**Relevant information on components, organisms and products resulting from synthetic biology techniques**

**(China)**

**1. Whether synthetic biology is a new and emerging issue related with biological conservation and the sustainable use of its components.**

At present, the scientific community has not yet found credible evidence to prove that synthetic biology may have impacts on the biological conservation and the sustainable use of its components. For that consideration, it is not appropriate to address synthetic biology as a new and emerging issue.

If the application of synthetic biology techniques had been identified as a new and emerging issue related with biological conservation and the sustainable use of its components to be addressed by the COP, then it is believed several overlaps and gaps could be identified with the applicable provisions of the Biosafety Protocols and the Nagoya Protocol related to this technology.

**2. Possible gaps and overlaps with the applicable provisions of the Biosafety Protocols related to components, organisms and products resulting from synthetic biology techniques**

Some provisions of the Biosafety Protocol realize the administration of components, organisms and products resulting from synthetic biotechnology， but there still have some gaps. They are article 1, 3, 4, 5, 15 and 16. The following conclusions could be drawn:

1) The objective of the Biosafety Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology (article 1), and specifically focusing on transboundary movements (scope). However, the article 5 (pharmaceuticals) also provided this Protocol shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organizations. Therefore, the Protocol does not apply to the transboundary movement of pharmaceuticals that resulting from the commercialization of synthetic biotechnology.

2) The modern biotechnology referred in sub para (i) article 3 (use of terms) means the application of:

a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or b. Fusion of cells beyond the taxonomic family. Such technology can overcome natural physiological reproductive or recombination barriers, and it is not techniques used in traditional breeding and selection. According to the definitions given by  the scientific community, some synthetic biotechnologies do not fall into the scope of modern biotechnology which defined in this Protocol, such as minimal genome, protocells, some chemical synthetic biology methodologies (i.e. the synthesis the other types of XNA by replacing sugar molecules, rather than DNA) and synthesis of artificial life, etc. Therefore, modern biotechnology referred by the Protocol could not complete cover all synthetic biotechnologies.

3) Article 15 (risk assessment) could be the basis of environment risk assessment of the components, organisms and products resulting from synthetic biology techniques, and article 16 (risk management) have also give parties the rights to regulate the environment release of the components, organisms and products resulting from synthetic biology techniques. Therefore, Parties could regulate such components, organisms and products in accordance with article 15 and 16 of the Protocol.

In summary, the Biosafety Protocol could partly meet the Parties’ regulatory needs to transfer, handling, use, environment risk assessment and management of components, organisms and products resulting from synthetic biotechnologies.

However, the term of modern biotechnology need to be revised to ensure all synthetic biotechnologies, including minimal genome, protocells, chemical synthetic biotechnolog y and synthesis of artificial life.

For the products resulting from synthetic biotechnologies, whether it is appropriate to evaluate and regulate the social, economic and culture impacts caused by such products, depending on the legitimacy, rationality and necessity for the CBD to take measures on it.

3. **Possible gaps and overlaps with the applicable provisions of the Nagoya Protocols related to components, organisms and products resulting from synthetic biology techniques.**

Some provisions of the Nagoya Protocol have relationship with the components, organisms and products resulting from synthetic biology techniques. They are article 3, 5, 15 and 17. The following conclusions could be drawn:

1) According to Article 5, 15 and 17, the user of genetic resources shall share the benefits arising from the utilization of genetic resources with the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. User countries shall also take measures, as appropriate, to monitor and to enhance ransparency about the utilization of genetic resources. However, the application of synthetic biotechnologies could provide the user an opportunity to synthesis genetic resources they need after access to the information (i.e. DNA or molecular structure) of genetic resources, rather than genetic resources itself. Thus the benefit sharing with providers could be avoided due to the information of genetic resources does not fall within the scope of the Nagoya Protocol.

2) The components, organisms and products resulting from synthetic biology techniques is out of the scope of the Nagoya Protocol, because the genetic resources resulting from such techniques do not come from the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. However, only the benefits arising from the utilization of the genetic resources deriving from the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention shall be shared according to the Article 15 (genetic resources) of the CBD and the Nagoya Protocol.

In summary, the application of synthetic biology techniques may have the potential damage to the benefits of the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. However, there is hardly any commercialized product resulting from synthetic biology techniques, and no scientific report could be found to prove such product does harm to the conservation and sustainable use of genetic resources, and has substantial social, economic and cultural impact.