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AD HOC TECHNICAL EXPERT GROUP ON  
DIGITAL SEQUENCE INFORMATION ON  
GENETIC RESOURCES  
Montreal, Canada, 17-20 March 2020

### SYNTHESIS OF VIEWS AND INFORMATION RELATED TO DIGITAL SEQUENCE INFORMATION ON GENETIC RESOURCES

#### INTRODUCTION

1. The Conference of the Parties to the Convention on Biological Diversity at its fourteenth meeting and the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol on Access and Benefit-Sharing at its third meeting each adopted decisions on digital sequence information on genetic resources (decisions [14/20](#) and [NP-3/12](#), respectively). They decided to establish a science and policy-based process on digital sequence information on genetic resources.

2. To assist this process, the Conference of the Parties invited Parties, other Governments, indigenous peoples and local communities, and relevant organizations and stakeholders to submit to the Executive Secretary as follows:

(a) Views and relevant information (i) to clarify the concept, including relevant terminology and scope, of digital sequence information on genetic resources and if and how domestic measures on access and benefit-sharing consider digital sequence information on genetic resources; and (ii) on benefit-sharing arrangements from commercial and non-commercial use of digital sequence information on genetic resources (decision 14/20, para. 9);

(b) Information on their capacity-building needs regarding the access, use, generation and analysis of digital sequence information on genetic resources, in particular for the three objectives of the Convention (decision 14/20, para. 10);

3. The Executive Secretary was requested to prepare a compilation and synthesis of the views and information submitted (decision 14/20, para. 11 (a)).

4. By notification (2017-37) of 5 February 2019,<sup>1</sup> the Executive Secretary invited the submission of views and expression of interest to undertake studies pursuant to decisions 14/20 and NP-3/12. The list of Parties, non-Parties and organizations that submitted views and information is presented in the annex. The full text of all submissions has been made available online and a compilation has been made available to the meeting as document CBD/DSI/AHTEG/2020/1/INF/1.<sup>2</sup>

5. More than 30 submissions were received representing views and information from a large number of countries and organizations. Many of the submissions were quite detailed and contained a wealth of information. The information is very valuable for understanding the breadth and complexity of the issues but posed a significant challenge in preparing a synthesis that is as concise and easy to comprehend as possible.

6. A table of contents is provided below to assist in understanding the structure of the document.

<sup>1</sup> Available at <https://www.cbd.int/doc/notifications/2019/ntf-2019-012-abs-en.pdf>.

<sup>2</sup> Available at <https://www.cbd.int/dsi-gr/2019-2020/submissions/>.

7. Finally, it should be noted that, in view of the coordinated process on this issue under the Convention and the Nagoya Protocol, references to “Parties” in the present document means Parties to the Convention.

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## **I. CLARIFYING THE CONCEPT, INCLUDING RELEVANT TERMINOLOGY AND SCOPE, OF DIGITAL SEQUENCE INFORMATION ON GENETIC RESOURCES (DECISION 14/20, PARAGRAPH 9)**

### **A. General considerations**

8. The policy-based process on digital sequence information established by decision 14/20 includes, inter alia, the commissioning and peer review of a study on the concept and scope of digital sequence information on genetic resources and how digital sequence information is currently used,<sup>3</sup> which has been developed taking into account a wide range of sources, including the submissions which are the subject of the present synthesis. Accordingly, the study considers the issues of scope and terminology concerning digital sequence information in considerably greater detail than the sections below.

9. Certain submissions considered that clarifying terminology is an important first step,<sup>4</sup> or even essential<sup>5</sup>, in order to properly assess the potential impact of addressing digital sequence information within the Convention and the Nagoya Protocol. Other submissions considered that clarifying terminology is less of priority than clarifying the scope of digital sequence information<sup>6</sup> and others cautioned that terminology, when agreed, needs to be ‘future-proof’ as far as possible, so that it will not be rendered obsolete by technological developments and so that it can provide legal certainty.<sup>7</sup>

10. Several submissions considered technological advances associated with molecular biology and noted or inferred that the speed and the transformative nature of these advances, which have resulted in increased sequencing capacity at reduced cost and increased capacity of repositories and databases, present a significant challenge in clarifying the scope and identifying harmonized terminology associated with digital sequence information.<sup>8</sup>

11. Several submissions considered the nexus between a genetic resource and information associated with a genetic resource, in clarifying the concept of digital sequence information. Whereas some submissions distinguish digital sequence information from the underlying genetic resource it describes,<sup>9</sup> others consider the distinction artificial and/or noted that generation of digital sequence information requires access to and utilization of the underlying genetic resource.<sup>10</sup>

### **B. Clarifying the concept and scope of subject matter comprising digital sequence information**

12. Several submissions referenced or considered<sup>11</sup> the various types of information that may be relevant to the utilization of genetic resources which were identified in the report of the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources pursuant to its meeting held in Montreal, Canada, in February 2018.<sup>12</sup>

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<sup>3</sup> CBD/AHTEG/DSI/2020/1/3. Available at <https://www.cbd.int/meetings/DSI-AHTEG-2020-01>.

<sup>4</sup> Switzerland.

<sup>5</sup> LERU.

<sup>6</sup> Brazil; Mexico; South Africa; African Union Commission on behalf of the African Group; Third World Network.

<sup>7</sup> African Union Commission on behalf of the African Group; CETAF; SPNHC; Joint submission by Consortium of German Natural History Collections and others.

<sup>8</sup> Mexico; European Union and its Member States; African Union Commission on behalf of the African Group.

<sup>9</sup> Australia; United States of America, Switzerland, INSDC.

<sup>10</sup> Belarus; Colombia; Madagascar; Brazil; India; African Union Commission on behalf of the African Group.

<sup>11</sup> Switzerland; Costa Rica; Third World Network.

<sup>12</sup> Comprising the following: (a) nucleic acid sequence reads and the associated data; (b) information on the sequence assembly, its annotation and genetic mapping. This information may describe whole genomes, individual genes or fragments thereof, barcodes, organelle genomes or single nucleotide polymorphisms; (c) information on gene expression; (d) data on macromolecules and cellular metabolites; (e) information on ecological relationships, and abiotic factors of the environment; (f) function, such as behavioral data; (g) structure, including morphological data and phenotype; (h) information related to taxonomy; (i) modalities of use. The AHTEG report is available at <https://www.cbd.int/doc/c/4f53/a660/20273cadac313787b058a7b6/dsi-ahteg-2018-01-04-en.pdf>

13. Several submissions concluded that the subject matter constituting digital sequence information should be narrow in scope, limited to arrangements of nucleotides on a strand of naturally occurring DNA or RNA, as exemplified by submissions which elaborated along the following lines:

(a) Order of nucleotides in DNA or RNA, such as nucleotides arrangements comprised of Adenine, Thymine<sup>13</sup> or Uracil<sup>14</sup>, Guanine, and Cytosine, and this includes non-coding and coding sequences, regulatory sequences, conserved sequences, genes that encode specific traits, DNA without known function, and ‘junk’ DNA;<sup>15</sup>

(b) Nucleotides as found in nature, in the genome or encoded by the genome of a specific resource, and the genome includes nuclear and extra-nuclear DNA and coding (gene) and non-coding DNA sequences;<sup>16</sup>

(c) Larger nucleotide elements could comprise the entire genome of an organism, a clade (pengagenome) or an environmental sample (metagenome).<sup>17</sup>

14. Several submissions advocating a narrow scope of digital sequence information limited to nucleotide sequences, explicitly identified elements that should be taken not to constitute digital sequence information, for example:

(a) Amino acids or other molecules resulting from natural metabolic processes which are associated with or dependent on the genome;<sup>18</sup>

(b) Information developed through research, as distinguished from nucleotide sequence data (because neither NSD nor a genetic resource have intrinsic information, however, they can be considered as providing data);<sup>19</sup>

(c) Information arising from analysis or further application of digital sequence information<sup>20</sup> such as sequence assembly, sequence annotation, genetic maps, metabolic maps, three-dimensional structure information or physiological properties related to it.<sup>21</sup>

15. Conversely, other submissions took a broader view, beyond nucleotide sequence information, of the scope of subject matter that should be taken to constitute digital sequence information, as exemplified by the following:

(a) Amino acid sequences of proteins and associated metadata;<sup>22</sup>

(b) Amino acids including both raw sequence information and processed/annotated sequence information;<sup>23</sup>

(c) Information on genetic or biochemical composition including nucleic acid sequence gene reads and associated data, sequence assembly it’s annotation and gene mapping describing the genome, individual genes or fragments thereof, organelle genome, gene expressions, macromolecules and cellular metabolites;<sup>24</sup>

(d) Information concerning nucleic acid sequence of a genetic resource (DNA, cDNA, RNA, SNPs, STRs), extending to sequence of amino acids, molecular information (such as methylation patterns) and associated metadata;<sup>25</sup>

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<sup>13</sup> In DNA.

<sup>14</sup> In RNA.

<sup>15</sup> United States of America; Japan; EuropaBio; CETAF; SPNHC; Joint submission by Consortium of German Natural History Collections and others; Joint submission by Natural History Museum UK and others.

