## U.S. Views and Information Regarding Digital Sequence Information on Genetic Resources 31 May 2019

## **Terminology and Scope**

The United States defines digital sequence information (DSI) on genetic resources to refer to the genetic sequence data (GSD) that describe the order of nucleotides in DNA or RNA in genetic material. Recognizing that there is a lack of understanding of the term DSI on genetic resources, we use the more precise and broadly understood term, GSD, in our response going forward.

We note that GSD are neither genetic material nor a genetic resource. It is essential to maintain a conceptual and definitional distinction between genetic material itself and data associated with that material.

## U.S. views regarding access to GSD and benefit-sharing

The United States considers that GSD are essential for scientific research, including research that contributes directly to conservation and sustainable use of biodiversity. It is our view that ready access to publicly available information on genetic resources, including GSD, spurs innovation and provides other broad benefits for society, including enhancing scientific research and collaboration, increasing food security, and protecting public health.

We believe that the scientific norm of rapidly sharing information, including GSD, fosters international collaboration and is itself a form of benefit-sharing that creates other non-monetary benefits, such as voluntary capacity-building, education, and training. Recognizing that, the United States has made it a policy priority to promote access to scientific data resulting from federally funded research. We consider that the greater the amount of GSD that are shared broadly for study and comparative analysis, the greater the potential benefit for society.

As best practice, GSD are publicly available via international data repositories, such as GenBank and the International Nucleotide Sequence Database Collaboration, as well as in journals found in print and online, including pre-print publication resources. Most major scientific journals require that supporting data, such as GSD, be submitted to a publicly accessible database in order for manuscripts to be published. Both the U.S. National Institutes of Health and the National Science Foundation require papers that contain federally funded research data be made publicly accessible within 12 months of publication.

The U.S. Government supports several initiatives that enable the timely exchange of data that are essential for research, innovation, and protecting human, animal, and plant health. For example, the United States is a party to the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, a specialized international ABS instrument that explicitly recognizes exchange of information as a mechanism for benefit-sharing (ITPGRFA Article 13.2). The United States is also a partner in the Global Open Data for Agriculture and Nutrition (GODAN) initiative, which promotes proactive sharing of open data to address challenges and advance food security. In addition, U.S. researchers are collaborating internationally on the Earth BioGenome Project, an effort to sequence and make available GSD about all eukaryotes.

We believe that regulations that restrict or delay access to and sharing of GSD would likely lead to a significant reduction in data-sharing, which could negatively impact efforts to promote the sustainable use and conservation of biodiversity. We consider that moves to force changes to procedures for information management within laboratories would also carry significant costs and have negative implications for innovation. In our view, these dynamics could stifle research, hindering progress in agriculture, human and animal health, and other sectors.

We maintain that timely access to data, including GSD, and the international collaborations that develop around shared data, are key to achieving the objectives of the CBD and the Nagoya Protocol. We remain concerned about any effort to constrain, regulate, or introduce delays in the long-standing scientific best practice of rapid, open exchange of information, including GSD. These concerns are particularly acute for situations where timely access is essential, such as identifying and managing invasive species. We urge Parties to be mindful of potential detrimental effects on public and private research and innovation, for biodiversity conservation and other sectors.