

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
8	Terminology & Use sections	The lack of a definition of DSI remains a barrier to a fruitful discussion.
8	9&10	The authors write that “Differences in terminology in scientific circles reflect differences in the material referred to, as well as the speed and transformative nature of technological change today, which make it difficult to harmonize terminology”. But DSI is information (and NOT “material”). Its existence depends on sophisticated analytical equipment, synthetic reagents AND human and computer-aided interpretation. DSI doesn’t exist in nature.
10	35	It is inaccurate to make such a general comment. It really depends per sector. In plant breeding, sequencing and analysing physical samples still plays a major role. “SOME research is based on sequences accessed through databases or parts registries, but OTHER groups sequence and analyze physical samples”.
10	38-39	“Field collections of physical samples are a much smaller part of research strategies ... than they were twenty years ago” – this is probably due to uncertainties with ABS regulations.
11	35	For the field of agriculture, we are not familiar with the described approaches.
13	29	Delete “Although not explored in the study” throughout the whole of the study. This because if something is not explored in the study, it is then an opinion which has not been asked for and which is therefore out of the scope of this study.
13	29-38	The issues in this paragraph, and the detail description in 7.3.2. are not due to DSI. Either explain how it relates to DSI or delete the paragraph.

15	Under “Monetary benefits”	“Experience from funds established under the ITPGRFA and the WHO PIP Framework may provide relevant lessons in this regard” is written in the Overview, but on page 61 it says “the value of this [PIP]model for monitoring use of sequences in other sectors is likely limited” and the scale of influenza virus is tiny compared to the scope for DSI under the CBD. The summary should state that there are not yet scalable models for addressing monetary benefit of DSI at this moment in time.
16	17-18	Add to the sentence “...since sequences from the same species from the same habitat might differ...” the words “or sequences from dozens of specimens from very different origin or even from very different species might be similar.”
16	21-38	“Monitoring the Utilization of Digital Sequence Information”. Errors in the raw DNA sequence data generation, transmission to others, and deriving a consensus sequence also can cloud the monitoring process. These features also distinguish DSI from “natural” resources which only have diversity, not errors.
18	30	The focus should also be on food and agriculture. After all, the conclusions of the AHTEG will have a significant impact on that sector, since the International Treaty on Plant Genetic Resources for Food and Agriculture does not cover all countries and also not all crops. Since the plant breeding sector is heavily impacted by the regulations under the CBD and Nagoya Protocol, the activities of this sector with regard to DSI and the benefits resulting from these activities should also be properly highlighted and taken into consideration.
18	37	Information about who the interviewees are is missing.
19	9-17	Recommend the deletion of this paragraph. The study is about sequence information. DSI is quite well described in the next paragraph (line 19-28), the lines 9-17 can be removed.
22	15	In agriculture, it is the other way around. The initial focus has been on specific traits, which is now shifting to full sequences.
24	8	“Digital sequence information is the product of sequencing technologies that have become faster, cheaper, and more accurate in recent years the past half century.”
25	33-34	”The field is guided by digital sequence information in order to apply gene editing techniques like CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats)/Cas9, and increasingly gene synthesis, envisions to create new organisms and systems. It also uses digital sequence information among many of its tools.”
25	44-45	Delete “Both the vector and the hosts are also often owned by companies that have associated intellectual property” because it is not accurate nor is it relevant to the point being made.
26	24-25	“More than 300 billion.” Can you provide more detail and breakdown, and better description, preferably in chapter 3.1.2. – 3.1.4., or alternatively delete the sentence. E.g. 3.1.2. refers to a number in footnote 8. That number appears to be the value of the grain and commodities produced by farmers, not the revenues generated by the plant and microbe sectors.
26	40 et seq.	“neither sold not patented”, “not report to shareholders”. Better to state that “In preparation of this report, industry consultants were not contacted for information about the value of industrial biotechnology, nor did we find literature on this subject.”
27	36	There seems to be more emphasis on uses outside agriculture instead of within agriculture, as the heading of the paragraph suggests. The current paragraph gives an incomplete overview of how it is used within agriculture. Plant breeding should be included.
28	1	“ which can then be used may be used in attempts to edit agricultural crop genomes.”