<sup>16</sup> EuropaBio; ICC.

<sup>17</sup> Joint submission by Natural History Museum UK and others.

<sup>18</sup> EuropaBio; ICC

<sup>19</sup> Joint submission by Natural History Museum UK and others;

<sup>20</sup> CETAF, Joint submission by Consortium of German Natural History Collections and others.

<sup>21</sup> EuropaBio; ICC.

<sup>22</sup> Costa Rica.

<sup>23</sup> Iran.

<sup>24</sup> India.

<sup>25</sup> Mexico.

(e) DNA and RNA sequences in all their forms including assembled and annotated genomes and partial sequences as well as sequences of alternative forms such as cDNAs, codon optimized sequences, etc., and extending to amino acid sequences, SNPs, STR counts, and epigenetic and molecular characterization information (e.g. structures, DNA methylation, etc.) and sequence associated metadata (e.g. 'passport' data, phenome-genome data, etc.)<sup>26</sup>

16. Additionally, submissions suggested certain specific types of data/information that should not be taken to constitute digital sequence information (i.e. unrelated to the proponent's position on scope concerning nucleotide sequence information):

(a) Information concerning human genetic resources because the second meeting of the Conference of the Parties determined that human genetic resources are not included within the framework of CBD;<sup>27</sup>

(b) Subject matter addressed by other instruments such as WHO PIP-Framework and the International Treaty on Plant Genetic Resources for Food and Agriculture;<sup>28</sup> and

(c) Information arising from man-made genetic sequences.<sup>29</sup>

17. One submission noted that attempting to clarify the concept of digital sequence information is not straightforward and raises more questions than it answers, particularly as the term digital sequence information is potentially broad in scope and doesn't encompass a single type of data.<sup>30</sup> This was echoed in three submissions<sup>31</sup> which posed a range of questions or scenarios highlighting difficulties associated with clarifying the concept of digital sequence information, including the following which are paraphrased for illustrative purposes:

(a) Is digital sequence information limited to hereditary biomolecular strings or can it also encompass non-hereditary strings such as amino acids? Is the scope limited to naturally occurring biomolecules only or also lab-modified or hypothetical biomolecules? Does it include DNA digital storage?<sup>32</sup>

(b) Should digital sequence information be limited to genomic DNA or also include RNA and sequences, such as a retrovirus? Should digital sequence information be limited to native DNA (i.e. the form found in nature) or should it include only the coding regions? Should digital sequence information include regulatory DNA that does not code for proteins but has other effects (e.g. processing genes)? What about information relating to the secondary or tertiary structure of DNA? What about annotations to digital sequence information?<sup>33</sup>

(c) Does digital sequence information include genes, chromosomes, chromosome fragments, coding sequences, all of them or more? What about laboratory generated mutants, for example developed through mass mutagenesis or precision approaches such as CRISPR? How should identical genetic sequences found across different countries be dealt with, for example, sequences from river waters, migratory species, etc.? What are the tolerance levels for variations within a DNA sequence? How should environmental sequence data be handled given that much of the sequence data it contains may not be attributed to a specific organism? Is 'scope' limited to a specific use of digital sequence information or the sequence?<sup>34</sup>

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<sup>26</sup> Third World Network.

<sup>27</sup> Japan.

<sup>28</sup> Japan.

<sup>29</sup> ICC.

<sup>30</sup> BIA.

<sup>31</sup> Canada; BIA; LERU.

<sup>32</sup> Canada.

<sup>33</sup> BIA.

<sup>34</sup> LERU.

## C. Clarifying terminology associated with digital sequence information on genetic resources

### 1. General considerations regarding terminology

18. Historical developments concerning digital sequence information were noted in several submissions, including:

(a) COP's acknowledgement that the term "digital sequence information" may not be the most appropriate term<sup>35</sup> and the use of digital sequence information as a placeholder for a term that enables a more fact and science-based discussion<sup>36</sup>; and

(b) That the term digital sequence information apparently arose during the 2015 meeting of the CBD's Synthetic Biology AHTEG (resulting from a combination of the phrase 'digital sequences' with 'genetic sequence information') and was intended to capture the notion of the speed at which large amounts of digital sequence information may be transmitted globally.<sup>37</sup>

19. Several submissions explicitly considered the term digital sequence information to be inappropriate, ill-defined, ambiguous, imprecise, lacking clarity, consensus or being otherwise problematic.<sup>38</sup> Comments exemplifying this sentiment include:

(a) Digital sequence information is too ill-defined, general/broad to be operationally meaningful as it can have a variety of interpretations under different contexts;<sup>39</sup>

(b) Discussions on digital sequence information are challenging due to lack of consensus or definition as to what constitutes digital sequence information;<sup>40</sup> and

(c) Digital sequence information is not an appropriate term to capture all of the different types of information concerning genetic resources that may constitute digital sequence information.<sup>41</sup>

### 2. Evaluation of the constituent terms 'digital', 'sequence' and 'information'

20. Several submissions evaluated the constituent term 'digital' and all concluded this component of the term 'digital sequence information' is unnecessary, inappropriate or redundant.<sup>42</sup> The fact that a genetic sequence can be conveyed through a digital medium, such as computer database or online, serves to highlight the speed and ease with which new technological developments facilitate cross-border transfer of sequence information<sup>43</sup>, but this does not refer to any characteristic of the sequence itself.<sup>44</sup> The term unnecessarily excludes non-digital mediums (e.g. paper) in which genetic information may be stored and transferred and is unsuited to accommodate technological advances that facilitate transfer of information (e.g. quantum computing).<sup>45</sup> It was also noted also that scientists do not use term 'digital' when referring to 'sequence' in a biological context.<sup>46</sup>

<sup>35</sup> South Africa; African Union Commission on behalf of the African Group. As per decision 14/20 adopted by the Conference of the Parties to the Convention on Biological Diversity available at <https://www.cbd.int/doc/decisions/cop-14/cop-14-dec-20-en.pdf> which acknowledges that the term "digital sequence information" may not be the most appropriate term capture the various types of information on genetic resources that may be relevant to the objectives of the Convention.

<sup>36</sup> African Union Commission on behalf of the African Group; Republic of Korea; South Africa; ICC; Third World Network. ICC noted the Report of the Ad Hoc Technical Expert Group on digital sequence information, pursuant to meeting held in February 2018, in Montreal, Canada, also used DSI as a placeholder term. The Report is available at <https://www.cbd.int/doc/c/f99e/e90a/71f19b77945c76423f1da805/dsi-ahteg-2018-01-04-en.pdf>.

<sup>37</sup> Third World Network.

<sup>38</sup> African Union Commission on behalf of the African Group; Canada; Ethiopia; India; Switzerland; CETAF; EuropaBio; ICC; Joint submission by Natural History Museum UK and others.

<sup>39</sup> Canada.

<sup>40</sup> Switzerland.

<sup>41</sup> India.

<sup>42</sup> Argentina; Brazil; Canada; Mexico; Republic of South Korea; CETAF; ICC; SPNHC; Third World Network; Joint submission by Consortium of German Natural History Collections and others; Joint submission by Natural History Museum UK and others.

<sup>43</sup> Brazil; Mexico; Joint submission by Natural History Museum UK and others; SPNHC.

<sup>44</sup> ICC.

<sup>45</sup> Argentina; Mexico; Republic of South Korea; CETAF; SPNHC; Third World Network; Joint submission by Natural History Museum UK and others.

<sup>46</sup> Republic of South Korea.

21. Several of submissions evaluated the constituent term ‘sequence’ and support for this component of the term ‘digital sequence information’ varied according to views on the appropriate scope of subject matter for digital sequence information. For example, two submissions indicated this component is central to the concept of digital sequence information, including for the purpose of limiting the scope of subject matter to the sequential order of nucleotides,<sup>47</sup> and one of these considered a further term or descriptor is needed to distinguish between biomolecular sequences and other types of sequences (e.g. mathematical or sequence of events).<sup>48</sup> Conversely, a submission considered the term ‘sequence’ to be unduly restrictive as it does not accommodate other types of information that may be contained in biomolecules.<sup>49</sup>

22. Several of submissions evaluated the constituent term ‘information’ and a broad range of views were expressed regarding its adequacy to describe the concept of ‘digital sequence information’ and whether it should be retained in the term to ultimately replace ‘digital sequence information’.<sup>50</sup> Some considered this component to be inappropriate or undesirable on the basis that it is too general and open to interpretation.<sup>51</sup> Others highlighted the need to distinguish ‘information’ (which is generally achieved after data analysis or dependent on data processing), from ‘data’ (which is intrinsic and can be observed in naturally occurring states)<sup>52</sup> and some of these expressed an explicit preference for the term ‘data’ as a genetic resource has no intrinsic ‘information’ when accessed.<sup>53</sup> Additionally, submissions cautioned that information arises as the result of research on a genetic resource and may be subject to intellectual property rights (IPRs), thus it should be excluded from the term to replace digital sequence information as the inclusion of IPRs would be beyond the scope of a country’s sovereign rights regarding genetic resources.<sup>54</sup>

### *3. Digital sequence information terminology in other international fora*

23. Several submissions noted comparable assessments regarding terminology, scope and access and benefit-sharing (ABS) policy implications concerning ‘digital sequence information’ (howsoever called) which are being undertaken in other international fora.<sup>55</sup> Relevant insights concerning terminology include:

(a) It is useful to consider terminology and discussions in other fora to further clarify concept under CBD and Nagoya Protocol;<sup>56</sup>

(b) Inconsistent terminology is being utilized across international fora including, ‘digital sequence information’, ‘genetic sequence data’ and ‘in silico’;<sup>57</sup>

(c) ‘Genetic sequence data’ (GSD) is an established term under World Health Organizations Pandemic Influenza Preparedness Framework, in which GSD is defined as the order of nucleotides found in a molecule of DNA or RNA, containing the genetic information that determines the biological characteristics of an organism or virus;<sup>58</sup>

(d) The Commission on Genetic Resources for Food and Agriculture of the Food and Agriculture Organization of the United Nations (FAO) recommends use of term GSD;<sup>59</sup> and

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<sup>47</sup> Brazil.

