United States Department of State
Bureau of Oceans, and International
Environmental and Scientific Affairs
Washington, D.C. 20520

20 September 2013

Dr. Braulio Dias
Executive Secretary
Convention on Biological Diversity
393 Saint-Jacques Street, Suite 300
Montréal, Québec, CANADA H2Y 1N9

Dear Dr. Dias:

The United States is pleased to have the opportunity to review the background document *New and Emerging Issues Relating to the Conservation and Sustainable Use of Biodiversity – Potential Positive and Negative Impacts of Components, Organisms and Products Resulting from Synthetic Biology Techniques on the Conservation and Sustainable Use of Biodiversity* prepared in response to Decision XI/11 on new and emerging issues relating to the conservation and sustainable use of biodiversity.

We appreciate the efforts of the Secretariat to continue to provide information for the Parties to the Convention on Biological Diversity to consider on this timely topic. Below and attached are our comments on the background document's content, scope, and balance for your consideration.

In our considered view, based on the information provided in the paper, synthetic biology does not appear to meet the criteria for a new and emerging issue as defined by Parties to the Convention. An analysis, as requested in decision XI/11, of whether the criteria set out in paragraph 12 of decision IX/29 apply to synthetic biology, was not done. Furthermore, the background paper's sections on potential positive and negative impacts of synthetic biology are not supported by peer-reviewed scientific literature. Instead, the content is overly reliant on non-peer reviewed white papers from organizations with a pre-determined point of view on synthetic biology.

We appreciate that the prospects for potential benefits of emerging technologies must be balanced by an awareness of possible risks. For example, the Presidential Commission for the Study of Bioethical Issues (2010) in the United States called for responsible stewardship of synthetic biology and for prudent vigilance to be exercised with regard to its potential risks. Such an approach carefully monitors, identifies, and mitigates potential and realized harms over time. As future developments in synthetic biology occur, decisions will be revisited and amended as warranted by additional information arising about potential risks and benefits.

Sincerely,

Barbara M. De Rosa-Joynt
Chief for Biodiversity
U.S. National Focal Point
for the Convention on Biological Diversity

Attachment: as stated.

U.S. comments on the *New and Emerging Issues Relating to the Conservation and Sustainable Use of Biodiversity-Potential Positive and Negative Impacts of Components, Organisms and Products Resulting from Synthetic Biology Techniques on the Conservation and Sustainable Use of Biodiversity*[1]

Lack of agreement on what constitutes synthetic biology and how it is novel
We support the acknowledgement that there is no agreed upon definition of synthetic biology, as evidenced by the various definitions proposed in Box 1 on Page 4, nor is there agreement on whether and how synthetic biology differs from conventional genetic engineering (i.e., recombinant DNA techniques). This point is illustrated on Page 9 where the author notes that while start-up companies often use the term synthetic biology, established companies with a history of genetic engineering rarely do. The lack of an agreed upon definition, and the fact that the report's author does not clarify which definition of synthetic biology they used, makes it impossible to determine which of the many current and near-term products listed in the report should be considered as synthetic biology or resulting from synthetic biology. For the same reason, it is also impossible to determine which of the many products listed (e.g., agricultural crops on Page 11) actually use modern biotechnology techniques considered "novel" or which fall into the category of synthetic biology. Furthermore, it is not evident that current advances in biotechnology demand a wholesale reconsideration of genetically engineered organisms in the context of conservation and sustainable use of biological diversity.

Most products reviewed in the report are not destined for environmental release
The report does not make it clear that many of the products mentioned (e.g., chemicals and medicines) are not destined for environmental release; the background document incorrectly implies that most synthetic biology applications are either already in the environment or will be soon. Many of the products profiled will be produced in contained facilities, with appropriate biosafety controls.

Reliance on non-peer reviewed literature and lack of balance in sources
We would like to call attention to the paper's reliance on non-peer reviewed literature from organizations that are dedicated opponents of synthetic biology. Evaluation and oversight should be based on the best reasonably obtainable scientific, technical, and other information, in order to facilitate an informed awareness of the potential benefits and risks. We note with concern that, instead of citing peer-reviewed publications, the background paper cites seventy-five times in thirty-three pages white papers from ETC Group, Friends of the Earth, and the International Civil Society Working Group on Synthetic Biology (a coalition organized largely by ETC Group and Friends of the Earth). Statements about potential biodiversity impacts of synthetic biology by such groups are neither scientifically peer-reviewed nor based on empirical analysis; thus the issue does not meet the requirements set forth by the Parties in Decision IX/29[2] for consideration as a new and emerging issue at the SBSTTA.

Scope of issues considered in the report outside of Convention on Biological Diversity
The scope of issues covered in the background document falls outside the objectives of the Convention. Biosecurity considerations relating to synthetic biology, potential pathways for biosecurity threats, and responses to biosecurity concerns (Pages 24-28) are not within the scope of an overview of how synthetic biology may impact conservation and sustainable use of biological diversity; biosecurity concerns are covered in other relevant bodies. Similarly, intellectual property considerations (Pages 32-33) related to synthetic biology are best handled in the World Intellectual Property Rights Organization and relevant trade-related agreements and processes.

[1] http://www.cbd.int/emerging/
[2] http://www.cbd.int/decision/cop/default.shtml?id=11672