

**Sra. Cristiana Paşa Palmer**  
**Secretaria Ejecutiva**  
**Convenio sobre la Diversidad Biológica**  
**Presente**

Tengo el agrado de referirme a la notificación 2017-115 de fecha 8 de noviembre de 2017, con referencia SCBD/SPS/DC/VN/KG/NH/86967, por la cual solicita que las Partes envíen a Usted, aportaciones al proceso de revisión por pares del documento "*Fact Finding and Scoping Study in Digital Sequence Information on Genetic Resources*" con el fin de dar continuidad al proceso establecido en la decisión XIII/16.

Anexo encontrará el documento preparado para atender dicha Notificación, esperando puedan ser tomados en consideración.

Sin otro particular, hago propicia la ocasión para enviarle un cordial saludo.

**Atentamente**  
**La Directora General y**  
**Punto Focal Nacional para el Protocolo de Nagoya**



**Biól. Edda Veturia Fernández Luiselli**

C.c.p. Mtro. Enrique Lendo Fuentes. Jefe de la Unidad Coordinadora de Asuntos Internacionales. Presente.  
Mtra. Norma Salomé Munguía Aldaraca. Dir. Gral. para Temas Globales. SRE. Presente  
Biól. Hesiquio Benítez Díaz. Dir. Gral. de Cooperación Internacional e Implementación, CONABIO. Presente



## TEMPLATE FOR COMMENTS

Contact information		
<b>Surname:</b>		
<b>Given Name:</b>		
<b>Government (if applicable):</b>	MEXICO	
<b>Organization:</b>	Punto Focal Nacional del Protocolo de Nagoya	
<b>E-mail:</b>	<a href="mailto:edda.fernandez@semarnat.gob.mx">edda.fernandez@semarnat.gob.mx</a> ; puntofocal.pnaypb@semarnat.gob.mx	
<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
1	7-9	<p>Title: “ <i>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</i>”</p> <p>We note that according to Decision XIII/16 the objective of the study is: “...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...” For that reason in the Title of the Study is necessary to consider.</p>
8	5 (line)	After “digital sequence information”, we suggest the word “introduced” to replace “used”. This proposal reflects a coherence language in accordance with the footnotes of the Decisions CBD XIII/16 and Nagoya Protocol (NP) 2/1.
8	13 (line)	After “ITPGRFA”, we suggest to add the word “fora”. This proposal pretends to generate clarify. The legal text (ITPGRFA) does not have these definition.
8	16-19	“ <i>The WHO PIP Framework uses the term genetic sequence data, which they define as: “The order of nucleotides found in a molecule of DNA or 18 RNA... contain[ing] the genetic information that determines the biological characteristics of an organism 19 or a virus”</i> . This definition is of particular interest as it vinculates genetic sequence data with organisms and virus, what is considered as “physical samples” along the document. It is useful not to forget this in the different sections of the document
13	7 (line)	After “powerful tool for”, we suggest to add the phrase “strengthen the” before “implementation”. We consider that the phrase complete the idea regard that the genetic sequence analysis is a relevant tool.
13	35-36	When in lines 35-36 it is said that “ <i>The replacement of cash crops with new biotechnology products also has potential impacts on small farmer livelihoods</i> ”, we suggest that it is important to add that the impacts are not just limited to small farmers livelihoods, this replacement could also have other environmental and socioeconomic impacts, the Cartagena Protocol deals with these other potential impacts in its text.

15	27- 29	On Cut-off points. See comment for pg 59 lines 32-35
19	9 (line)	After “digital sequence information”, we suggest the word “introduced” to replace “used”. This proposal reflects a coherence language in accordance with the footnotes of the Decisions CBD XIII/16 and Nagoya Protocol (NP) 2/1.
29	34	In opinion of Mexico is necessary to develop a new subsection under 4.1 regarding the patent databases as a repositories of DSI.
34	30-34	<p><i>“Generation of “New” Digital Sequence Information from Physical Samples.</i>  <i>Most digital sequence information is accessed through databases or parts registries, but some groups seek out physical samples through field collections, citizen science sourcing programs, and many acquire samples and digital sequence information through ex situ collections.”</i></p> <p>It is somehow surprising to see that access to a genetic resource (as a physical sample) to obtain digital sequence information is considered as a kind of “secondary source” of information. Even if databases or part registries might nowadays have become so important, and seem to be considered, at least for some, “conceptually” independent from living organisms, it must not be forgotten that without living organisms those databases wouldn’t even exist. This should not be left out of the equation in discussions on access and benefit sharing... even in the cases when existing biodiversity is only used “as an inspiration” (pg 36, lines 22-23).</p>
43	22 (line)	We suggest to add a footnote to the phrase “Target 13”. The proposal of footnote is the following: “In accordance with the COP Decision XIII/2, paragraph 5b), vi) the identification and characterization of biodiversity in the centres of origin or/and centres of genetic diversity is relevant to identify the origin geographic from genetic resources (i.e in Zeder M.A. <i>et al</i> 2006) and to achieve the Nagoya Protocol and CBD objectives.
46	11 (line)	After “powerful tool for”, we suggest to add the phrase “strengthen the” before “implementation”. We consider that the phrase complete the idea regard that the genetic sequence analysis is a relevant tool.
46	19-23	“7.2.2 <i>Developing new crops, and minimizing genetic erosion</i> ” . The characterisation of genetic resources has been very useful in conventional crop breeding programs. It would be important to incorporate this kind of information in the text, not only the reference to “synthetic biology” efforts; the latter is already mentioned in section 7.3 as a technology associated with digital sequence information.
47	7 and 25	The section on potential positive impacts of technologies associated with digital sequence information is written in a very assertive way, while the section on potential negative impacts uses the word “concern” in four occasions as well as the word “fear”. A more objective wording would be more suitable and greatly appreciated.
	Chapter 8	Chapter 8 “ <i>Digital Sequence Information, Fair and Equitable Benefit Sharing, and the Nagoya Protocol</i> ” deals with very interesting thoughts and facts around the “benefit” aspects, and chapter 4 contains very valuable information in terms of how digital sequences are accessed in databases, but it would still be necessary to openly discuss further the aspects relative to the “Access to genetic resources through the access of digital sequence information”, as this link is unbreakable, as mentioned in the WHO definition cited in page 8: “...genetic sequence data, which they define as: “The order of nucleotides found in a molecule of DNA or RNA... contain[ing] the genetic information that determines the biological characteristics of an organism or a virus””
48	13 (line)	We suggest the word “utilization” to replace “use”. This proposal reflects a coherence language in accordance with the Nagoya Protocol provisions.
48	31 (line)	We suggest the word “utilization” to replace “use”. This proposal reflects a coherence language in accordance with the Nagoya Protocol provisions.