<sup>48</sup> Canada.

<sup>49</sup> Argentina.

<sup>50</sup> Canada; European Union and its Member States; Republic of South Korea; CETAF; SPNHC; Joint submission by Consortium of German Natural History Collections and others; Joint submission by Natural History Museum UK and others.

<sup>51</sup> European Union and its Member States; Republic of South Korea.

<sup>52</sup> Canada; CETAF; SPNHC; Joint submission by Consortium of German Natural History Collections and others; Joint submission by Natural History Museum UK and others;.

<sup>53</sup> Republic of South Korea; CETAF; SPNHC; Joint submission by Consortium of German Natural History Collections and others; Joint submission by Natural History Museum UK and others;.

<sup>54</sup> CETAF; SPNHC; Joint submission by Consortium of German Natural History Collections and others; Joint submission by Natural History Museum UK and others.

<sup>55</sup> Australia; Brazil; Argentina.

<sup>56</sup> Switzerland.

<sup>57</sup> Australia; Brazil.

<sup>58</sup> Japan; European Union and its Member States; Canada, Brazil.

<sup>59</sup> Switzerland.



(e) A Working Group<sup>60</sup> established under the International Treaty on Plant Genetic Resources for Food and Agriculture (International Treaty) had been considering whether to address issues related to digital sequence information in the revised text of the Standard Material Transfer Agreement used under the International Treaty, including the appropriate terminology to use.<sup>61</sup>

#### 4. Preferred/suggested terminology

24. Several of submissions suggested alternative or preferred terminology to be used in place of digital sequence information, including the following (with accompanying reasoning, where provided):

- (a) Dematerialized information and dematerialized genetic resources;<sup>62</sup>
- (b) In silico;<sup>63</sup>
- (c) Natural information;<sup>64</sup>
- (d) Sequence information;<sup>65</sup>
- (e) Sequence information originating from genetic resources;<sup>66</sup>
- (f) Sequence data;<sup>67</sup>
- (g) Genetic information;<sup>68</sup>
- (h) Genetic information on genetic resources;<sup>69</sup>
- (i) Genomic sequence data;<sup>70</sup>
- (j) Genetic sequence data<sup>71</sup>, support for which focused on:
  - (i) Common use of the term by the scientific community<sup>72</sup> and an established term under the World Health Organizations Pandemic Influenza Preparedness Framework;<sup>73</sup>
  - (ii) Precise terminology to depict the order of nucleotides found in a molecule and which delimits the scope of ‘sequence’ as related to a genetic resource;<sup>74</sup>
- (k) Genetic resource sequence data<sup>75</sup>, support for which focused on the following:
  - (i) ‘Genetic resource’ is a defined term in the CBD and so provides a necessary link with DNA or RNA sequences in a specific genetic resource;

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<sup>60</sup> The Ad Hoc Open-ended Working Group to Enhance the Functioning of the Multilateral System (MLS) of access and benefit-sharing (ABS) of the International Treaty on Plant Genetic Resources for Food and Agriculture.

<sup>61</sup> Noted by Brazil, Argentina, and the ITPGRFA. Following the 8<sup>th</sup> Governing Body Meeting in Rome in October 2019, there does not appear to be consensus for Working Group to continue this work so it is unclear if/how the issue of DSI will continue to be addressed in this fora in the future.

<sup>62</sup> Brazil (noted); ITPGRFA (noted).

<sup>63</sup> Australia (noted); Brazil (noted).

<sup>64</sup> Brazil (noted); South Africa (Noted); African Union Commission on behalf of the African Group (one of two preferred).

<sup>65</sup> India (noted).

<sup>66</sup> Iran (noted).

<sup>67</sup> India (noted).

<sup>68</sup> Argentina (preferred); South Africa (noted); African Union Commission on behalf of the African Group (one of two preferred); Ethiopia (one of two preferred); ITPGRFA (noted).

<sup>69</sup> Brazil (preferred).

<sup>70</sup> Canada (one of two preferred).

<sup>71</sup> Brazil (noted); Canada (one of two preferred); Ethiopia (one of two preferred); European Union and its Member States (noted); Japan (preferred); Republic of South Korea (preferred); South Africa (noted); Switzerland (noted); United States of America (noted); CETAF (noted); INSDC (noted); SPNHC (noted); Joint submission by Natural History Museum UK and others (noted).

<sup>72</sup> Republic of South Korea; Japan; European Union and its Member States.

<sup>73</sup> Japan.

<sup>74</sup> Republic of South Korea; Japan; CETAF; INSDC.

<sup>75</sup> EuropaBio; ICC; IFRA and IOFI.

- (ii) ‘Sequence’ results from the process of determining the order of nucleotides in DNA genome or RNA molecule of a genetic resource of a specific species; and
- (iii) ‘Data’ refers to the actual genetic sequence data of a specific genetic resource.

(l) Nucleotide sequence data;<sup>76</sup>

(m) Nucleotide sequence data on genetic resources,<sup>77</sup> which was clarified to mean nucleotide sequence data generated by sequence determination of accessed genetic resources in the process of their utilization within the framework of the CBD and the Nagoya Protocol.<sup>78</sup>

#### **D. Perspectives on the use of digital sequence information on genetic resources**

##### *1. Scientific norms and established practices*

25. The policy-based process on digital sequence information established by decision 14/20 includes, inter alia, the commissioning and peer-review of a Combined Study on Digital Sequence Information in Public and Private Databases and Traceability<sup>79</sup> which has been developed taking into account a wide range of sources. The study considers scientific norms and established practices concerning digital sequence information in considerably greater detail than the sections below.

26. Digital sequence information is generated mostly from basic research on plants, animals, fungi, bacteria and viruses<sup>80</sup> in which DNA sequences from collection materials are placed in the public domain for taxonomic, phylogenetic or evolutionary studies.<sup>81</sup> A significant portion of this data is generated by publicly funded research-focused institutions worldwide and this work is typically carried out with non-commercial aims and often involving international co-operation.<sup>82</sup>

27. Open exchange of DNA sequences and related data has become standard practice in non-commercial scientific research in which public international data repositories facilitate the and the rapid sharing of digital sequence information.<sup>83</sup> This open access model has been driven by the policies of research funders and scientific journals which since the 1990’s have seen a discernible shift towards open access science to support scientific research globally.<sup>84</sup> One submission, however, noted that the perceived open-access model should not be equated with ‘free’ or ‘unrestricted’ and most databases don’t provide information regarding how the information was obtained or if IP or other restrictions apply to the commercial use of such data/information.<sup>85</sup>

28. Several submissions noted that the International Nucleotide Sequence Database Collaboration (INSDC)<sup>86</sup> has been adopted by the scientific community as the data infrastructure for the open sharing of sequences, both in terms of data exchange systems and supporting technical data standards.<sup>87</sup> Relevant insights included:

(a) INSDC’s core databases are freely accessible to researchers in all countries<sup>88</sup> and place no restriction on the access, use and redistribution of data pursuant to an open data policy which is

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<sup>76</sup> European Union and its Member States (noted); CETAF (preferred); LERU (preferred); Natural History Museum Vienna (preferred); Joint submission by Consortium of German Natural History Collections and others (preferred); Joint submission by Natural History Museum UK and others (preferred).

<sup>77</sup> JBA (preferred).

<sup>78</sup> JBA.

<sup>79</sup> Available at <https://www.cbd.int/meetings/DSI-AHTEG-2020-01>.

<sup>80</sup> South Africa.

<sup>81</sup> Natural History Museum Vienna.

<sup>82</sup> Natural History Museum Vienna.

<sup>83</sup> EuropaBio; ICC; Natural History Museum Vienna; SPNHC; Joint statement from group of stakeholder organizations; Joint submission by Consortium of German Natural History Collections and others.

<sup>84</sup> INSDC; Natural History Museum Vienna; Wellcome Sanger Institute; Joint submission by Consortium of German Natural History Collections and others; Joint submission by Natural History Museum UK and others.

<sup>85</sup> Mexico

<sup>86</sup> A partnership between the National Institute of Genetics’ DNA Data Bank of Japan (DDJB), the European Molecular Biology Laboratory’s European Bioinformatic Institute (EMBL-EBI), and the US National Institutes of Health’s National Library of Medicine, National Center for Biotechnology Information (NCBI).

