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Convention on Biological Diversity: Recent Decisions Affecting U.S. Engineering Biology

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The Convention on Biological Diversity (CBD) has three main objectives: the conservation of biological diversity, sustainable use of the components of biological diversity, and the fair and equitable sharing of benefits arising from the use of genetic resources. The United States is the only U.N. member state not to have ratified the CBD; however, it was signed and submitted to the Senate in 1993. The United States participates in certain CBD processes; including serving on ad-hoc technical expert groups. However, U.S. non-party status limits its ability to negotiate language and prevents the U.S. from voting on decisions. The potential impacts and oversight of engineering biology's tools, technologies, and applications are topics of sustained international interest within the CBD process. Decisions adopted at the CBD may affect the strategic competiveness of U.S. engineering biology researchers and companies, including how and where they can operate, as well as the use of their applications and products. Through its oversight of the State Department and other federal agencies, Congress may consider whether the U.S. position at the CBD is appropriate, how U.S. involvement affects decisions, and its impact on U.S. engineering biology researchers and companies.

Synthetic biology, a component of engineering biology, was introduced in the CBD in 2010 to examine whether the scope and definitions pertaining to biotechnologies in the CBD were sufficient. This included the development of an operational definition of synthetic biology. Two protocols to the CBD, the Cartagena Protocol on Biosafety (CP) and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (NP) also address engineering biology.

Engineering biology applications may challenge current risk assessment and oversight processes established by domestic and international frameworks, including the CBD. For example, engineered gene drives—genetic elements that have the potential to increase, or drive, the inheritance of a genetic trait through a population—are designed to spread throughout an environment, potentially crossing national borders, and, in some instances, integrate into a species' lineage. Whereas previous biotechnologies used in the natural environment have typically been designed to terminate after one life cycle or be contained in a particular area (e.g., genetically modified crops).

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Digital sequence information (DSI)—digitized data derived from genetic resources and a key enabling technology of engineering biology—has also been the focus of recent debate. The NP requires the sharing of benefits arising from the use of genetic resources in a fair and equitable way. Parties to the protocol have been negotiating whether DSI falls within its scope, and if so, whether the current access and benefit sharing (ABS) mechanisms are sufficient or whether a new mechanism is needed to incorporate DSI into the ABS framework.

The United Nations Biodiversity Conference in December 2022 adopted three decisions under the CBD, CP, and NP that potentially affect U.S. interests. In each instance below, Congress may examine through its oversight of the State Department and other federal agencies who may participate in and contribute to the activities described. In addition, Congress may examine what level of U.S. involvement is appropriate in order to determine its impact on and how resulting decisions may affect U.S. investments and strategic competiveness in engineering biology.

1. The parties adopted decision CBD/COP/15/L.18, which establishes a process for broad and regular horizon scanning (a method to help assess whether policies are adequate to deal with future technologies), monitoring, and assessment of the most recent technological developments in synthetic biology. The decision establishes an open online forum and multidisciplinary ad hoc technical expert group to support the processes. The decision invites Parties, other governments, indigenous peoples, local communities, and relevant organizations to submit information to inform the three processes to facilitate international cooperation, technology transfer, capacity building, and knowledge sharing.

   The horizon scanning process will likely capture research and applications developed with U.S. public and private investments.

2. The CP to the CBD aims to ensure the safe handling, transport, and use of living modified organisms (LMOs) that may have adverse effects on biological diversity and risks to human health. The December 2022 conference adopted decision CBD/CP/MOP/10/L.8, which establishes a process to develop additional voluntary guidance materials to support case-by-case risk assessment of LMOs containing engineered gene drives, with a focus on mosquitos. The decision calls upon Parties, other Governments, and relevant organizations to continue to disseminate information and share experiences related to risk assessments of LMOs, including living modified fish and organisms containing engineered gene drives.

   U.S. leadership and investment in the development of gene drives and expertise in risk assessments of biotechnologies could be of importance to help frame future decisions.

3. Decision CBD/COP/15/L.30, adopted at the December 2022 conference, recognizes that there are divergent views on the scope of DSI under the CBD. It also establishes a process to develop and operationalize a multilateral mechanism for benefit sharing from the use DSI on genetic resources. The decision does not change the compliance obligations of the NP regarding the utilization of genetic resources.

   Decisions made under this framework could affect U.S. companies and researchers that collaborate with, operate in, or require genetic resources from other countries. Specifically U.S. entities' access to, and use of DSI—including from databases containing DSI that U.S. researchers and companies collected and developed.

For additional CRS analysis on engineering biology see:

CRS Report R47265, *Synthetic/Engineering Biology: Issues for Congress*, by Todd Kuiken

CRS Report R47274, *White House Initiative to Advance the Bioeconomy, E.O. 14081: In Brief*, by Marcy E. Gallo and Todd Kuiken

CRS Report R44824, *Advanced Gene Editing: CRISPR-Cas9*, by Marcy E. Gallo et al.

CRS In Focus IF12285, *eDNA/eRNA: Scientific Value in What's Left Behind*, coordinated by Todd Kuiken

Author Information

Todd Kuiken
Analyst in Science and Technology Policy

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