U.S. Submission on Synthetic Biology
In Response to Decision 14/19 on Synthetic Biology
15 February 2019

The United States is pleased to provide the following information in response to CBD Notification No. 2018-103

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

Further in the same decision, the Conference of the Parties invited Parties, other Governments, indigenous peoples and local communities, and relevant organizations to provide the Executive Secretary with relevant information to contribute to the work of the AHTEG, namely on:

(a) The relationship between synthetic biology and the criteria set out in decision IX/29, paragraph 12, in order to contribute to the completion of the assessment requested in decision XII/24, paragraph 2, building on the preliminary analysis prepared by the Executive Secretary in document SBSTTA/22/INF/17;

The United States supports efforts to ensure that the issue of synthetic biology be evaluated formally against the criteria in Decision IX/29. Our view is that the CBD Secretariat's contribution (SBSTTA/22/INF/17) to the completion of the assessment requested in decision XII/24 and reiterated in decision XIII/17 was not procedurally appropriate. Specifically, much of the content of the Secretariat's "analysis" was extraction of phrases out of context from AHTEG meeting reports rather than strict adherence to the consensus recommendations provided by AHTEG members. Accordingly, the Secretariat's "analysis" is not an accurate representation of AHTEG conclusions, and in the U.S. view, the relationship of synthetic biology to the criteria for new and emerging issues set out in decision IX/29 has not been properly evaluated. It is the work of the AHTEG on Synthetic Biology to explicitly conduct this analysis and provide its recommendations to SBSTTA.

(b) New technological developments in synthetic biology since the last meeting of the Ad Hoc Technical Expert Group in December 2017, including the consideration, among other things, of concrete applications of genome editing if they relate to synthetic biology, in order to support a broad and regular horizon scanning process;

Since the 2017 AHTEG, we have seen an increasing number of potentially beneficial applications of biotechnology tools with relevance to the objectives of the Convention. New applications of synthetic biology approaches have the potential to deliver beneficial applications in public health and medicine, agriculture, biomanufacturing, industrial processes, species conservation, environmental remediation, water resources management, and invasive species control, to name a few. For each of these new products, the United States applies a coordinated, risk-based system to assess and manage any potential health and environmental risks posed by biotechnology products, and to ensure biotechnology products are safe for the environment, health, research, production, and trade. This system facilitates oversight of planned introductions of biotechnology products into the environment and focuses on the characteristics of the

biotechnology product, the environment into which it will be introduced, and the application of the product – not the process by which the product is developed.

The United States encourages independent and cooperative scientific research, development, and capacity building in fields relevant to biotechnology and biological engineering, both domestically and with partners around the world. The United States also encourages the developers and users of these technologies (e.g., biotechnology companies, researchers, funders) to consider norms, standards, best practices, and technical safeguards that can identify and mitigate potential negative impacts while encouraging innovation that maximizes the potential benefits. The United States encourages Parties to make use of the mechanisms that the Convention already has at its disposal (e.g., the Cartagena Protocol on Biosafety, AHTEGs, Open Ended Online Fora, Biosafety Clearing House) to support the objectives of the Convention while ensuring support for the global research community conducting responsible research and development.

(c) The current state of knowledge by analysing information, including but not limited to peer-reviewed published literature, on the potential positive and negative environmental impacts, taking into account human health, cultural and socioeconomic impacts, especially with regard to the value of biodiversity to indigenous peoples and local communities, of current and near-future applications of synthetic biology, including those applications that involve organisms containing engineered gene drives, taking into account the traits and species potentially subject to release and the dynamics of their dissemination; and

The United States encourages independent scientific research, development, and capacity building in many fields relevant to biotechnology and biological engineering, both domestically and with partners around the world. For example, recombinant human insulin was first licensed in 1980 and is now used worldwide to treat diabetes in humans. Medical research with transgenic mice and other organisms produced through biological engineering has enabled the elucidation of diseases and therapies for humans and animals. Genetic engineering has improved crop production methods by reducing soil erosion, decreasing fuel and chemical pesticide use, increasing disease- and pest-resistance within plants, increasing on-farm insect biodiversity, raising crop product quality, and improving farm productivity and farmer income.

