

Executive Secretary  
Convention on Biological Diversity  
United Nations Environmental Program

**RE: Submission on decision COP XIII/16, paragraph 2, and Nagoya Protocol NP- 2/14: digital sequence information<sup>1</sup>**

From the Sustainability Council of New Zealand, a charitable trust and NGO

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## **CBD Protocols Require Protection from Bypass by New Technology**

**Advances in technology are set to undermine protections that parties have invested a great deal to secure through protocols to the CBD. They threaten to make bypass of the protocols routine unless steps are taken to amend treaty arrangements.**

It has become easier, cheaper, and faster to sequence organisms and, at the same time, gene synthesis and related synthetic biology technologies have made it possible to convert this data back into DNA and to use it in a living organism. Thus the need for the physical transfer of samples is waning: electronic transfer can suffice. The techniques are now capable of synthesizing and transmitting entire organisms of high economic value. Relevant data includes DNA, RNA, and amino acid sequences as well as accompanying characterization information.

Those manufacturing synthesis equipment and providing synthetic sequences are largely unregulated. In addition to the risk of bypass of the intent of the protocols and the potential for harm to biodiversity that this entails, the practice has raised national security concerns as the equipment allows transmission of copies of deadly pathogens that have been reproduced using synthetic methods.

Acknowledging the importance of upholding the objectives and articles of the Convention in the face of rapid scientific and technological innovation, it is submitted that the Parties to the Cartagena Protocol on Biosafety and the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress consider how best to extend requirements for advance informed agreement to address the risks presented by digital sequence transfers and the potential remedies identified below.

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<sup>1</sup> Pursuant to decision XIII/16, paragraph 2, I am pleased to invite Parties, other Governments, indigenous peoples and local communities, and relevant organizations and stakeholders to submit views and relevant information on any potential implications of the use of digital sequence information on genetic resources for the three objectives of the Convention. Pursuant to decision NP-2/14, paragraph 2, I also invite these submissions to include information relevant to the Nagoya Protocol.

One threat to the protocols arises from the ability to transfer representations of DNA sequences over the internet, such that no physical transfer takes place but the genetic code is virtually transferred so as to allow ready physical reproduction. A second threat arises from the ability for an LMO to be imported as a set of "latently viable" parts ready to be reconstituted, rather than the import of a whole viable organism. These threats could be addressed by insisting that sequence data be treated as equivalent to the physical LMOs it represents, and extending advance informed agreement rules as follows:

**Virtual Transfer:** If some part of the sequence of any nucleic acid component of an LMO is covered by a utility patent, and the sequence for the LMO is to be virtually transferred across a national boundary and used to physically produce an LMO, then prior informed agreement is required. Should such a sequence be transferred across national boundaries but there is no physical production of an LMO, no prior consent is required unless and until physical production is intended.

**Kitset LMOs:** If a series of nucleic acid sequences are virtually or physically transferred across a national boundary and used to physically produce an LMO, where some part of the sequence of any nucleic acid component of the LMO is covered by a utility patent, then prior informed agreement is required. Should such nucleic acid sequences be transferred across national boundaries but there is no physical production of an LMO, no prior consent is required unless and until physical production is intended.

### **Definitions**

- *Virtual Transfer:* The transfer of a nucleic acid sequence by means other than shipment of a physical copy, and includes but is not limited to electronic transfer of a representation of that sequence.
- *Utility Patent:* Issued for the invention of a new and useful process, machine, manufacture, or composition of matter, or a new and useful improvement thereof, it generally permits its owner to exclude others from making, using, or selling the invention. Note: The great bulk of patent documents issued by the USPTO in recent years have been utility patents, also referred to as "patents for invention".

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