<sup>87</sup> United States of America; JBA; INSDC.

<sup>88</sup> JBA.

determined by governments, funding sources, institutional governance and INDC International Advisory Committee;<sup>89</sup>

(b) Contributors are encouraged to provide contextual metadata which describes digital sequence information including, where applicable, information regarding the origin of a biological sample associated with digital sequence information such as where and when it was obtained, and where it is stored;<sup>90</sup>

(c) The INSDC databases were accessed from 172 countries from all regions between 2014 and 2016 (i.e. used by literally every country in the world)<sup>91</sup> and one of them, EMBL-European Bioinformatics Institute (EMBL-EBI), is subject to more than 100 million searches a year.<sup>92</sup>

(d) Since 1982 the number of bases accessible through INSDC databases has doubled approx. every 18 months and as at April 2019 the number of base pairs recorded were over 321 billion.<sup>93</sup>

29. Several of submissions noted these public databases allow sequences to be compared to thousands of other sequences from different organisms and that it is this aggregation of data that generates the greatest value for scientific research.<sup>94</sup> Illustrative insights include:

(a) The true value of digital sequence information comes from aggregated datasets where patterns of conserved features or differences across of thousands of genome sequences can easily be identified and this is fundamental to providing biological insights concerning genetic resources; and<sup>95</sup>

(b) Submissions to public databases adds value and drives knowledge generation from the entire corpus of data as few scientific interpretations rely on a single sequence, rather it is the aggregation of many sequences that adds most value.<sup>96</sup>

## *2. Use and application of digital sequence information*

30. A broad range of scenarios in which digital sequence information is used in scientific research and innovation have previously been covered in the ‘Synthesis of views and information on the implications of the use of digital information on Genetic Resources for the three objectives of the Convention and the objective of the Nagoya Protocol’ accompanied by ‘Case studies and examples of the use of digital sequence information in relation to the objectives of the Convention and the Nagoya Protocol’, which were made available to the meeting of the Ad Hoc Technical Expert Group on digital sequence information on genetic resources, held in February 2018.<sup>97</sup>

31. Several submissions in the present call similarly highlighted the use of digital sequence information in scientific research and innovation, including in public health (epidemic outbreaks, vaccine development, antimicrobial resistance, food safety and surveillance, and control of infectious diseases)<sup>98</sup>; species identification and taxonomy;<sup>99</sup> conservation, sustainable use and/or biodiversity

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<sup>89</sup> INSDC.

<sup>90</sup> INSDC.

<sup>91</sup> ICC; JBA; Joint statement from group of stakeholder organizations; Joint submission by Consortium of German Natural History Collections and others.

<sup>92</sup> Joint submission by Natural History Museum UK and others.

<sup>93</sup> BIA.

<sup>94</sup> ICC; INSDC; CETAF; Wellcome Sanger Institute; Joint submission by Consortium of German Natural History Collections and others.

<sup>95</sup> Wellcome Sanger Institute.

<sup>96</sup> INSDC.

<sup>97</sup> Available at: <https://www.cbd.int/meetings/DSI-AHTEG-2018-01>. The document was also considered by the 22nd meeting of the Subsidiary Body on Scientific, Technical and Technological Advice held 2-7 July in Montreal, Canada, as well as the 14th meeting of the Conference of the Parties to the Convention on Biological Diversity and 3rd meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol on Access and Benefit-Sharing, held 17-29 November 2018 in Sharm El-Sheikh, Egypt.

<sup>98</sup> European Union and its Member States; United States of America.

<sup>99</sup> Canada.

management;<sup>100</sup> plant and animal health,<sup>101</sup> breeding and food security;<sup>102</sup> monitoring and control related to public health, invasive species and regulatory compliance;<sup>103</sup> and industrial processes and developing new materials.<sup>104</sup>

32. One submission noted that it has become a technological reality that genetic resources can be accessed as digital sequence information in databases independently of access to the underlying biological material and result in commercial applications (i.e. independently of access or benefit sharing within the ABS framework of the CBD).<sup>105</sup> Two examples were provided:

(a) ‘Crop OS’, a product of Benson Hill Biosystems funded by Google Ventures which relies on machine-based analysis of a variety of public and proprietary digital sequence information and which is sold to biotechnology and plant breeding institutions; and

(b) The use of digital sequence information associated with an Ebola virus to make a vaccine for commercial use, independent of the virus sample to which ABS conditions would have been imposed through the Material Transfer Agreement mediating the transfer.

## II. DOMESTIC MEASURES AND BENEFIT-SHARING ARRANGEMENTS FROM COMMERCIAL AND NON-COMMERCIAL USE

### A. Domestic measures on access and benefit-sharing concerning digital sequence information on genetic resources

33. The policy-based process on digital sequence information established by decision 14/20 includes, inter alia, the commissioning and peer-review of a fact-finding study on how domestic measures address benefit-sharing arising from commercial and non-commercial use of digital sequence information on genetic resources, and address the use of digital sequence information on genetic resources for research and development<sup>106</sup> which was developed by subject matter experts relying on a wide range of sources, including the views and information submitted and synthesized in this document.<sup>107</sup> This section should be read with this limitation in mind and the peer-reviewed, fact-finding study on domestic measures is more comprehensive.

#### 1. *Comments on measures that do not explicitly address digital sequence information on genetic resources*

34. Several of submissions indicated their national ABS framework does not address digital sequence information<sup>108</sup> and some of these elaborated that they are unsupportive of measures that restrict access digital sequence information, irrespective of the type of use.<sup>109</sup>

35. Several of submissions indicated that their national ABS framework does not address digital sequence information, however, digital sequence information is nevertheless understood to be within the scope of their domestic ABS framework. Illustrative examples include:

(a) The national ABS legislation of Colombia in which access to genetic sequence information is considered equivalent to accessing a genetic resource, and access contracts incorporate a

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<sup>100</sup> Australia; European Union and its Member States; South Africa; United States of America; ICC; Joint submission by Natural History Museum UK and others.

<sup>101</sup> South Africa; Japan; European Union and its Member States; CIPA; ICC; INSDC.

<sup>102</sup> Japan; South Africa; United States of America; CIPA; ICC; INSDC.

<sup>103</sup> European Union and its Member States South Africa; CIPA; iBOL; Wellcome Sanger Institute.

<sup>104</sup> CIPA.

<sup>105</sup> Third World Network.

<sup>106</sup> CBD/AHTEG/DSI/2020/1/5. Available at <https://www.cbd.int/meetings/DSI-AHTEG-2020-01>.

<sup>107</sup> Other sources of information include the ABS Clearing-House (ABSCH), literature and website reviews, interviews, and responses to a survey specifically on domestic measures which was designed by the authors and circulated by the CBD Secretariat, to which thirty-six Contracting Parties responded, as indicated in Section 1.4 ‘Methodology and Sources of Information’ of the study.

<sup>108</sup> Australia; Canada; Japan; Republic of South Korea; Switzerland; BIA (referring to UK legislation).

<sup>109</sup> Australia; Japan; Republic of South Korea; United States of America.

clause requiring the prior approval of the Ministry of the Environment and Sustainable Development for the grant of intellectual property rights, or the publication/dissemination of genetic or chemical information obtained by accessing a genetic resource or its derivatives, if it has potential for potential for bioprospecting, or industrial/commercial exploitation.<sup>110</sup>

(b) The Biological Diversity Act of India in which the submission further elaborated that Section 6, which refers to ‘information on biological resource’, is sufficiently broad to cover digital sequence information;<sup>111</sup>

(c) The Biodiversity Act 2004 of South Africa in which:

- (i) ‘Genetic resource’ is defined to include ‘any genetic material or genetic potential characterization or information of any species’ and therefore access to digital sequence information is considered to constitute access to a genetic resource;<sup>112</sup>
- (ii) Mutually agreed terms and access permit templates include mandatory clauses that address access for commercial use and terms and conditions governing third-party transfer which could include the utilization of digital sequence information on genetic resources, whether stored in public or private databases;<sup>113</sup>
- (iii) The legislation reflects a policy solution aimed at ensuring fair and equitable sharing of benefits with a country of origin where a genetic resource underpins the creation of sequence data which has been accessed and used for commercial purposes.<sup>114</sup>

36. Several of submissions indicated or inferred that their national ABS framework does not explicitly address digital sequence information, however, they acknowledged that its use can be governed by a provider country through prior informed consent (PIC) and mutually agreed terms (MAT) for access to the underlying genetic resources.<sup>115</sup>

37. One submission indicated that their national ABS framework does not currently address digital sequence information, however, modifications are underway to address this.<sup>116</sup>

2. *Comments on measures that explicitly address digital sequence information on genetic resources*

38. One submission indicated that national ABS measures explicitly address digital sequence information to confirm that digital sequence information is considered beyond scope of the national ABS framework.<sup>117</sup> Conversely, three submissions confirmed that national measures are in place to regulate access and benefit-sharing associated with digital sequence information.<sup>118</sup> These submissions elaborated as follows:

(a) Costa Rica’s biodiversity law<sup>119</sup> explicitly addresses access to genetic and biochemical resources (in situ and ex situ) as well as ‘associated knowledge’, with the objective of regulating basic research, bioprospecting and economic exploitation. Its ABS framework provides facilitated access for

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<sup>110</sup> Colombia.

