TEMPLATE FOR COMMENTS

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Title of document reviewed:	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	General Comments: - In the Executive Summary it is stated that for the purpose of this study, the terms used in the different fora are used fluidly, but for the most part, the term "digital sequence information" is used in this study. This is in line with the CBD COP Decision XIII/16. However, in our view, the scoping study would benefit by using the more specific terms wherever possible in order to clearly understand, which information (e.g., DNA sequences, RNA sequences, amino acid sequences, genetic sequence data, etc.) a specific section or paragraph refers to. In particular, in those sections or paragraphs that clearly address a specific type of information, the agreed terminology should be used (e.g., "genetic sequence data" in the context of the PIP-Framework). In general, it seems that in most sections and paragraphs this report mainly looks at genetic sequences (see specific comments below), but to a lesser degree at other biological (sequence) information. Because of this lack of a clear terminology many sections and paragraphs remain fuzzy. - The study mainly contains qualitative information and statements by a series of researches. It states, for instance, that "although the science is moving away from physical material, its use is still necessary and important for most research projects". Unfortunately the study only provides little quantitative information (e.g., in Chapter 4.1.2), which would provide a clearer picture on the actual importance of "digital sequence information" compared to "physical material" in research or in different industry sectors. The study would benefit by including more quantitative information and more transparent references of the sources of the information. - The study would also benefit by including a Chapter that provides an overview of existing regulations, which may deal with certain aspects of "digital sequence information", such as for example database regulations in the EU.

1	7-12	We request to amend the title of this study to be more in-line with the respective Terms of Reference, e.g. *"Digital Sequence Information – A Fact-Finding and Scoping Study to clarify terminology and concepts and to assess the extent and the terms and conditions of the use of digital sequence information on genetic resources in the context of the Convention and the Nagoya Protocol"*.
23	17-23	We propose the deletion of this paragraph, since it is not clear what is meant by "modifying 'information' with either 'natural' or 'artificial'." Moreover, we do not see the relevance of this paragraph here, since it is rather referring to policy implications, which should not be the purpose of this study.
24	1-39	This page reviews to some extent how digital sequence information is produced and it describes DNA sequencing technologies. - It would be useful to also briefly describe the approaches and techniques used in proteomics and metabolomics, as these also lead to "digital sequence information." - It would also be useful to add a subheading "How is digital sequence produced and by whom?" to be more coherent with the following subheadings' logic (see also comment to pages 34-36 below).
25	15-16	We agree that there is often no clear cut between academic, government, or industry research. Yet, some research projects still remain purely academic, while others may include industrial or other application aspects, and again others may be purely industrial. This seems to be the case for most types of research and not just for "research using genetic sequences". We therefore propose the following amendment: *Distinctions between academic, governmental, or industry research using genetic sequences have come blurred, as have distinctions between different industrial sectors and other research types in general. Yet, some research projects still remain purely academic, while others may include industrial or other application aspects, and again others may be purely industrial.*
27	19	Within the PIP-Framework of WHO, the term "genetic sequence data" is used. We are of the view, that where terminology is clear, the study should not use "digital sequence information", but the more precise terminology (see general comment above).
29-34		The chapter 4 should also include a section that looks at how sequence information is published, and analyse the importance of publications in the context of accessing, storing, and managing "sequence information". This is in particular important, as genetic sequence information may be found in "digital" as well as in "analogue" formats.
34-36		Chapter 5.1 describes the generation of "new" digital sequence information arising from field collections and citizen science. It mainly looks at that from the "bioprospecting" perspective. However, genetic sequence information is also produced in many modern biodiversity research projects, in particular in phylogeny studies, in systematics, or in applied conservation projects (e.g., molecular markers). Furthermore, to our knowledge, the same or similar "digital sequence information" is generated multiple times and by multiple researchers, as scientists in different labs around the world often sequence the same species and sometimes even the same samples. The section should therefore be amended in order to provide a more comprehensive picture on how and by whom digital sequence information is produced (see also comment to page 24 above).
39	28-29, 32-34, etc.	Chapter 6 looks at some databases that seem to attach conditions to the use of "digital sequence information". However, many databases or initiatives cited in this chapter, rather apply conditions or MTAs in order to transfer physical material and not to use digital sequence information (e.g., BiOS, BioBricks Foundatioan and OpenPlant). Moreover, these databases or initiatives seem to be rather specific (not the same ones as described in Chapter 4). On page 30, it is stated that there are more than 1500 publicly accessible biological databases. It remains unclear how many databases really attach conditions to the use of digital sequence information, and how such conditions look like.

48-63		Chapter 8 is rather long and contains issues, that are somewhat overlapping with issues described in previous chapters. For instance, it describes how open access and open source databases work, which seems to overlap with information found in Chapters 4 and 6. Although we support the mentioning of these approaches also under this chapter, they could be shortened and would thus better focus on the relevance in the context of benefit-sharing. On the other hand, the chapter is not looking at how the benefits from "digital sequence information" arising through the utilization of genetic resources could be captured under the "bilateral approach" in the Nagoya Protocol, e.g., through addressing "digital sequence information" in mutually agreed terms (see for instance Swiss submission from 8 September 2017 in response to CBD Notification 2017-37).
51	16-34	We appreciate the section on scientific publications. Again, this section may better fit into Chapters 4 or 6, as it is one way how "sequence information" is accessed, stored, and managed.
61 and 62	40-43 and 1-13	This paragraph is misleading, as to our knowledge, disclosure requirements for genetic resources in patent applications do not monitor the use of "digital sequence information", but rather the origin/source of genetic resources. On the other hand, "digital sequence information" may be found in the published patent specification, as far as it is relevant for a specific invention. We propose to either delete the entire paragraph (as we do not see its relevance in this context) or for it to be more precise in order to better reflect the actual functioning and role of the patent system. In the latter case, we request the following amendments: *Information included in patent applications has received attention as a way to enhance the transparency in the context of and/or to monitor the use of genetic resources. Some governments require patent applications for an invention (directly) based on or using biological material or genetic resources to include the source or origin of the material. However, such disclosure requirements normally do not monitor the use of "digital sequence information," but rather of the physical material. Digital sequence information may, however, be found in the published patent specifications, as far as it is relevant for the specific invention. Oldham et al (2013) … scrutiny. In a number of countries, intellectual property offices ~~are the~~ form part of the official checkpoints established under the Nagoya Protocol, ~~which could~~ and assist in the ~~this~~ monitoring approach.*
63	20-21	As stated in our general remarks, the study fails in providing a clear picture on the quantitative importance of "digital sequence information" compared to "genetic resources" as such. Moreover, although researches also make use of "digital sequence information", to our knowledge, most labs certainly still work with physical material and not just with information. Any conclusion should therefore be drafted carefully. We propose the following amendment, which should also be reflected in the Executive Summary: *Physical samples are still of interest to and are broadly used by researchers, but the~~ir role~~ use/importance of "digital sequence information" in the research and commercialisation process seems to be ~~is~~ changing~~, and the future is unclear~~.*