U.S. Submission on Synthetic Biology
In Response to Decision XIII/17 on Synthetic Biology
16 June 2017

The United States is pleased to provide the following information in response to CBD Notification Ref.: SCBD/SPS/DC/DA/MW/86375

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

In paragraph 10 of decision XIII/17 the COP invited Parties, other Governments, relevant organizations and indigenous peoples and local communities to submit the following information to the Executive Secretary:

a. Research, cooperation and activities noted in paragraph 9 of decision XIII/17;

"9. Encourages Parties and invites other Governments and relevant organizations, in the context of the three objectives of the Convention and taking into account, if appropriate and in accordance with domestic legislation or national circumstances, socio-economic, cultural and ethical considerations:

(a) To conduct research on the benefits and adverse effects of organisms, components and products of synthetic biology on biodiversity, with a view to filling knowledge gaps and identifying how those effects relate to the objectives of the Convention and its Protocols;

(b) To promote and enable public and multi-stakeholder dialogues and awareness-raising activities on the potential benefits and potential adverse effects of organisms, components and products of synthetic biology on biodiversity, involving all relevant stakeholders and with the full and effective engagement of indigenous peoples and local communities;

(c) To cooperate in the development of guidance and capacity-building activities with a view to assessing the potential benefits and potential adverse effects of organisms, components and products of synthetic biology and, if necessary, updating and adapting current methodologies for risk assessment of living modified organisms to organisms resulting from synthetic biology, as appropriate;"

The United States understands synthetic biology to be a continuum of biological engineering tools and techniques enabling the development of progressively advanced biotechnology products. More than forty years of research, education, and product development using recombinant DNA techniques have led to clear benefits relevant to the Convention's objectives, and these benefits will continue with continued application of these biological engineering tools and techniques. 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.

The United States believes that regulation and oversight of emerging biotechnologies, as with other technologies, should protect safety, health, and the environment while avoiding

unjustifiable barriers to innovation, stigmatization of new technologies, or creation of trade barriers. Research in the field of biological engineering improves our understanding of biological systems and contributes to efforts addressing food security, environmental, energy, and health challenges. Regulation and oversight should be based on the best available scientific evidence, and with an awareness of the impacts of such regulation and oversight on basic research, product development, commercialization, and public health, safety, and security. Any measures taken should have sufficient flexibility to accommodate continually new knowledge, taking into account the evolving nature of emerging biotechnologies and their applications.

In addition to the extensive research of the private sector, a number of U.S. government departments and agencies fund research in the area of biological engineering, including the Departments of Agriculture, Defense, Health and Human Services, and Energy as well as the National Science Foundation; National Institute of Standards and Technology; and, the National Aeronautics and Space Administration. The research focuses on fundamental understandings of biological systems as well as technology development to speed the application of biological engineering and enable commercialization of research. There are specific programs in areas associated with stability and evolution of genetically engineered organisms, including mechanisms of containment and biosafety to reduce the likelihood of adverse effects as well as specific programs to examine the relationship between environmental pressures, ecology and evolution.

The National Science Foundation (NSF), in partnership with the Woodrow Wilson International Center for Scholars and the Center for Nanotechnology and Society at University of Arizona, developed a roadmap for progress in evaluating potential environmental risks associated with synthetic biology and assessing public perception and societal risks and benefits of biological engineering. Efforts at the NSF-funded Synthetic Biology Engineering and Research Center at University of California Berkeley (SynBERC) address environmental risk and societal concerns. An NSF-wide working group on synthetic biology that includes representatives from the biological sciences, physical sciences, engineering, and the social and behavioral sciences provides a mechanism for coordinating the agency's efforts in the area of synthetic biology and biological engineering. Finally, NSF has partnerships with a number of international entities including the United Kingdom's Biotechnology and Biological Sciences Research Council and the European Commission to fund research in the area of biological engineering and synthetic biology. In many of these joint research programs, consideration of the responsible conduct of research (including ecological and societal impact) is a review criterion. There are discussions about increasing such international activities, which could increase research capacity and training in partner nations.

b. Evidence of benefits and adverse effects of synthetic biology vis-à-vis the three objectives of the Convention;

The United States supports research and development of innovative applications of biotechnology and biological engineering. 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. We note that a great deal of the biological engineering research and development in the United States is aimed at reducing dependence on petroleum products as the primary substrates for production of many important chemicals and fuels.