31	41	INSERT: BLAST searches are very routine, and they lead to practical problems: If a researcher finds an identical sequence from multiple providers, and proceeds with that sequence, it is impossible to assign a single provider. Often, a researcher finds highly similar sequences from diverse providers, and uses this information to inspire further use of DSI. Also here, impossible to define a provider.
34	36	Suggest to delete “in higher technology industries than in the early years of the CBD”, because ‘higher technology industries’ is not defined. Alternatively, provide facts and reference.
34	36	For plant breeding, this is not limited to academics and smaller companies.
39	28	For plant breeding, this is not common. Upfront clarity about applicable terms are essential, given the time and money invested in the development of a new variety.
40	2	The described example is not relevant. It describes what will be done with a physical sample, not what conditions of use are for sequence data.
41	19	Given the confidential nature of plant breeding, the obligation to share improvements will be difficult to accept.
45	39	DSI is useful WITHIN one ex situ collection. It becomes much more useful when data can be exchanged globally and used ACROSS all ex situ collections. Please add this message
46	Section 7.2.2	DSI is also starting to be used by genebanks to improve conservation methodologies and as a way to help breeders more efficiently and effectively identify genetically diverse materials that may be useful for their breeding programs. (e.g.: CIMMYT Seeds of Discovery, IRRI Rice Sequencing)
46	19	The paragraph gives the impression that only some groups are developing crops for global threats. This is an incorrect impression, since there is a whole sector dealing, on a daily basis, with the global challenges and making sure that the crops are suitable to deal with these challenges. Namely the plant breeding sector.
46	36	DSI is also used in agriculture, to monitor and characterize pests, diseases, to monitor weed resistance to herbicides, for resistance management.
46	37	Suggest to add a par 7.2.4.: DSI is used in quality control, in food safety tests, customer services.
47	6	General remark: Is synthetic biology explicitly in the scope of this study? If not, it should be less prominent in the entire document.
47	26-37	Very relevant problems, but occurs without involvement of DSI. Either quantify the causal effect of DSI for these problems, or delete this text.
48	1-4	There are numerous problems with invasive species, and toxic organisms, and these should be addressed. To our knowledge very few of these are related to DSI. It is unfair to relate these fears to DSI.
50	40	It is stated that an open source community provides legal certainty, which open access does not. This statement should be further explained. Why would open access not provided legal certainty?
51	15	Insert: Open access and open source offer a safe environment for working only IF they are fully recognized and respected by all other holders of sovereign rights and IP, and if they are well curated. WHO-PIP shows how difficult this requirement is.
52	30	Par 8.1.3.: insert text about epidemiology, disease monitoring, quality control, as described in 7.2.3.

52	41	Suggest to add a para 8.1.5. If DSI is used in open access or open source environment, one should explore whether and how it can be used to make products. Commercial use refrains from accessing material and DSI that is not perfectly documented. It would be a pity to support non-commercial use, if the downstream commercial use is blocked due to ABS legal uncertainty.
53	15	Can text be added, describing that: “commercial sale is inherently a process where a vendor SHARES value with a customer. Thus commercialization (of a product generated by using DSI) is benefit-sharing. Probably a very powerful way of benefit-sharing, since it can be upscaled, it does not depend on subsidies, it will only function for products that the customer considers relevant, etc.
53	40	A fee-for-use would selectively discourage work on DSI for less profitable purposes: orphan crops, neglected diseases. It would hinder innovation and investment in areas that are essential for achieving objectives of CBD / SDGs.
53	Section 8.2.1	This section on value neglects that there is no DSI without payment to create the information. DSI does not appear naturally like the morning dew, a person has to access equipment and expend effort and time to generate it. That effort also needs to be accounted in value determinations.
57	26	Except for the Nagoya Protocol and trade secrets, most forms of IP expire over time (often in about 20 year), or exhaustion after sale. This is part of the social contract and the balance of incentive for the inventor as well as for society and future inventors. The design of ABS processes at global level does not offer this balance.
61	9	These systems can connect a ‘primary’ DSI to its source GR. However, already the sequence annotation (where is a gene, what could be putative gene function) involves utilization, comparison to multiple other DSI, human judgement etc. Annotation is an incremental process often involving multiple users. An annotated sequence is thus linked to numerous other DSI, and other GR, and multiple users. Then, the next user will BLAST-search thousands of annotated sequences. The value is cumulative and cannot be attributed to a single source or a single provider country.
63	12	There are, however a range of challenges to realizing THE MONETARY BENEFIT SHARING VIA REDISTRIBUTION, linked in part
Overall		To lessen the illusion of rigor of such a preliminary study, throughout the Overview and Executive Summary words like “dramatic”, “profound”, “massive quantities” “rapidly”, “increasingly”, “heavily” “extensively”, “extremely” and “commonly” should be eliminated. Also the word “some” should replace most of the “a few” “many of” and “most” that are used throughout the document because number of the generalizations are not back by rigorous analysis nor methodical assessment.
		It could also be pointed out that a significant amount of DSI is generated by countries who are not party to the CBD.
17	Conclusion	The summary section is long, and for an executive summary it would probably be better to lead with the conclusions rather than have them buried on page 17.

Please submit your comments to secretariat@cbd.int or by fax at +1 514 288 6588.