

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	These comments offer detailed observations on the Executive Summary. The intent of limiting comments to the Executive Summary is to keep these comments at a digestible length and to avoid repetition. Comments made on the Executive Summary are intended to be carried over and applied to the pertinent parts of the extended paper.
8	23	<p><i>“Digital sequence information is the product of sequencing technologies...”</i></p> <p>While it is true that sequencing technologies have become faster and cheaper in recent years, it is not clear or decided that DSI is the “product of sequencing technologies”. Some DSI certainly could be, for example, RNA sequences. But there are other types. Many might consider, for example, characterization and collection of information of genetic resources to be part of DSI.</p> <p>Even in the realm of DSI that is typically stored and represented as a sequence, it is not always the case that this is the product of what all would agree is a sequencing technology <i>per se</i>. The DSI may have been altered by a human, algorithm, or other means that is not a “sequencing technology” (e.g. cDNAs), or the sequence may have been elucidated using a technology that may not be strictly understood as a “sequencing technology”, for example, mass spectrometry.</p>
8	31-33	It is unclear if this correct to the extent suggested. It is true that in some cases DSI has been used to “identify and mitigate risks to threatened species” etc, however the extent of this benefit is not clear and in some cases it remains hypothetical. Passages such as this one, asserting usefulness that may not be entirely real to date, should be qualified.

8	34-35, 38	<p>It is unclear what distinction(s), if any, the authors intend to draw between, on the one hand, DSI and “sequencing technologies” as mentioned in the preceding paragraph and, on the other hand, “genomic technologies” and information from bioinformatics mentioned in the present paragraph. These four things might well be understood to be the same, and indeed should be understood to be largely and maybe wholly the same. If the authors do draw any distinction(s), they should be precisely described.</p> <p>Line 38, however, mixes the terms sequencing and bioinformatics in a manner that might be read as suggesting distinctions. Again, if the authors draw distinction(s), they should be precisely described, as the products of “bioinformatics” and “genomic technologies” may both be understood to be encompassed by DSI.</p> <p>For the purposes of this paper, it is further unclear why it is necessary to specifically speak of metagenomics as being distinct from other efforts to generate biodiversity DSI of biodiversity samples.</p>
9	1-8	<p>This paragraph is too loosely written and contains phrases of unknown or ambiguous meaning. What is a “dynamic knowledge hub” or a “diffuse scientific collaboration” that is more diffuse or scientific or dynamic than something that is not based on DSI? Can the development of an alleged scientific “norm” or “collaborative and inter-disciplinary approaches” be attributed to DSI? If such a norm exists at all?</p> <p>The first three sentences of this paragraph seem to convolute the Internet and DSI, attributing to “these technological and scientific advances” (which ones?) what arguably are effects of information technology that occur independent of DSI.</p> <p>The reference to “open innovation” is unclear in meaning, seems contradicted by the existence of private data hordes and intellectual property, and becomes even more unclear when read beside references to “open source”.</p> <p>Lines 5-6 seem to discuss a particular scenario, the adding of incremental value along a chain. While perhaps this is the case in some instances, it is merely one scenario for DSI. Economic value, for example, might be derived from a patent on a sequence found in one database, and that value might accrue only to one entity in a “chain”.</p> <p>Lines 7-8 are the first in a series of references to “blurred” distinctions between academic, government, and industry research. While we agree with this idea, we note that these lines have been blurred since the beginning of the CBD, and it is not clear what the particular point is with respect to DSI. Perhaps it should be clearly stated that any access system developed for DSI must apply benefit sharing provisions to all users, since intent may be unclear or change, or because institutional policies of so many users of DSI require assertion of intellectual property rights (a subject given too limited consideration in the paper as a whole) and generation of economic value.</p>