<sup>111</sup> India.

<sup>112</sup> South Africa.

<sup>113</sup> South Africa.

<sup>114</sup> South Africa.

<sup>115</sup> Belarus; Madagascar; Switzerland.

<sup>116</sup> Ethiopia elaborated that it anticipates issuing an ABS proclamation which will incorporate digital sequence information into the scope of genetic resources by defining genetic resource as “any material of biological resource containing genetic information having actual or potential values for humanity and includes derivatives.”

<sup>117</sup> JBA. The submission indicated that the domestic ABS framework implementing the Nagoya Protocol in Japan stipulates that information concerning genetic resources such as nucleic acid sequences is outside the scope of application because it does not fall under the category of genetic resources to which Protocol applies. This stipulation is not explicitly mentioned in the submission by the Government of Japan.

<sup>118</sup> Costa Rica; Brazil.

<sup>119</sup> Ley de Biodiversidad #7788.

non-commercial use of digital sequence information, subject to the competent national authority's right to intervene to restrict the publication of genetic sequences (as discussed further in para. 42 below);

(b) Brazil's biodiversity law<sup>120</sup> defines 'genetic heritage'<sup>121</sup> to include 'information of genetic origin'<sup>122</sup> and establishes an ABS framework which in 2017 introduced streamlined administrative procedures for obtaining access authorization, prior informed consent and mutually agreed terms. This framework is implemented through 'SisGen', a declaratory register operating as a 'one-stop-shop' which distinguishes between research and commercial uses of genetic resources, including digital sequence information.

(c) Several African countries are described as having or as implementing, national ABS legislation which defines 'genetic material' or its equivalent to explicitly include digital sequence information (including Ethiopia, Malawi, South Africa, Uganda).<sup>123</sup>

39. Brazil's 'SisGen' model for facilitated access shifts focus from 'control of access to genetic resources' towards 'economic exploitation of genetic resources' and reduces transaction cost by focusing on triggering events to invoke tracking and tracing. It notes that SisGen's key objective is to foster R&D arising from Brazil's genetic diversity and to facilitate access to genetic resources, including digital sequence information, in order to generate benefits that will fund biodiversity conservation and sustainable use. Brazil recommends that its 'SisGen' model for facilitated access could be considered a model for adoption by other CBD Parties.

40. A detailed description of Brazil's model for facilitated access can be found in its submission<sup>124</sup> as well as the study on domestic measures.<sup>125</sup> Since implementing SisGen Brazil has received 449 notifications declaring genetic heritage of in-silico origin, from which 64 notifications concern technological development activities with commercial potential<sup>126</sup> and as yet no notifications concerning a finished product have been registered. For illustrative purposes, Brazil provides three example notifications providing information on research and development activities arising from the access and use of Brazilian genetic heritage comprising digital sequence information, summarized as follows and further information concerning benefit-sharing arising from the commercial exploitation of finished products derived from digital sequence information utilization are anticipated to be shared through the ABS Clearing-House:<sup>127</sup>

(a) Example #1: use of informatic techniques to find pharmaceutical receptors (proteins), deposited in the Protein Data Bank (PDB), which are associated with natural products from Brazilian biodiversity. The declaration associated with this activity records database of molecules with biological activity, ZINC & SEA, as the source of the in-silico origin.

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<sup>120</sup> Law #13,123 as regulated by Decree #8,772 in force since 2017 and as was complemented by Provisional Act # 2,186-16/2001.

<sup>121</sup> The term 'genetic heritage' which is used in Brazil's 1988 constitution, is considered and used as equivalent to the term 'genetic resources' under the CBD.

<sup>122</sup> Whether contained in samples or all or part of a plant, fungal, microbial or animal species, in the form of molecules and substances originating from the metabolism of these living beings, and in extracts obtained from in-situ conditions (including domesticated or kept in ex-situ collections, if collected from in-situ conditions) within the Brazilian territory, on the continental shelf or in the exclusive economic zone.

<sup>123</sup> African Union Commission on behalf of the African Group. Further information concerning country-level ABS legislation is available in the study on how domestic measures address benefit-sharing arising from commercial and non-commercial use of digital sequence information on genetic resources, and address the use of digital sequence information on genetic resources for research and development (CBD/AHTEG/DSI/2020/1/5) available at <https://www.cbd.int/meetings/DSI-AHTEG-2020-01>.

<sup>124</sup> Accessible at <https://www.cbd.int/abs/DSI-views/2019/Brazil-DSI.pdf>.

<sup>125</sup> Study on how domestic measures address benefit-sharing arising from commercial and non-commercial use of digital sequence information on genetic resources, and address the use of digital sequence information on genetic resources for research and development (CBD/AHTEG/DSI/2020/1/5) available at <https://www.cbd.int/meetings/DSI-AHTEG-2020-01>.

<sup>126</sup> i.e. 64 are equivalent to 'benefit-sharing arrangements arising from commercial use of genetic sequence information on genetic resources' and the remaining 385 are equivalent to 'benefit-sharing arrangements arising from non-commercial use of genetic sequence information on genetic resources'.

<sup>127</sup> Accessible at <https://www.cbd.int/abs/theabsch.shtml>.

(b) Example #2: records a databank from which a digital sequence information on a genetic resource was obtained in which the objective is to develop a prototype kit for confirmatory diagnosis as a complimentary technique for the detection and identification of a particular parasite. The declaration associated with this activity records a publicly funded antibody platform as the as the source of the Brazilian genetic heritage;

(c) Example #3: an invention comprising use of peptides synthetic derivatives of the toxins of a Brazilian invertebrate for the treatment of ocular disease. The declaration identified a ‘UniProtKB’ (a database which provides functional and sequence information on proteins) as the source of the digital sequence information.

## **B. Benefit-sharing arrangements from commercial and non-commercial use of digital sequence information on genetic resources**

41. No submissions explicitly addressed benefit-sharing arrangements or instances of benefit sharing arising from commercial use of digital sequence information on genetic resources.

42. One submission noted the extent of commercial use of digital sequence information on genetic resources is unknown and anticipated that digital sequence information accessed under research terms is being used commercially, potentially by multiple different users, without the original providers being aware of such use or involved in the process.<sup>128</sup>

43. Two submission indirectly addressed benefit-sharing arrangements arising from commercial use of digital sequence information on genetic resources in the coverage of their domestic ABS frameworks:

(a) Brazil’ framework providing facilitated access to digital sequence information includes options for mandatory benefit-sharing options which, subject to prescribed exemptions, are applicable in the event of commercial/economic exploitation of a product derived from utilization a genetic resource or digital sequence information;<sup>129</sup>

(b) Costa Rica’s ABS framework does not directly regulate commercial bioprospecting, however, as a matter of public policy, the national authority has the right to prevent publication of digital sequence information in specific circumstances (subject to justification) in order to prevent this information entering the public domain and being used commercially by third parties without fair and equitable sharing of benefits with the provider of the resource.<sup>130</sup>

44. Several submissions considered digital sequence information to constitute an important form of non-monetary benefit sharing on the basis of, inter alia, the benefits that accessibility of digital sequence information confers to society.<sup>131</sup> In doing so they did not distinguish between commercial and non-commercial uses and several of these are unsupportive of benefit sharing arrangements that impede access digital sequence information, irrespective of the type of use. Illustrative examples include:

(a) Australia does not support inclusion of digital sequence information in ABS arrangements on the basis of the benefits associated with the current open access regime to digital sequence information, including increased scientific information, discovery and progress, and increased innovation and increased value to biological diversity that such information provides;

(b) Japan recognizes MAT may theoretically cover benefit sharing from the use of the digital sequence information, however, it considers open access to digital sequence information is an important form of benefit-sharing which contributes to conservation and sustainable use of biodiversity as well as other important areas, including food security, human and animal plant health;

(c) Canada recognizes that providers and users may negotiate mutually agreed terms for the utilization of genetic resources which may govern how genetic sequence information can be used and shared, however, it strongly supports the free exchange of genetic sequence data;

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<sup>128</sup> South Africa.

<sup>129</sup> Brazil.

<sup>130</sup> The submission notes that a study of specific instances in which it is necessary to restrict publication of DSI should be undertaken by the Parties.

<sup>131</sup> Australia; Canada, European Union and its Member States; Republic of South Korea; Japan; United States of America.

(d) European Union and its Member States consider that PIC cannot and should not be required for access to digital sequence information, including from publicly available databases.

