

## TEMPLATE FOR COMMENTS

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<b>Title of document reviewed:</b>	The Emergence and Growth of Digital Sequence Information in Research and Development: Implications for the Conservation and Sustainable Use of Biodiversity, and Fair and Equitable Benefit-Sharing – A Fact-Finding and Scoping Study Undertaken for the Secretariat of the Convention on Biological Diversity	
Comments on the draft fact-finding and scoping study		
Page #	Para #	Comment
0	0	The report provides a good summary of the relevance, use and terminology of digital sequence information and its storage, however more emphasis can be placed on the shared benefits derived from the current system and certain implementation issues remain
7-17	0	The Executive Summary should be brief so that it can be easily linked to the literature review and its associated analysis and conclusions.  Information provided from page 3 to 17 could be linked to the specific section of the report.
47	7.3.1	There is a discussion of the potential positive environmental impacts of DSI however there is no mention of the validated positive impacts DSI has had on the conservation and sustainable use of biotechnology. For example, traditional breeding and genetic modification has had demonstrated effects on (i.) the increase on yields and reduced pressure on environmental resources; (ii.) increased tolerance to pests and diseases leading to decreased use of pesticides and; (iii.) Practices that enable more sustainable farming which are concrete demonstrations of established uses. There are also other applications relevant to the conservation of biodiversity such as the use of medicines developed with the use of DSI.

48-63	0	<p>The report has provided an informative outline of opportunities and challenges for fair and equitable sharing of benefits derived from Digital Sequence Information on Genetic Resources in the context of the Nagoya Protocol.</p> <p>It is clear from this report that the challenges presented outweigh the opportunities in the context of the Nagoya Protocol.</p> <p>The report did not make reference to any Article under the Nagoya Protocol that could assist in addressing the challenges identified. It would be useful for this report to share some light on the opportunities presented by the Nagoya Protocol to address the dilemma of benefit sharing in this context.</p> <p>It is clear from this report that the Parties to the Nagoya Protocol should start working towards finding innovative/creative policy solutions aimed at ensuring fair and equitable sharing of benefits with the original providers of genetic resources, in this context.</p> <p>Although, there is a need to recognise that there are a number of benefits of the current system of benefit sharing. Any recommendations that may lead to changes in this system must balance the benefits and adverse effects of such changes. There is a possibility that changes may unintentionally affect various role-players, including marginalised communities. For example, if strategies lead to a divestment of innovation in certain industries such as healthcare or agriculture or insert barriers to research and development of products there may be unintended negative effects on the same communities whom ABS is meant to protect. There is also often a large gap between DSI and a product. This must be considered when making any recommendations.</p>
51-	0	<p>The access to international data can help any country to drive its Science. The benefit of findings from this work will return to country in which the work is commercialised. A drive to help smaller countries to dive their expertise levels in these fields, with appropriate product development, etc. would benefit a region more than to try and protect billions and billions of DNA bases being produced annually.</p> <p>Though the work stated very well that biodiversity is often investigated in bigger partnership with international partners, with benefits often to the bigger partner, I would like to highlight something else I've missed that link to this:</p> <ol style="list-style-type: none"> <li>1. A lot of the funding agencies would “spend their money at home” rather, therefore NGSing, a costly technology for large-scale work, is often performed at “cheaper site” – which is always at the senior partner’s country. This has a large negative impact on capacity building within a country within the NGSing field since the big projects that could drive the costs of the technology down locally, are always outsourced to the bigger, better established country.</li> <li>2. A second concern is the lost of the data to the sequencing facilities’ terms and conditions. At some stage some of these facilities indicate that they may use your data for “other purposes” – details often not stated... The sequence data may therefore be used even before it is deposited to an official database such as genebank. It would be interesting to assess whether this is still the case or not since sequence data might require protection even earlier than believed. A fact to be investigated still.</li> </ol>

60	0	<p>What is patentable? One cannot patent a gene or DNA sequence without a function linked to it (the IP). The function could range from a new phenotype, e.g. drought resistance, to a novel usage of the DNA sequence, e.g. adapter, binding site, etc. which is then linked to the DNA/RNA/protein sequence.</p> <p>The sequence was always there provided by nature but the patent applicant can find or demonstrate a link between the process and the DNA sequence, thus assigning a novel function or process to the gene region not yet known, i.e. new IP. This usually requires access to the organism and therefore the other regulations apply on benefit sharing...</p> <p>This underlines an important question not clearly stated in the work: <i>What do we see as the “value” or “IP” we should protect for the country and its people from their biodiversity, that is contained within the digital sequence information?</i> Without clearly stating “on what” the cost benefit sharing should happen, it would be really difficult to protect it in a field driven by increasingly larger numbers of DNA sequences.</p>
0	0	<p>The work does highlight variability between DNA sequences from the same site/population or between different sites/populations.</p> <p>I would like to add to that with the “wobble effect” in the DNA code which was not mentioned here, i.e. two protein sequences can be exactly the same but differ more than 30% on a DNA level. This plasticity in the genetic code allows silent mutations to occur without impacting on the function/protein.</p> <p>However, it also complicates how digital data might be protected... e.g. A gene is found from and species originating from country X and linked to a specific trait of interest. The inventor optimises the codon usage of the DNA region for his host organism of interest, thus changing (and adding IP) to the original sequence. This significantly changes the DNA sequence and since IP was added to the DNA that is now synthetic, can the original country still claim ownership?</p>
0	0	<p>Last thought. I feel that if a country wants to protect their “Biodiversity IP” then the generation of that IP should be identified up front and protected as such.</p> <p>Also, the data generation should take place at a local site and the data generated should be placed in a proprietary database from the start. For example: An ethnic diverse population in a country is being sequenced and used for DNA-trait linking studies. Once this data, or even the material, have left the country of origin, it would be really difficult to restrict/manage/control the use of the dataset thereafter.</p> <p>The true value from this dataset can only be regulated through the control of access to the data to start with since only then the user is forced to accept the terms.</p>
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Please submit your comments to [secretariat@cbd.int](mailto:secretariat@cbd.int) or by fax at +1 514 288 6588.