U.S. Submission in Response to the Invitation for Peer Review
Of the Outcomes of the Process
In Response to Decision XII/24 on Synthetic Biology
30 January 2016

The United States appreciates the opportunity to provide its views in response to the CBD Secretariat's invitation in Notification 2015-139 dated 3 December 2015 to provide comments during the peer review process for reports generated as outcomes of the process in response to Decision XII/24 on Synthetic Biology. We also appreciate the Secretariat's work capturing the diversity of opinions and interventions expressed in the online forums and the Ad Hoc Technical Expert Group on Synthetic Biology. The U.S. comments are focused on the Report of the meeting of the Ad Hoc Technical Expert Group on Synthetic Biology: UNEP/CBD/SYNBIO/AHTEG/2015/1/3UNEP/CBD/SYNBIO/AHTEG/2015/1/3.

Adoption of the working definition of synthetic biology by the Convention

The United States does not support the proposal for the Convention to adopt the Ad Hoc Technical Expert Group on Synthetic Biology's (AHTEG) operational definition of synthetic biology (para 66a). This working definition was developed by a small group of experts to aid the AHTEG members in understanding the parameters of the topic being discussed, and thus how synthetic biology may relate to the Convention's objectives. There are many definitions of synthetic biology in use around the world, which the AHTEG consulted when composing this definition, and we think it is important for countries to be able to use definitions that fit their research and oversight context. For example, many scientists in the United States and elsewhere understand synthetic biology to encapsulate a continuum of biological engineering tools and techniques leading to progressively advanced biotechnology products. Adopting any specific definition under the Convention may imply that Parties should use the Convention's definition for the purposes of implementing the Convention and its Protocols.

Adoption of a definition that contains elements irrelevant to specific research or oversight objectives of a Party could unnecessarily constrain the achievement of their objectives. Furthermore, the proposed definition appears to overlap substantially with the definition of a Living Modified Organism (LMO) under the Cartagena Protocol on Biosafety. This overlap raises the question of whether the activities envisioned under the Convention or its Protocols are duplicative with respect to the existing international bodies that develop standards and guidance with respect to protecting the health of plants, animals, and humans (e.g., International Plant Protection Convention, World Organization for Animal Health (OIE), and Codex Alimentarius).

Relationship between synthetic biology and the Nagoya Protocol

The United States notes that digital genetic information is not covered under the Convention or the Nagoya Protocol and do not agree that there could be a shift in understanding of what constitutes a genetic resource. We therefore do not support calls to set up mechanisms for "clarifying the issue of digital genetic resource information as it relates to access and benefit sharing," and we stress the need to adhere to topics that are within the scope of the CBD and Nagoya Protocol. Additionally, we do not support including digital information (e.g., sequence data) under a definition of synthetic biology.

We would like to clarify that Articles 15 and 16 of the Convention are about access to genetic resources and access to technology transfer. Articles 15 and 16 of the Nagoya Protocol address compliance. Thus Paragraph 31 of the report should be revised to reflect this, ideally by removing reference to the Nagoya Protocol. Objective 3j on page 8 of the report should also be modified to reflect the text of the different Articles by deleting reference to the Nagoya Protocol.

We would like to clarify that the Nagoya Protocol focuses on the genetic resources used as starting materials before the new biotechnology product is generated, not the final product. Thus Paragraphs 39 and 41 should be revised in the report to include the idea that "fair and equitable benefits arising from the utilization of genetic resources **that provide inputs** into synthetic biology." Additionally, as the Nagoya Protocol does not cover digital information or sequence data, Paragraph 3m on Page 9 is not accurate and should not be included in the final report.

Finally, we note the need to adhere to Objective 3 of the Convention -- the fair and equitable sharing of benefits arising out of the utilization of genetic resources. Determining the fair and equitable sharing of benefits of synthetic biology or biological engineering as implied in Paragraph 62 of the report is outside the Convention's mandate.