45. Conversely, several submissions considered that benefit-sharing arrangements for commercial and non-commercial use of digital sequence information on genetic resources should be differentiated. Illustrative examples include:

(a) Digital sequence information should be publicly available/accessible for non-commercial use only (i.e. educational, training and research purposes only), whereas commercial use/application should be subject to benefit-sharing.<sup>132</sup>

(b) Benefit-sharing for digital sequence information should be triggered according to the type of use, without regard for the identity of the user, be it a company or a non-profit.<sup>133</sup> The submission elaborates as follows:

- (i) Downstream users may derive commercial uses from digital sequence information initially published for non-commercial purposes;
- (ii) Public or academic users may be subject to institutional policies or regulatory requirements to seek intellectual property or commercially exploit research involving digital sequence information if it has commercial potential;
- (iii) Genuine non-commercial uses will not trigger benefit-sharing;
- (iv) Suggests data use agreements or database terms and conditions should allow digital sequence information to remain publicly accessible while protecting sovereign rights of provider countries over their genetic resources.

46. One submission recommended a potential model for benefit-sharing arrangements from commercial and non-commercial use of digital sequence information on genetic resources.<sup>134</sup> The model is in the form of the Material Transfer Agreement used by the South Africa's Department of Health for the transfer of human biological materials which are defined to include data, such as digital sequence information. The terms of the MTA seek to ensure that benefits derived from commercial or non-commercial research are shared in a manner that is fair and equitable, including regarding secondary use of materials comprising digital sequence information. Notable features of the MTA include:

(a) The country of origin retains ownership of human biological materials (i.e. including in the case of data concerning human biological materials, irrespective of where the data is stored);

(b) MTA applies to all providers and recipients of human biological materials for use in commercial and non-commercial research;

(c) Scope of benefits includes, inter alia, sharing information use of research results, royalties, acknowledgement of provider as source of the materials, publication rights, transfer of technology or materials and capacity building.

### **III. CAPACITY-BUILDING NEEDS RELATED TO DIGITAL SEQUENCE INFORMATION ON GENETIC RESOURCES**

47. One submission considered that consensus on whether DSI is subject to access and benefit-sharing under the Convention and the Protocol should be prioritized before further discussions concerning capacity-building take place.<sup>135</sup>

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<sup>132</sup> Belarus; Iran.

<sup>133</sup> Third World Network.

<sup>134</sup> South Africa.

<sup>135</sup> South Korea.



48. Several submissions acknowledged the need for and/or the importance of capacity-building related to digital sequence information on genetic resources.<sup>136</sup> It is generally accepted that a lack of capacity in many countries hinders greater use of digital sequence information<sup>137</sup> and that there is a need to enhance capacity to generate, analyze, access and use digital sequence information on genetic resources,<sup>138</sup> particularly for developing countries which are typically the megadiverse countries/regions in which the genetic resources used to generate digital sequence information, originate.<sup>139</sup> Capacity-building with regard to digital sequence information needs to take into account national needs and priorities of any particular country to make productive use of capacity-building and technology transfer<sup>140</sup> and it is considered particularly important that capacity-building meets the needs of communities that have contributed to conservation and generation of knowledge benefit from creation of genetic resources in order to ensure they are not left behind as technology continues to advance.<sup>141</sup>

49. Several of submissions identified specific needs/modalities and/or priorities for capacity-building. Illustrative examples include:

(a) Intensifying capacity building through Massively Open Online Courses (MOOC) which could be coordinated with INSDC databases and/or new sequencing Centers;<sup>142</sup>

(b) Intensifying joint research involving generation and analysis of digital sequence information including training as part of research (which often made available to visitors and colleagues from developing countries) and the application of genetic markers for improved biodiversity management;<sup>143</sup>

(c) Improving access to sequencing equipment, computer software and know-how<sup>144</sup> and providing foundry support for synthesizing modified/synthetic sequences for R&D, including for commercial purposes;<sup>145</sup>

(d) Strengthening bioinformatics, datamining and use of databases/repositories,<sup>146</sup> particularly regarding use of digital sequence information for analysis of environmental DNA (e.g. samples of organisms taken from soil and water to monitor the species composition)<sup>147</sup> as well as use of digital sequence information for taxonomical works (e.g. to establish a collection of microorganisms),<sup>148</sup>

(e) Training targeting regulatory institutions and enforcement bodies (in science, technology, trade, industry, agriculture and health) responsible for developing or implementing ABS policies;<sup>149</sup>

(f) Training targeting indigenous/local communities which preserve biodiversity, in order to incorporate more actively into these discussions and decision making concerning digital sequence information;<sup>150</sup>

(g) Strengthening/developing global standards for ABS targeting researchers and technical staff who collect, process and/or manage biological materials that are used for DNA sequencing;<sup>151</sup>

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<sup>136</sup> Canada; European Union and its Member States; Ethiopia; India; Madagascar; South Africa; African Union Commission on behalf of the African Group; Joint statement from group of stakeholder organizations; Joint submission by Consortium of German Natural History Collections and others; Joint submission by Natural History Museum UK and others.

<sup>137</sup> Joint submission by Natural History Museum UK and others.

<sup>138</sup> India; Ethiopia.

<sup>139</sup> Madagascar; African Union Commission on behalf of the African Group; Joint statement from group of stakeholder organizations.

<sup>140</sup> African Union Commission on behalf of the African Group.

<sup>141</sup> African Union Commission on behalf of the African Group.

<sup>142</sup> Joint submission by Consortium of German Natural History Collections and others.

<sup>143</sup> iBOL; Joint submission by Consortium of German Natural History Collections and others.

<sup>144</sup> Iran.

<sup>145</sup> Canada; South Africa; African Union Commission on behalf of the African Group.

<sup>146</sup> Costa Rica.

<sup>147</sup> Japan.

<sup>148</sup> Japan.

<sup>149</sup> South Africa.

<sup>150</sup> Mexico.

<sup>151</sup> South Africa

(h) Strengthening/developing development of model legal terms to authorize access to digital sequence information and mechanisms for sharing of benefits arising from their use;<sup>152</sup>

(i) Increasing regional projects to strengthen capacity related to digital sequence information, synthetic biology, benefit-sharing and intellectual property associated with managing genetic resources in the context of the post-2020 agenda for the CBD;<sup>153</sup>

(j) Socioeconomic development linked to fair and equitable sharing of benefits derived from the commercialization of digital sequence information;<sup>154</sup>

50. Several submissions provided generalized examples of capacity building activities and/or initiatives they are involved in.<sup>155</sup> Illustrative examples include:

(a) Training students from ‘provider’ countries to work in labs; joint research involving generation and analysis of NSD; making DNA labs available to visiting researchers and colleagues from developing countries;<sup>156</sup>

(b) Training packages which focus on digital sequence information, for examples as provided by the European Nucleotide Sequence Archive (ENA) maintained by the EMBL-EBI, which allows researchers who do not have access to the infrastructure and resources required for large scale sequencing projects to still benefit from these resources;<sup>157</sup>

(c) Non-commercial biodiversity research focused organizations engage in capacity building as good/standard practice within the sector and this typically involves: training concerning sequencing and data analysis at graduate, postgraduate, and professional levels; intake of PHD students and research partnerships involving researchers from developing countries; collaborations involving sequencing at cost for external researchers and supporting infrastructure growth in ‘provider’ countries;<sup>158</sup>

(d) Training for research, joint research involving generation and analysis of NSD, in-house training at bachelors, masters and PHD levels and informally through professional contact; also compiled information on best practices for ABS and organized workshops for members comprising 686 organizations from 24 countries located in Africa, Asia, Australia, Europe and North America.<sup>159</sup>

51. Several of submissions acknowledged the CBD Secretariat’s existing capacity building training program as part of its Global Taxonomy Initiative (GTI) to promote biodiversity and sustainable use through training on DNA barcoding targeting regulatory authorities focusing on illegal trade (including forestry/fisheries authorities and protected area managers)<sup>160</sup> and SCBD barcoding support.<sup>161</sup>

#### **IV. IMPLICATIONS FOR THE OBJECTIVES OF THE CONVENTION AND THE NAGOYA PROTOCOL**

##### **A. Considerations on scope of the Convention and the Nagoya Protocol**

52. Several of submissions considered digital sequence information not to be within the scope of the ABS framework of the CBD and the Nagoya Protocol, including on the basis that digital sequence information is distinct from and does not equate to, is not equivalent to, or does not fall within the definition of, ‘genetic material’, ‘genetic resource’ and/or ‘derivatives’.<sup>162</sup> Additionally, two submissions

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<sup>152</sup> Colombia; Costa Rica.

<sup>153</sup> Colombia.

<sup>154</sup> South Africa.

<sup>155</sup> CETAF; SPNHC; Wellcome Sanger Institute; Joint submission by Consortium of German Natural History Collections and others; Joint submission by Natural History Museum UK and others.

<sup>156</sup> CETAF; Joint submission by Consortium of German Natural History Collections and others.

<sup>157</sup> Wellcome Sanger Institute.

<sup>158</sup> Joint submission by Natural History Museum UK and others.

<sup>159</sup> SPNHC.

<sup>160</sup> South Africa.

<sup>161</sup> CTAF; SPNHC; Joint submission by Consortium of German Natural History Collections and others.