Genome editing techniques, including engineered gene drives, are expected to accelerate the rate at which scientists can apply biotechnology to address medical, environmental, and agricultural challenges. These technologies are also revolutionizing biological research, advancing our understanding of living organisms and systems, and becoming vital to powering the global economy.

Engineered gene drives have the potential to provide important benefits to conservation and human health, particularly in the areas of vector population control to help manage infectious diseases or to use new non-pesticide approaches to control pests that cause agricultural, economic, and environmental damage. At the same time, we consider that application of these technologies requires careful consideration by scientists and policymakers, to ensure that questions regarding safety and security are adequately addressed. In our view, governments, academia, and the private sector should collaborate to review governance and oversight

mechanisms and address potential risks associated with applications of genome editing and synthesis technologies in ways that preserve the benefits these applications are expected to provide.

The United States believes that regulation and oversight of emerging technologies, like engineered gene drives, should protect safety, health, and the environment while avoiding unjustifiable barriers to innovation, stigmatization of new technologies, or creation of trade barriers. We maintain that regulation and oversight should be based on the best available scientific evidence and be aware of the potential benefits and the potential costs of such regulation and oversight. To the extent possible, new technologies and their applications should in our view be considered within existing governance and legal frameworks. As with all emerging technologies, we believe policies should enable innovation and investment, and avoid *ex ante* regulation. Moreover, we consider that a balanced approach should be taken to provide sufficient flexibility to continually accommodate new knowledge, taking into account the evolving nature of emerging biotechnologies and their applications.

The U.S. government welcomes the opportunity to work with other governments to better understand the state of scientific advances, to consider appropriate steps to mitigate the potential risks from emerging technologies and to engage with research communities to achieve benefits.

(d) Living organisms developed thus far through new developments in synthetic biology that may fall outside the definition of living modified organisms as per the Cartagena Protocol.

The United States understands synthetic biology as it is discussed in the research and development community: a continuum of biological engineering tools and techniques that can lead to progressively advanced biotechnology products. In the U.S. experience, when making a policy decision regarding the safe handling and use of an organism, it is most valuable to consider: 1) the characteristics of the organism in question, and 2) the novelty of those characteristics. There are numerous internationally recognized resources in existence that provide frameworks for how to consider the characteristics of organisms:

United States Environmental Protection Agency (EPA):

- https://www.epa.gov/risk/risk-assessment-guidelines

International Plant Protection Convention (IPPC):

- https://www.ippc.int/en/core-activities/capacity-development/training-material-pest-risk-analysis-based-ippc-standards/
- http://www.fao.org/docrep/009/a0450e/a0450e00.htm
- http://www.acfs.go.th/sps/downloads/34163_ISPM_11_E.pdf

Organization for Economic and Cooperation and Development (OECD):

- http://www.oecd.org/chemicalsafety/biotrack/oecdandrisksafetyassessmentinmodernbiotechnology.htm

World Organization for Animal Health (OIE):

- http://www.oie.int/en/our-scientific-expertise/specific-information-and-recommendations/invasive-alien-animal-species/

World Health Organization (WHO):

- http://www.who.int/tdr/publications/year/2014/guide-fmrk-gm-mosquit/en/]

The operational definition of synthetic biology, carefully formulated by the AHTEG, was acknowledged by Parties as "a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems."

Article 3 of the Cartagena Protocol on Biosafety (CPB), provides the following definitions:

> g) "Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;
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> (h) "Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;
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> (i) "Modern biotechnology" means the application of:
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> a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
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> b. Fusion of cells beyond the taxonomic family,
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> that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

We recommend that Parties consider new developments in synthetic biology in line with their own national priorities and obligations under the Convention and its Protocols. We believe that the operational definition of synthetic biology can assist countries in considering new technological developments under the Convention. We consider that the definitions within the CPB provide countries with clear language with which to interpret a legally binding agreement.