harmful organism and design and release of intentionally harmful organism (bio-weapons).

(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;

Does not pertain to ICFRE

(vii) 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;

More importantly, synthetic biology may promote digital access to information contained in the genetic resources, without physical access to the genetic resources and may evade Nagoya protocol on access and benefit sharing (ABS).

(b) Information on measures undertaken in accordance with paragraph 3 of the decision, including the identification of needs for guidance; and

There are gaps and inadequacies in the current regulatory framework in respect of synthetic biology techniques. The existing regulations governing genetic engineering were framed much before the emergence of synthetic biology. Hence, precautionary approach adopted by COP-11 may continue to be the guiding principle.

(c) 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.

The information may continue to be gathered by the Secretariat on these techniques, a compilation of which may be considered by SBSTTA prior to COP-13.