9	12-14	<p>At this point and later, the authors make reference to open source. This reference, and others, seem to reflect the ideological aspirations of open source in another field at face value, and to then imply that there is reason to think the same concept has application in biodiversity for “‘democratizing’ science, and even the means of production”.</p> <p>This is overenthusiastic. We note that efforts to develop open source seeds have not met great success, and that the open source inspired segment of synthetic biology is, and may remain, of limited economic and practical significance and is likely to ultimately be overshadowed by an industry more reliant on exclusivity-based approaches.</p> <p>While perhaps a study of how the experience of the open source software movement might offer lessons for dealing with DSI would be useful, it is premature to imply that “open source” may offer practical solutions for DSI and, indeed, to do so seems to pre-empt the CBD’s own discussion. As such, it seems prudent to limit discussions and suggestions about open source models at this point in the CBD’s deliberations.</p>
9	18-19	<p>What is the meaning of “artificial”? A “host organism” is still an organism. “Artificial” and “host” are unnecessary, potentially confusing, and should be deleted. “Bio-based” also appears unnecessary. Is not anything produced under such circumstances “bio-based”?</p>
9	23-24	<p>Minimally, delete “synthetic” and replace “generated” with “synthesized”. Alternatively, and preferably, delete ‘synthetic’ and replace “using particular genetic resources” with “from Digital Sequence Information”.</p>
9	26	<p>This sentence ends too soon as it does not point out a key implication. Sequences and genes of interest are not merely “identified” by mining, but their use is enabled, through both biotechnological means (e.g. synthesis) and traditional breeding.</p>
9	29-33	<p>The reference to synthesis from sequence information is important but somewhat misstated. It should rather be said that synthesis of sequence information (“re-materialization” is one way of saying it) is one of the major purposes for which DSI is accessed, stored, and managed. Although it is, as the paper notes, not the only purpose, and that benefits may be derived from those other purposes as well.</p> <p>The issues surrounding database adjectives, e.g. “public”, “publicly-accessible” “open”, etc) are quite difficult. There are also, of course, private databases and hordes, which also might be called <u>DSI <i>ex-situ</i> collections</u>. The word “public” should be deleted here.</p> <p>It also does not seem to be the case that parts registries, at this point in time, merit prominent individual discussion. These might rather be subsumed in the general scope of databases, which range from being entirely closed and/or proprietary to being on the internet and employing no terms of access whatsoever.</p>

9	37-38	Care should be used with the term “publicly accessible”. It has gained a particular meaning in the WHO PIP Framework, and there sometimes appear to be different understandings of the term. We would consider a publicly-accessible database to include databases employing mandatory data access and use agreements that impose benefit sharing obligations consistent with the Convention and Nagoya Protocol, provided that access to the database is afforded to any person or entity that has entered into the agreement.
9 and 10	9:40 10:1-5	These lines can be deleted as they represent a level of detail not necessary in the summary.
10	6-11	This paragraph states in specific terms related to three databases what can and should be stated in a more generic manner. Line 9-10’s reference to use should clarify that a search of the database might involve “use” of its entire contents, but the user is not provided with non-matching sequences. Line 10-11’s reference to policies belongs elsewhere, in a balanced discussion of policies in use and possibilities.
10	16-20	The issues mentioned here – about publication and database accessions – really deserve more clear explanation if they are to be mentioned here. Why have such policies evolved? One big reason is data hoarding. Another is problematic concepts of “open access” that very well may be presently incompatible with the CBD. As such, the discussion of the issues raised here needs nuance, and elucidating the underlying reasons why these policies exist casts them in a more accurate and informative light for the present discussion on access and benefit sharing.
10	25-32	As stated earlier, registries seem to be given excessive and distracting attention in this paper. The section may be deleted and registries mentioned in passing in the preceding paragraphs, as they can be accommodated under the scope of databases. Perhaps the most salient aspect of registries for the purposes of this paper is not their existence per se, but rather the value potentially imparted by the way that they join elements of DSI, including sequence, testing and characterization data, and organization.
10	35-37	This sentence may not be correct. We are aware of numerous large sequencing efforts involving both new collections and physical <i>ex situ</i> collections. These efforts generate new <i>ex situ</i> collections of DSI. If “databases” here is meant to refer to only publicly-accessible databases, excluding private databases, this would be problematic. Private databases are large and growing, for example, the data maintained by sequencing companies and seed companies. Parts registries should be deleted.