The Cartagena Protocol recognizes the need to consider potential adverse effects that living modified organisms (LMOs) may have on the conservation and sustainable use of biological diversity, and also take into account risks to human health. In the absence of evidence of likely harm, the United States supports taking the least restrictive measures possible to achieve reasonable safety objectives. Notably, peer-reviewed, independent studies have demonstrated that the use of biotechnology crops has led to an increase in insect biodiversity on farms in the United States, largely by reducing the use of broad spectrum insecticides. https://www.nap.edu/download/23395

Under Article 26 of the Cartagena Protocol, Parties considering importation of LMOs may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity. Peer-reviewed, independent studies have quantified socio-economic aspects of biotechnology crops, including farmer adoption and changes in incomes. These studies have demonstrated that farmers in both the developed and developing world have adopted biotechnology crops at unprecedented rates, due to the benefits of increased farm productivity and on-farm profit. http://www.pgeconomics.co.uk/page/43/

c. Experiences in conducting risk assessments of organisms, components and products of synthetic biology, including any challenges encountered, lessons learned and implications for risk assessment frameworks;

Genome editing and synthesis technologies are expected to accelerate the rate at which scientists can develop applications of biotechnology to address medical, environmental and agricultural challenges. These technologies are also revolutionizing biological research, advancing our understanding of living organisms and systems, and are becoming vital to powering the global economy. At the same time, application of these technologies also brings associated safety and security concerns – including the possibility of accidental harm and intentional misapplication. Governments, academia, and private sectors should collaborate to review governance and oversight mechanisms and address risks associated with applications of genome editing and synthesis technologies in ways that preserve the benefits these technologies can provide.

Governance and oversight of emerging technologies, including genome editing and synthesis technologies should be based on an awareness of the potential benefits and risks, avoiding unjustifiable barriers to innovation, stigmatization of new technologies, or creation of trade barriers. At the same time, we have a collective and shared responsibility among government, academia, and the private sector, to safeguard the opportunities provided by these technologies against potential risks of accidents, misuse, and unanticipated consequences. The U.S. government is working with those in the private sector and academia most familiar with these

technologies and who will likely be responsible for making further advances to discuss current and future best practices and technical provisions that could be developed and instituted to help maximize benefits and minimize risks. The U.S. government welcomes the opportunity to work with other governments to better understand the state of scientific advances, consider appropriate steps to mitigate the potential risks from applications of genome editing and synthesis, and engage with research communities to achieve benefits.

d. Examples of risk management and other measures that have been put in place to avoid or minimize the potential adverse effects of organisms, components and products of synthetic biology, including experiences of safe use and best practices for the safe handling of organisms developed through synthetic biology;

The United States believes that transparency in decision making and public dissemination of methodologies used to develop and finalize decisions, are essential to the development and review of national risk assessment efforts. The United States has a transparent, robust, practical, science-based approach to enable the safe use of organisms for a variety of applications from education to research, to medical fields, to food production, crop production and animal husbandry. This approach embraces the spectrum of tools common to regulatory frameworks, ranging from guidance for best practices, to laws that set standards for product attributes, to regulations for specific activities and uses. The United States has mechanisms in place to ensure safety as well as to detect and monitor adverse health outcomes for humans, plants, animals, and the environment. We encourage sharing of these best practices.

In the realm of biomedical research, the National Institutes of Health (NIH) published its first guidelines for the creation and containment of recombinant DNA organisms in 1976. Updated guidelines, the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), were issued in 2013 to cover research involving recombinant or synthetic nucleic acid molecules, and detail safety practices and containment procedures for basic and clinical research involving recombinant or synthetic nucleic acid molecules, including the creation and use of organisms and viruses containing recombinant or synthetic nucleic acid molecules. Any entity receiving NIH funding for recombinant or synthetic nucleic acid molecule research is obligated to follow the NIH Guidelines for all research involving recombinant or synthetic nucleic acid molecules, regardless of a specific project's funding source. Many companies and other research institutions voluntarily follow the NIH Guidelines as best practice, even if they are not receiving NIH funding.

The U.S. government has also issued voluntary guidance to manufacturers of synthetic DNA (Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA, 2010) to reduce the potential risks arising from the use of synthetic DNA.

Moreover, there are a number of international fora and arrangements where nations can share, communicate and develop international guidelines for regulatory frameworks and risk management. Some, such as the Organization for Economic Co-operation and Development's (OECD) Environmental Risk Assessment Toolkit, offer guidance on risk assessment and provide consensus information useful in a risk assessment. The United States participates in the OECD Working Group on Harmonization of Regulatory Oversight in Biotechnology, which produces

consensus documents on the biology of organisms as well as guidance documents relevant to risk assessment practices. The United States serves as a Vice Chair in the OECD Working Party on Bio, Nano and Converging Technologies (BNCT), in which synthetic biology issues are also addressed.

e. Regulations, policies and guidelines in place or under development which are directly relevant to synthetic biology;

The United States believes that regulation and oversight of emerging technologies should protect safety, health, and the environment while avoiding unjustifiable barriers to innovation, stigmatization of new technologies, or creation of trade barriers. Regulation and oversight should be based on the best available scientific evidence, and with an awareness of the potential benefits and the potential costs of such regulation and oversight. Any measures taken should have sufficient flexibility to continually accommodate new knowledge, taking into account the evolving nature of emerging biotechnologies and their applications.

