Digital Sequence Information = Nucleotide Sequence Data! But more clarity is needed on its scope.

Introduction

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (the Nagoya Protocol on Access and Benefit Sharing (ABS)) is a supplementary agreement to the 1992 Convention on Biological Diversity and entered into force on October 12th, 2014. It aims to ensure a fair and equitable sharing of benefits arising from the utilisation of genetic resources and, if relevant, the use of any associated traditional knowledge (aTK).

While accepting the benefits of the use of Digital Sequence Information (DSI) for the three objectives of the Convention on Biological Diversity, the League of European Research Universities (LERU) strongly disagrees with the proposal to include DSI under the Nagoya Protocol. Inclusion of DSI would be against the spirit of open science, would damage environmental, life sciences and biodiversity research, and would be detrimental to less developed countries. Open access to DSI allows scientists from all over the globe - irrespective of finance, status or location - to be able to do molecular research. This undoubtedly aids provider countries as well as preventing single users from profiteering from what they have sequenced. Sharing data leads to cost savings in research projects and adds value to the data. Without open access to DSI, such research will be significantly hindered.

There is considerable uncertainty over the term DSI. LERU has submitted this short note to the Convention on Biological Diversity to outline both what we believe is meant by the term DSI and what DSI covers, and to outline some questions which need clarifying to ensure that the term is both legally robust and workable¹.

The Need for a Globally Accepted Legal Definition of Digital Sequence Information

There is currently no universally agreed definition of the term DSI². However, a clear universally agreed definition of DSI is essential in order to assess the potential impact of including DSI within the scope of the Nagoya Protocol. Hence, before discussing the potential for including DSI within the Nagoya Protocol, the scope of this discussion should be clearly focused, based on a shared, accepted and scientific definition of DSI.

It is our firm belief that DSI, for the overwhelming majority of scientists, only encompasses nucleotide/genetic sequence data, nucleotide sequence information or genetic sequences, which

¹ Part of this note was first published in November 2018, prior to the 14th meeting of the Conference of Parties to the Convention on Biological Diversity and the 3rd meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol on Access and Benefits Sharing in Sharm-El-Sheik, Egypt, in November 2018. https://www.leru.org/files/LERU-Nagoya-Statement-November-2018.pdf

² Fact-Finding and Scoping Study on Digital Sequence Information on Genetic Resources in the Context of the Convention on Biological Diversity and the Nagoya Protocol (CBD/DSI/AHTEG/2018/1/3) https://www.cbd.int/doc/c/b39f/4faf/7668900e8539215e7c7710fe/dsi-ahteg-2018-01-03-en.pdf

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we term 'nucleotide sequence data'. These are currently found within open access databases such as the INDSC (International Nucleotide Sequence Database Collaboration). Occasionally, it may be extended to encompass protein sequence data as well. It would be our preference to use the unambiguous term 'nucleotide sequence data' in place of the current placeholder term, 'DSI'³ which is unclear and open to considerable interpretation.

If DSI *is* considered within the scope of the Nagoya Protocol, it is crucial that there is a precise, and legally-binding definition of DSI. Without this, researchers, and other users, will risk inadvertently contravening the Protocol. Thus, LERU believes it is necessary to clarify what types of genetic sequences would be included under the umbrella term DSI. For example:

- Does DSI include genes, chromosomes, chromosome fragments, coding sequences, all of them or more?
- How should laboratory generated mutants (either developed through mass mutagenesis or precision approaches such as CRISPR) be handled? In LERU's view, the researcher developing the mutant should also be credited for his/her part in generating the material.
- How should identical genetic sequences found across different countries be dealt with? For example, sequences from river waters, migratory species, etc.?
- What are the tolerance levels for variations within a DNA sequence? Different organisms exhibit very different rates of mutation.
- How should environmental sequence data be handled? Much of the sequence data recovered in this case may not be attributed to a specific organism.
- How are artificial sequences and those consisting of novel base pairs treated⁴.
- What would come under 'scope' the specific use of DSI or the sequence?

In conclusion, LERU strongly supports further consultation with relevant parties in this area to develop a consensus view on what DSI is (and what it is not). Universities can, and should, play a major role in these discussions to ensure that the definition is fit for purpose and leaves no room for misinterpretation.

Perspective

The university sector carries out a large amount of sustainability and biodiversity research worldwide, mostly without commercial intent. Such research is vital at a time in which there is a growing acceptance of the urgent need for immediate, and more substantial, actions to promote conservation and prevent further biodiversity loss across the world.

LERU strongly believes that DSI should *not* fall within the scope of the Nagoya Protocol. In LERU's view, the benefits for biodiversity and conservation research arising from free and unhindered open access to digital sequence information far outweigh any potential (financial) benefits which providers could gain from restricting access to DSI using Nagoya Protocol frameworks.

LERU believes there are still too many unknowns over what DSI is, and how DSI could be incorporated into the Nagoya Protocol, to make it a viable option at present. LERU is delighted that the Convention on Biological Diversity is actively seeking opinions on the DSI concept, which we hope will result in a robust description for DSI. LERU believes the term 'nucleotide sequence data' is a perfect and precise term to use in place of DSI. Only when there is an agreed definition of DSI (or another appropriate term) can any system for ABS be investigated. The university sector, as a key provider of knowledge and capacity sharing on biodiversity, should be fully consulted at every stage to ensure that a robust and workable system is developed.

³ For the rest of this paper, we use the term DSI, as this is the term currently used by the CBD.

⁴ <u>https://phys.org/news/2017-10-letters-dna-functions.html</u>