10	38-39	In the modern world, does it matter if the collection and sequencing of physical samples is conducted by “high tech industries”? No, it does not. What matters is who has access to the DSI. So the observation in these two sentences is potentially misleading.
11	1-4	<p>Again, for present purposes, it really does not matter who does the sequencing of physical samples, be they companies, universities, or others. Access and use of them, in the context of ABS, is more important. “Persists” seems to suggest that sequencing of physical samples is becoming a relic. With so much biodiversity uncharacterized, and such known value in diversity, such an assertion seems highly debatable.</p> <p>As the ability to interpret sequences and identify value grows, one can easily imagine things moving in an opposite direction than what this paragraph suggests, and that sequencing of physical samples isolated in nature will become more prevalent. In fact, this is occurring in medicine, where direct sequencing of pathogens (i.e. physical specimens from nature) is on a dramatic rise. As comparable tools become available for more sophisticated (lengthy genome) organisms, the same may very well occur there.</p>
11	5	Like the preceding paragraph, Line 5 seems to prematurely and without cause declare the impending death of sampling from nature. There are strong arguments that things will end up moving in the opposite direction, once the necessary tools and experience are available. Particularly where there is economic benefit to be derived from biodiversity.
11	18-20	In addition to again implying that sequencing of physical samples is a relic, this paragraph mentions several things, including information on phenotype and its relation to genotype and various types of characterization information. It is important to note that, in addition to being generated in most cases from use of physical material, such information may itself in many cases be considered DSI.
11	21	Replace “A” with “Another”. The preceding paragraphs also contain information on advances with relevance for ABS! Here the key observation is that of the second sentence.
11	27	Delete “parts”. “Parts” refers to a particular conceptualization of biology by a particular group of synthetic biologists. Mention should be made of the increasing length and complexity of sequences that can be easily synthesized and/or assembled.
12	5-9	This paragraph is a bit unbalanced and maybe tries to include too much. Whether terms are binding or not, or understood or “assented to”, or are enforceable etc, depend on many factors. The third sentence in particular seems to highlight negatives, while none of the paragraph mentions any advantages. Of course it is not clear where a “click wrap” ends, and an “agreement” begins.

12	10-27	This discussion of “open source” is somewhat premature. This commenter is aware of only limited use of open source agreements for biological materials, and the paragraph appears to unquestioningly bring over assertions derived primarily from experience in non-biological realms into the question of ABS for biodiversity DSI. As was commented earlier, it is quite possible that open source agreements offer relevant experience, but it is too early to, for example, to broadly assert that “materials” (are materials DSI?) are made “immune from the assertion of IPR” (quite likely debatable).
12	20	Delete reference to open source agreements here. Perhaps it should be clearly said that a user agreement might or might not include ABS provisions, though it should when viewed from the perspective of the CBD’s third objective. The important point here for the study is that some biodiversity databases successfully deploy a user agreement, evidencing that there is no intrinsic obstacle to doing so, and that user agreement can include ABS provisions, if it is decided to do so.
12	33-34	The penultimate sentence of this para (increasing use of sequence-based diagnostics for biodiversity) seems to contradict the Summary’s earlier suggestions (page 11) that sequencing of samples from nature is on the decline, and is consistent with an expectation that, in fact, cheaper/faster/mobile sequencing technologies will lead to an <i>increase</i> in such DSI generation and use.
13	15	DSI’s contribution extends beyond “identifying and characterizing” and can also include synthesis of materials from DSI. (Not only in agriculture.)
13	18	Use of DSI in epidemiology and other aspects of healthcare is routine and extends far beyond “emergency situations”. The reference to emergencies should be deleted.
13	21-28	The paper should avoid iteration of a wide variety of speculative and “possible” impacts, particularly in the summary, and it is best to delete lines 21-28. If such hypothetical positive impacts are to be iterated, then possible negative impacts should be similarly listed.
13	29	To these concerns it might be added that reliance on DSI as a means of diversity storage (i.e. as a 21 st Century “ <i>ex situ</i> collection”) could have negative effects on efforts to preserve the real thing, i.e. in-situ conservation, by generating a false sense of security.

14	1-6	<p>The authors' characterization of monetary benefits accruing from DSI as "speculative" is incorrect. There are numerous instances, trait patents for example, of monetary benefits being generated from DSI. Disease diagnostics are another example.</p> <p>This paragraph appears to inappropriately endorse specific forms of benefit sharing for DSI, such as "access to databases", forms that Parties and others may neither want nor consider benefit sharing. For example, equal access to a database is not equitable access, if some users are more able to capitalize on the contents than others. In the end it is for the provider to determine what constitutes equitable benefit sharing.</p>
14	8-19	<p>We do not agree that access to "publicly available databases" can be called benefit sharing <i>per se</i> and this assertion should be removed. Reference to taxpayers of some countries etc, is frankly ridiculous and ignores the benefits that accrue to the countries supporting such databases which, after all, is the reason they do so. And if "every contributor of data and research results from around the world" is performing benefit sharing, why does the paper (incorrectly) characterize the INSDC databases as Northern benefit sharing?</p> <p>In short, the analysis in this entire paragraph is deeply flawed and it should be deleted in its entirety.</p>
14	20-28	<p>This paragraph ignores intellectual property issues.</p> <p>The third sentence of this paragraph contains prejudicial and ideologically-tinged language about databases, and the sentence afterwards overstates the case to claim "open source" (which is not well-defined) "ensures" access to DSI. What if a contributor submits some DSI but keeps others? What if the conditions imposed are unacceptable from the provider standpoint?</p> <p>This paragraph is highly problematic absent more specific shared understandings of the meaning of "open access" and "open source" in the context of DSI.</p>
14	30-37	<p>"Cloud laboratory" is vague and unclear in meaning. Are authors proposing here a specific benefit sharing structure for DSI? (A problem across this page.) If so, that would seem to go beyond their charge. It is not clear at all that a "cloud laboratory" in which provider countries give samples in return for sequencing services is a viable or desirable approach at all, and it is frankly a bit disturbing that this idea seems to be being promoted in this paper. Providers may very well consider themselves already owners of sequences, so where is the benefit?</p> <p>This paragraph's assertions appear to go beyond the author's charge and it should be deleted.</p>