Comprehensive framework for addressing the impacts of organisms, components, and products resulting from synthetic biology

The United States does not support the need for or development of a comprehensive framework for addressing the impacts of organisms, components, and products resulting from synthetic biology or biological engineering as proposed in Paragraph 65 of the report. We also do not think it necessary to assess potential gaps in under the Convention and its Protocols with regard to the components and products of synthetic biology as proposed in Paragraph 66j of the report, as there are many existing international forums whose scope of work encompasses addressing the safety of different products, whether they are chemicals, living organisms, pharmaceuticals, or other substances and products produced from biological engineering or otherwise.

Furthermore, it is up to each country to determine, in accordance with existing international obligations, how to conduct oversight of organisms, components and products resulting from biological engineering, including synthetic biology. Many countries already have regulatory frameworks to address safety to plants, animals and humans. In addition, the World Trade Organization Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) has already set out the rights and obligations governing trade in this area, and the SPS Agreement likewise addresses the relevant international standard setting bodies which provide standards and guidance for evaluating safety in a scientifically sound manner (e.g., Codex Alimentarius, International Plant Protection Convention, and the World Organization for Animal Health). Additional measures would be duplicative or possibly contradictory to existing instruments that provide such guidance.

Fostering research and innovation in emerging technologies

The United States believes that regulation and oversight of emerging technologies should protect safety, health, and the environment while avoiding unjustifiably inhibiting innovation, stigmatizing new technologies, or creating trade barriers. A great deal of research in the field of biological engineering

supports basic understanding of biological systems and contributes to a better understanding of how to address food security, environment, energy, and health challenges. Regulation and oversight should be based on the best available scientific evidence, and with an awareness of the potential benefits and costs of such regulation and oversight on basic research, product development, and commercialization. Any measures taken should have sufficient flexibility to accommodate new evidence and learning and to take into account the evolving nature of information related to emerging technologies and their applications.

Tapping into existing AHTEGs on Risk Assessment and Socio-Economic Considerations

The United States has concerns about bringing synthetic biology into existing AHTEGs on risk assessment and socioeconomic considerations under the Cartagena Protocol as proposed in Paragraph 66d of the report. These AHTEGs have full work programs and limited resources. The AHTEG on Risk Assessment and Management is on its second iteration of the basic Guidance document and has not yet reached consensus on this document. The United States would like to recall that Article 26 of the Cartagena Protocol on Socio-Economic Considerations is an optional, not mandatory, component for implementation. The AHTEG on Socio-Economic Considerations is already facing a considerable challenge in completing its mandate under its terms of reference. Adding synthetic biology to the work of the current AHTEGs would further delay ongoing work programs. The United States supports concentrating the efforts and resources of the current AHTEGs on completing the current programs of work.

Additionally, we believe it premature to attempt to evaluate the socio-economic considerations arising from the impact of living modified organisms from synthetic biology on the conservation and sustainable use of biological diversity, when we lack empirical evidence on the first precondition for such analysis: what are substantiated impacts on conservation and sustainable use of biodiversity from synthetic biology applications?

Coordinating and establishing synergies with other organizations

The United States supports coordinating with other international organizations whose mandates are relevant to synthetic biology, but we know of few that have taken up this topic in a substantive way and suggest removing the list in Paragraph 66e as it is speculative. In particular, the new UN Technology Facilitation Mechanism is not an organization, and its modalities are not yet formulated or agreed upon.

Continued information gathering using a clearinghouse mechanism

While we agree that continued discussion and collection of information around the topic of synthetic biology are useful, starting a new clearing-house for synthetic biology seems premature. The United States is concerned with continued use of the Biosafety Clearing House (BCH) to house compilations of information related to synthetic biology. As such the BCH was implemented to support the exchange of information to facilitate Parties' obligations and compliance with the terms of the Cartagena Protocol on Biosafety. The BCH is not meant as a general repository for information. To be useful, it is imperative that information submissions be managed for scientific rigor and quality, regardless of the mechanism by which Parties determine best to share information.