<sup>162</sup> Australia; Canada; European Union and its Member States; Japan; Republic of South Korea; Switzerland; United States of America; CIPA; BIA; IFRA and IOFI; JBA; LERU; Wellcome Sanger Institute.

stressed that to consider/equate digital sequence information a genetic resources would require a renegotiation of CBD/Nagoya to redefine ‘genetic material’.<sup>163</sup>

53. Conversely, several of submissions explicitly considered digital sequence information to be within the scope of the ABS framework of the CBD and Nagoya Protocol, and hence subject to PIC and/or MAT, and/or benefit sharing, including on the basis that access to digital sequence information is equivalent to access to genetic resources and/or falls within the definition of, ‘genetic material’, ‘genetic resource’ and/or ‘utilization of genetic resources’.<sup>164</sup>

54. Several submissions did not consider access to digital sequence information to be equivalent to access to genetic resources but nevertheless considered digital sequence information to be within the scope of the ABS framework of the CBD and Nagoya Protocol on the basis that its use can be governed by a provider country through PIC and MAT for access to the underlying genetic resources.<sup>165</sup>

55. One submission highlighted the Nagoya Protocol is in its infancy and that explicitly addressing digital sequence information within the scope of CBD/Nagoya Protocol, at this stage, would exacerbate existing challenges to implementation.<sup>166</sup> Conversely, another submission highlighted that enabling developing countries to better share in the monetary benefit arising from the utilization of digital sequence information represents a move towards a more sustainable, efficient and democratic model of development.<sup>167</sup>

56. Three submissions considered digital sequence information on genetic resources in the context of the negotiations to finalize the text of the Convention and/or Nagoya Protocol. One submission considered the record of negotiations to clearly show the Convention was intended to include material resources and the information they encode<sup>168</sup> whereas other submissions considered it was explicitly contemplated or understood as not being within scope in the negotiations for the Convention and/or the Nagoya Protocol.<sup>169</sup>

## **B. Benefits associated with the open exchange of digital sequence information**

57. Several submissions indicated they consider the open exchange of digital sequence information helps to achieve or further the objectives of the CBD,<sup>170</sup> for example by enabling conservation and sustainable use of biodiversity<sup>171</sup> as well as by advancing research and development that create significant downstream benefits (commercial and non-commercial).<sup>172</sup> In doing so, several of submissions considered:

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<sup>163</sup> Australia; BIA.

<sup>164</sup> Argentina; Belarus; Colombia; Costa Rica; Ethiopia; India; Iran; Madagascar; South Africa; African Union Commission on behalf of the African Group.

<sup>165</sup> Canada; European Union and its Member States; Japan; Switzerland; EuropaBio; ICC; JBA; Joint statement from group of stakeholder organizations; Wellcome Sanger Institute.

<sup>166</sup> BIA, citing a report from the Commission to the European Parliament and the Council highlighting constraints in ABS implementation and compliance included but not limited to financial resources devoted to implementation; lack of specialized personnel and qualified experts; administrative burden and costs; interpretation challenges. The ‘Report From the Commission to the European Parliament and the Council Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union’ is available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1548339471740&uri=COM%3A2019%3A13%3AFIN>.

<sup>167</sup> Brazil.

<sup>168</sup> African Union Commission on behalf of the African Group.

<sup>169</sup> Australia; Canada; Switzerland.

<sup>170</sup> Canada; Costa Rica; European Union and its Member States; Japan; Republic of South Korea; CTAF; CIPA; ICC; EuropaBio; SPNHC; Joint submission by Consortium of German Natural History Collections and others; Joint submission by Natural History Museum UK and others.

<sup>171</sup> EuropaBio.

<sup>172</sup> Europa Bio; ICC.

(a) Specific provisions of the CBD in support of their reasoning, including Article 5 regarding cooperation<sup>173</sup>; Article 15 regarding access to genetic resources<sup>174</sup>; Article 16 regarding access to and transfer of technology<sup>175</sup>; and Article 17 regarding the exchange of information<sup>176</sup>; and

(b) The open exchange of digital sequence information to be consistent with or to further the objectives of Aichi Biodiversity Target 19<sup>177</sup> (i.e. that by 2020, knowledge, the science base and technologies relating to biodiversity, its values, functioning, status and trends, and the consequences of its loss, are improved, widely shared and transferred, and applied).<sup>178</sup>

58. Several submissions explicitly considered the open exchange of digital sequence information to constitute an important form of non-monetary benefit sharing in furtherance of the objectives of the CBD and/or for the benefit of society.<sup>179</sup> Submissions elaborated on this point by highlighting:

(a) The availability of digital sequence information enhances scientific research, innovation and collaboration<sup>180</sup>, and allows scientists to replicate research results (which is a cornerstone of scientific research and which would not be possible if the data were not openly available);<sup>181</sup>

(b) The development of the field of genomics is a direct result of digital sequence information being shared globally in easy to access public databases<sup>182</sup> and this has allowed pooling of expertise and resources to solve problems of regional and global significance;<sup>183</sup>

(c) Once published, digital sequence information is available to international community at zero marginal cost<sup>184</sup> thus providing a greater return on investment for taxpayers and avoiding unnecessary duplication and substantial cost of generating data<sup>185</sup>, which leads to significant cost savings in research projects;<sup>186</sup>

(d) The availability of digital sequence information reinforces/creates other non-monetary benefits, such as capacity-building, education and training,<sup>187</sup> often involving international collaboration.<sup>188</sup>

59. Some of these submissions explicitly acknowledged concerns that freely available digital sequence information may be used for commercial purposes without triggering any obligation to share benefits with provider countries from which the genetic resource was acquired. However, on balance they considered that regulating open exchange of digital sequence information would do more harm than good<sup>189</sup> or that the benefits that that flow from such use outweigh the risks.<sup>190</sup>

60. By way of contrast, several submissions explicitly acknowledged the societal benefits generated by open exchange of digital sequence information and/or its role in furthering of the objectives of the

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<sup>173</sup> CIPA.

<sup>174</sup> CETAF; SPNHC; Joint submission by Consortium of German Natural History Collections and others.

<sup>175</sup> CIPA.

<sup>176</sup> CIPA. ICC.

<sup>177</sup> CETAF; SPNHC; Joint submission by Consortium of German Natural History Collections and others; Joint submission by Natural History Museum UK and others. As per the Aichi Biodiversity target available at <https://www.cbd.int/sp/targets/rationale/target-19/>.

<sup>178</sup> CETAF.

<sup>179</sup> Belarus; Canada; European Union and its Member States; Japan; United States of America; BIA; CIPA; CETAF; EuropaBio; ICC; INSDC; Natural History Museum Vienna; LERU; SPNHC; Wellcome Sanger Institute; Joint statement from group of stakeholder organizations ;Joint submission by Consortium of German Natural History Collections and others; Joint submission by Natural History Museum UK and others.

<sup>180</sup> United States of America; ICC; INSDC.

<sup>181</sup> CETAF; Natural History Museum Vienna; SPNHC; Joint submission by Consortium of German Natural History Collections and others.

<sup>182</sup> Wellcome Sanger Institute.

<sup>183</sup> ICC.

<sup>184</sup> CETAF; SPNHC.

<sup>185</sup> Wellcome Sanger Institute.

<sup>186</sup> LERU.

<sup>187</sup> Japan; United States of America.

<sup>188</sup> United States of America; ICC; INSDC; Wellcome Sanger Institute.

<sup>189</sup> Wellcome Sanger Institute.

<sup>190</sup> SPNHC; Joint submission by Natural History Museum UK and others.

CBD, and concluded that such benefits should not be considered in isolation in determining whether or not to regulate the open exchange of digital sequence information.<sup>191</sup> Submissions elaborated on this point as follows:

(a) Non-monetary benefits, however beneficial to society, are no substitute for and should not occur at the expense of sovereignty or monetary benefit sharing where there are commercial benefits arising from the utilization of a genetic resource;<sup>192</sup>

(b) Focusing on digital sequence information as a form of non-monetary benefit sharing misses the point of the fair and equitable sharing objectives under the convention<sup>193</sup> to the detriment of developing countries, farmers and indigenous/local communities who preserve biodiversity;<sup>194</sup>

(c) The speed with which technology for sequencing and analysis is maturing is resulting in a rapid accumulation of digital sequence information for which future commercial uses can be confidently foreseen<sup>195</sup> so if commercial users of digital sequence information can bypass benefit sharing obligations, implementing the third objective of the Protocol will prove impossible and the CBD and the Nagoya Protocol will be undermined.<sup>196</sup>

61. Two submissions stressed that non-monetary benefits and monetary benefit sharing for commercial use should not be considered as mutually exclusive as it is possible to allow facilitated access to digital sequence information for basic research and to regulate commercial use to ensure benefit sharing.<sup>197</sup> One of these stressed that it is possible to strike a fair balance to resolve the complexities and accommodate access and use of digital sequence information and presented its national ABS framework as a model for CBD Parties to consider (as further explained summarized in para. 39).<sup>198</sup>

### **C. Potentially adverse consequences of regulating access and/or use of digital sequence information**

62. Several of submissions, highlighted concerns regarding the potential for adverse consequences that could result from attempts to regulate access and/or use of digital sequence information under national ABS frameworks.<sup>199</sup> Concerns focused on the following, which are not mutually exclusive:

(a) Undermine efforts to promote the objectives of CBD/Nagoya concerning the sustainable use and conservation of biodiversity<sup>200</sup> as well as benefits to society, including non-monetary benefits related to training, capacity-building and knowledge/technology transfer;<sup>201</sup>

(b) Chilling effect on access and use of digital sequence information<sup>202</sup> and increasing barriers to scientific research, data sharing, and innovation across a wide array of research fields;<sup>203</sup>

(c) Reduced international collaboration and diminished ability to tackle complex global challenges which rely on open access research findings and data;<sup>204</sup>

(d) Decrease reproducibility thereby increasing the cost and duplication of scientific research;<sup>205</sup>

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<sup>191</sup> Brazil; Costa Rica; Mexico; African Union Commission on behalf of the African Group; Third World Network.