14	39	Is an “open science non-profit network” that includes private sector entities and/or public entities subject to Bayh-Dole type IP requirements really “open science non-profit”? What this paragraph refers to is unclear and unacceptably vague, and if specifics were provided about the composition and rules of such networks, it is unclear if this and other commentators would agree with the value judgments contained in the summary in this paragraph. Absent more grounded references, it should be deleted.
15	4-9	This paragraph repeats the incorrect assertion that monetary benefits from DSI are “speculative” (see comment 14:1-6). The sentence on negotiations regarding benefit sharing being deferred needs more context. After all, the purpose of this exercise as a whole is to develop benefit sharing approaches for DSI. So what has come before for DSI is, in effect, <i>ad hoc</i> , while the present process is about consistency and improvement. This lack of an existing coordinated effort bears mention when speaking of what exists at present. This subject is, in fact, working on the practicalities of implementation.
15	12-13	The opinion of database managers is irrelevant, nor is it clear that they would be in charge of a payment system. Reference to potential bureaucracy and costs should be balanced. The reference to “isolate data or reduce effectiveness” is vague and should be deleted. A global fund idea should not be linked to alleged difficulties, especially difficulties alleged by database managers and not contracting Parties or ABS experts, but rather evaluated on its own merits.
15	20-33	Use of the word intractable is incorrect and prejudicial. Rather, it could be said that “Determining the value of DSI can be challenging, and is a subject that merits careful consideration.” Reference to a temporal scope should be deleted. Many of the difficulties determining value that the authors mention are also difficulties with physical material, so this problem is not as novel or “intractable” as the paragraph suggests.
15, 16	15:37+ 16:1-10	Lines 37-40 present the policies of INSDC as immutable when they are, in fact, merely secondary obstacles to confront and overcome in order to implement the ABS provisions of the CBD and Nagoya. In discussions with the PIP Framework, INSDC databases stated that they are capable of tracking users. This, what the databases are capable of (rather than their policy preferences), is what the paper should make primary reference to. The policies of the CBD should guide INSDC databases, and not the other way around.
16	22-25	It is possible to envision a variety of monitoring schemes for DSI. These range from simple to complex and the degree to which the monitoring is “critical” may depend on the approach. Line 25 suggests that the identity of a sequence invariably erodes. This is not necessarily correct as there are means of preserving identity. With respect to identity erosion, what should be said is that approaches to ABS for DSI should seek to prevent erosion of identity.

16	34-35	The paper suggests that ABS measures for databases would inherently be “bureaucracy”, “expense”, and “layers of legal”. We do not agree that this is necessarily the case, and will depend upon the solution adopted.
16	37-38	The reference to separate databases is unusual and hard to understand how it would practically operate. Since ABS obligations will be incumbent on data users, who would arrive at a database and would then need to enter into an agreement that is enforceable, the “delinked” approach discussed here appears difficult or impossible. Until this is better described and understood, it should be deleted or minimized.
17	1	It is not a <i>fait accompli</i> that DSI is uploaded to a public database (ask seed companies about their private sequence collections), nor that uploading to a public database makes it “available for all to use” (there may be restrictions via IP or user agreements).
17	9-10	Delete “transformative” as it is unclear. The characterization of monetary benefits as “possible” is factually incorrect. This sentence as a whole, in the sense that it appears to suggest a benefit sharing scheme (when read beside preceding pages), is beyond the charge to the authors and should be deleted.
17	19-20	As with previous comments, we believe the assertion that sequencing of physical samples is disappearing is factually incorrect and even contradicted by other assertions in the paper.
17	23-30	The verbiage here parroting the philosophy – but not necessarily reality – of “new open and multi-party” collaborations is aspirational and out of place. The authors again appear to veer into the realm of suggesting specific benefit sharing systems based on their personal endorsement of some idealized, unidentified projects that likely only represent a small portion of overall research efforts in biology. This paragraph should be deleted.

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