49	3 (line)	We suggest the word “utilization” to replace “use”. This proposal reflects a coherence language in accordance with the Nagoya Protocol provisions.
49	7 (line)	We suggest the word “utilization” to replace “use”. This proposal reflects a coherence language in accordance with the Nagoya Protocol provisions.
53	15 (line)	We suggest the word “utilization” to replace “use”. This proposal reflects a coherence language in accordance with the Nagoya Protocol provisions.
55	35-37 (line)	In the opinion of Mexico, the quotation is tendentious because the interpretation is not base on official interpretation under the Nagoya Protocol. In this context, Mexico suggest, in line 35, to add the phrase “Some authors consider that the” (considering the citation) before the sentence.
56	32 (line)	We suggest the phrase, in parentheses, “forum shopping” after the word “jurisdictions”. This proposal pretends adding legal information to clarify the quotation.
57	36 (line)	We suggest the word “utilization” to replace “use”. This proposal reflects a coherence language in accordance with the Nagoya Protocol provisions.
59	32-35	<i>“At the same time, sequences of the same species, from the same habitat, might differ due to natural mutations, and these might occur very often and in a short time. If a sequence does not have a 100% match in the public databases, would it then be considered unique?”</i> This is a characteristic inherent to intra and inter-specific genetic diversity. The answer could be addressed, in a beginning, by looking at the “function” of a gene / sequence. For example, do two different sequences that encode for a protein with exactly the same function should be considered as different or should these be put together in the same box? It is useful to keep in mind that a commercial application derived from the utilization of a digital genetic sequence, in most if not all of the cases, owes it’s distinctive characteristics to the function(s) encoded by, or associated to, the genetic sequence(s) more than to the sequence(s) itself.
61	40 (line)	We suggest the word “utilization” to replace “use”. This proposal reflects a coherence language in accordance with the Nagoya Protocol provisions.
62	15 (line)	We suggest to add the word “regimen” after the phrase “benefit sharing”. This proposal reflects a coherence language in accordance with the Nagoya Protocol provisions and its ABS system.
62	20 (line)	We suggest the word “utilized” to replace “used”. This proposal reflects a coherence language in accordance with the Nagoya Protocol provisions.
63	10 (line)	We suggest to add the phrase “including to monitoring the utilization of genetic resources and its ABS regimen” after the word “biodiversity”. This proposal reflects a coherence methodologic as result from the Study. This Study includes many references about the Nagoya Protocol and its ABS regimen.
78	6	According to the addition page 43 line 22, please incorporate the following reference: Zeder, M.A., Emswiller, E., Smith, B.D. and Bradley, D.G. 2006. Documenting domestication: the intersection of genetics and archaeology. TRENDS in Genetics Vol. 22 No. 3 March 2006
<b>General comments</b>		

- For Mexico, a Patent is a document of a technical and legal nature, which due to the characteristics of the Patent System is a public document that is contained in databases of free access and that when it comes to inventions in the field of Biotechnology and that claim or protect gene sequences (DNA, RNA, cDNA, SNAPs and any type of RNA) describe in detail the sequences, and these are in bases in digital format, which allows to search and alignments between sequences.
- In the national patent examination for this type of inventions is necessary to search and sequence alignments with the databases that are described in the document (application), in accordance with the criterion of novelty. So for the Patent System it is essential that the databases are freely available to ensure that the rights conferred by patents meet the requirements of patentability.
- The free and public access of gene sequences is intimately linked to the exception of internationally established patent law, which allows gene sequences even when they have a patent right granted by the inventor or owner of the invention can be used in the field of research and development without the express permission of the owner of said right. Therefore, this same spirit must be applied in the use of the databases that contain them (patent and non-patent information).
- An important number of the sequences that are contained in all the databases mentioned (citations) in the Study are subject to a patent right. This case implies that their use in the commercial sphere must have the authorization of the owner of the patent right, under a license or assignment of right.
- In opinion of Mexico, the institutions that protect genetic information in their databases should be institutions to monitor to the utilization of genetic resources.
- The sequences found in databases that apply to the scope of the Nagoya Protocol are only those that are identical to the sequences found in the biological resource in situ in the country of origin. Therefore, the sequences modified from these are inventions derived from the sequences in situ and these should not be subject to regulation of Access from the country of origin but these be addressed in the field of ABS and to avoid generating barriers to Research and Development.