The United States has a coordinated, risk-based system to protect the environment and human and animal health, 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. Established as a formal policy in 1986 under the auspices of the Office of Science and Technology Policy (OSTP) in the Executive Office of the President, the Coordinated Framework for Regulation of Biotechnology describes the federal system for evaluating the safety of products developed using modern biotechnology (https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf). For example, in the case of genetically engineered plants, the U.S. agencies primarily responsible for oversight of the products of agricultural biological engineering include the Environmental Protection Agency (EPA), the Department of Agriculture's Animal and Plant Health Inspection Service (USDA-APHIS), and the Department of Health and Human Services' Food and Drug Administration (FDA). To consider another example, FDA's regulations for pharmaceutical approvals apply in the case of using genetically engineered microorganisms to produce recombinant human insulin – a product of biotechnology that was first licensed in 1980.

The EPA uses the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) to regulate the distribution, sale, use and testing of pesticidal substances including microorganisms and those plant-incorporated protectants produced in plants. The EPA uses the Toxic Substances Control Act (TSCA) to oversee the production, importation and use of microorganisms that are products of biological engineering, prior to commercialization of such organisms, including approval of research projects that intend to release engineered microorganisms into the environment. New chemical substances that result from biological engineering are also subject to review under related provisions of TSCA.

USDA-APHIS addresses the protection of plant and animal health under several laws, and these laws enable protection regardless of which biological engineering techniques are used. Directly

applicable laws under which APHIS protects plant and animal health are the Plant Protection Act, the Animal Health Protection Act, and the Virus Serum Toxin Act.

The FDA is responsible for ensuring the safety and proper labeling of human and animal foods, with the exception of edible meat and poultry, and processed egg products for human consumption, which fall under the authority of USDA. All foods, whether imported or domestic and whether derived from biological engineering techniques, must meet the same rigorous safety standards. Under the Federal Food, Drug, and Cosmetic Act, it is the responsibility of human and animal food manufacturers to ensure that the products they market are safe and properly labeled. In addition, any substance meeting the legal definition of a food additive in the United States must receive FDA approval before marketing. The FDA regulates genetically engineered animals under the new animal drug provisions of the Federal Food, Drug, and Cosmetic Act.

Using the current laws and regulations, the United States can address a range of products developed using biological engineering. The United States re-evaluates its regulations and approaches as new information and techniques become available. For example, the Update to the Coordinated Framework for the Regulation of Biotechnology was published in January 2017 (https://www.epa.gov/sites/production/files/2017-01/documents/2017_coordinated_framework_update.pdf), and the National Strategy for Modernizing the Regulatory System for Biotechnology Products, was published September 2016 (https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/biotech_national_strategy_final.pdf .)

Internationally, new frameworks to address biological engineering or resulting products are not needed. There are many arrangements for addressing the safety of different products, whether they are chemicals, living organisms, pharmaceuticals, or other substances and products produced from biological engineering or otherwise. Biological engineering products fall under a range of existing oversight mechanisms. For example, safety with respect to the health of plants, animals, and humans is already addressed under the Codex Alimentarius and the International Plant Protection Convention, as well as cooperative efforts under the World Health Organization, and the Organization for Economic Cooperation and Development. Like the United States, these international fora do not base their oversight on biological engineering techniques, but instead on the nature of the product and its intended use. Furthermore, it is the responsibility of each country to determine, in accordance with its existing international obligations, how to conduct oversight of organisms, components and products resulting from biological engineering, including synthetic biology. Many other countries also already have regulatory frameworks to address safety to plants, animals and humans.

f. Knowledge, experience and perspectives of indigenous peoples and local communities in the context of living in harmony with nature for comparison and better understanding of the potential benefits and adverse effects of synthetic biology.

The United States has existing programs to engage indigenous peoples via consultations, trainings, and other activities. As we continue to discuss current policy and potential new options for maximizing opportunities and minimizing potential safety and security risks

associated with the application of genome editing and synthesis technologies, the U.S. government will provide ample opportunities for stakeholder engagement and public participation to promote accountability, optimize decision-making, foster trust, and ensure that policy makers have access to timely and reliable information.