<sup>192</sup> African Union Commission on behalf of the African Group; Third World Network.

<sup>193</sup> Costa Rica; Mexico; African Union Commission on behalf of the African Group.

<sup>194</sup> Mexico; African Union Commission on behalf of the African Group.

<sup>195</sup> African Union Commission on behalf of the African Group; Third World Network.

<sup>196</sup> Mexico.

<sup>197</sup> Brazil; Costa Rica.

<sup>198</sup> Brazil.

<sup>199</sup> Japan; BIA; JBA; SPNHC; CIPA; CETAF.

<sup>200</sup> Switzerland; United States of America; CIPA; SPNHC; ICC; Wellcome Sanger Institute; Joint statement from group of stakeholder organizations; Joint submission by Consortium of German Natural History Collections and others.

<sup>201</sup> CIPA; ICC; EuropaBio; ICC; IFRA and IOFI; Joint submission by Consortium of German Natural History Collections and others.

<sup>202</sup> ICC; JBA; SPNHC; Joint statement from group of stakeholder organizations.

<sup>203</sup> Belarus; European Union and its Member States; United States of America; BIA; CIPA; ICC; INSDC; JBA; LERU; Wellcome Sanger Institute; Joint statement from group of stakeholder organizations.

<sup>204</sup> JBA

<sup>205</sup> ICC; LERU; Wellcome Sanger Institute; Joint statement from group of stakeholder organizations.

(e) increase legal uncertainty, transaction costs, regulatory burden, due diligence and/or bureaucracy<sup>206</sup> as elaborated by submissions expressing concerns addressing:

- (i) A shift to bilateral data-sharing agreements which may operate as a barrier to access, particularly for researchers in low- and middle-income countries;<sup>207</sup>
- (ii) Discourage overall investment in bio-based R&D and decreased use of digital sequence information;<sup>208</sup>
- (iii) Widespread non-compliance (exacerbating mistrust and hindering the incorporation of ABS to research workflows globally)<sup>209</sup> or avoidance (as researchers will be incentivized to avoid using digital sequence information from countries with onerous requirements),<sup>210</sup>
- (iv) Potential conflicts with other fields of law such as data protection, intellectual property rights, and trade secrets.<sup>211</sup>

63. Additionally, some submissions expressed concerns that countries are adopting different approaches for regulating access and use of digital sequence information under national legislation and that this is already leading to fragmentation, legal uncertainty and increased transaction costs.<sup>212</sup>

64. Several submissions warned that regulating access and use of digital sequence information under an ABS framework could be particularly disruptive to certain users and industries<sup>213</sup> including a disproportionate effect on academic and public institutions, particularly research institutions in developing countries,<sup>214</sup> as well as SMEs.<sup>215</sup>

65. Two submissions noted a shift in user behavior may already be underway regarding access and/or use of digital sequence information in life sciences industries.<sup>216</sup> An example was provided in which a major biotech company conducting research on ‘out of scope’ material decided, after conducting due diligence, not to pursue a similar research program over in-scope materials due to lack of legal certainty and operational clarity regarding the administrative processes in the country of origin.<sup>217</sup>

## V. POTENTIAL NEED FOR FURTHER INFORMATION

66. Several considerations relevant to clarifying the concept of digital sequence information were further identified, including:

(a) Further discussion on the relationship between digital sequence information and the objectives of the CBD;<sup>218</sup>

(b) A better understanding of the key actors (including private databases, public databases and indigenous/local communities)<sup>219</sup> as well as the ultimate beneficiaries of outcomes (e.g. new medicines, improved crops, new materials, etc.) that are facilitated by the open sharing of digital sequence information;<sup>220</sup>

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<sup>206</sup> European Union and its Member States; BIA; CETAF; CIPA; IFRA and IOFI; Wellcome Sanger Institute; Joint submission by Consortium of German Natural History Collections and others.

<sup>207</sup> Wellcome Sanger Institute;

<sup>208</sup> CIPA; IFRA and IOFI; Joint submission by Natural History Museum UK and others.

<sup>209</sup> CIPA; CETAF.

<sup>210</sup> CETAF; CETAF; SPNHC; Joint submission by Consortium of German Natural History Collections and others.

<sup>211</sup> Switzerland; SPNHC; Joint submission by Natural History Museum UK and others.

<sup>212</sup> CETAF; Joint submission by Natural History Museum UK and others; SPNHC.

<sup>213</sup> BIA; Joint statement from group of stakeholder organizations.

<sup>214</sup> ICC.

<sup>215</sup> BIA; Wellcome Sanger Institute.

<sup>216</sup> CIPA; BIA.

<sup>217</sup> CIPA.

<sup>218</sup> Canada.

<sup>219</sup> Mexico.

<sup>220</sup> CIPA.

(c) More comprehensive and fact-based information regarding how digital sequence information is collected, generated, shared and used in biological research,<sup>221</sup> including the use of digital object identifiers (DOIs) as metadata for sequencing and genotyping in research, and the disclosure of country of origin information in metadata;<sup>222</sup>

(d) Detailed case studies by the international business community in order to provide further insights on the well-functioning of the current system;<sup>223</sup>

(e) Economic modelling to quantify and compare the value which unencumbered access and use of digital sequence information represents for furthering objectives of CBD and Nagoya Protocol, as well as revenue potential and implementation costs for alternative models for regulating access and use digital sequence information;<sup>224</sup>

(f) Further research to identify cost-effective solutions that mitigate the risks of data being used for commercial purposes without monetary benefits flowing back to the country of origin, without increasing the risk of loss of non-monetary benefits;<sup>225</sup>

(g) Exploring mechanisms for greater harmonization/uniformity such as through universal regulatory mechanisms,<sup>226</sup> internationally harmonized mechanisms, and<sup>227</sup> multilateral ABS systems.<sup>228</sup>

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<sup>221</sup> Joint statement from group of stakeholder organizations.

<sup>222</sup> Costa Rica; ITPGRFA.

<sup>223</sup> EuropaBio.

<sup>224</sup> Joint statement from group of stakeholder organizations.

<sup>225</sup> Joint submission by Natural History Museum UK and others.

<sup>226</sup> Belarus.

<sup>227</sup> EcoHealth Alliance.

<sup>228</sup> Brazil; Costa Rica.

*Annex to the synthesis*

**LIST OF SUBMISSIONS**

As described above, by notification (2017-37) of 5 February 2019 the Executive Secretary invited the submission of views and expression of interest to undertake studies pursuant to decisions 14/20 and NP-3/12.

Submissions received by the Secretariat in response are listed below. The full text of submissions has been made available online.<sup>229</sup>

(a) Parties to the Convention:

Argentina, Australia, Belarus, Brazil, Canada, Colombia, Costa Rica, Ethiopia, European Union and its Member States, India, Iran, Japan, Madagascar, Mexico, Republic of Korea, South Africa, and Switzerland;

(b) A non-Party: United States of America;

(c) Intergovernmental and other relevant organizations and stakeholders:

- African Union Commission on behalf of the African Group;
- Secretariat of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA);
- Consortium of European Taxonomic Facilities (CETAF);
- Consortium of German Natural History Collections (Deutsche Naturwissenschaftliche Forschungssammlungen); German Life Sciences Association (Verband Biowissenschaften, Biologie und Biomedizin in Deutschland) and the Leibniz Biodiversity Research Alliance (Leibniz Verbund Biodiversität) (Joint submission by Consortium of German Natural History Collections and others);
- Chartered Institute of Patent Attorneys (CIPA);
- EcoHealth Alliance;
- EuropaBio - The European Association for Bioindustries,
- International Barcode of Life Consortium (iBOL);
- International Chamber of Commerce (ICC);
- International Fragrance Association (IFRA) and International Organization for the Flavor Industry (IOFI) (IFRA and IOFI);
- International Nucleotide Sequence Database Collaboration (INSDC);
- Japan Bioindustry Association (JBA);
- League of European Research Universities (LERU)
- Joint statement from group of stakeholder organizations
- Joint submission from the Natural History Museum UK, Royal Botanic Gardens Kew, and Royal Botanic Gardens Edinburgh (Joint submission by Natural History Museum UK and others);
- Natural History Museum Vienna;
- Society for the Preservation of Natural History Collections (SPNHC);
- Third World Network;
- UK BioIndustry Association (BIA); and
- Wellcome Sanger Institute.

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<sup>229</sup> <https://www.cbd.int/dsi-gr/2019-2020/submissions/>.