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### **SYNTHESIS OF VIEWS AND INFORMATION ON THE POTENTIAL IMPLICATIONS OF THE USE OF DIGITAL SEQUENCE INFORMATION ON GENETIC RESOURCES FOR THE THREE OBJECTIVES OF THE CONVENTION AND THE OBJECTIVE OF THE NAGOYA PROTOCOL**

*Note by the Executive Secretary*

#### **INTRODUCTION**

1. The Conference of the Parties to the Convention on Biological Diversity at its thirteenth 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 second meeting adopted decisions on digital sequence information on genetic resources in which they recognized the need for a coordinated and non-duplicative approach on this matter under the Convention and the Nagoya Protocol (decisions XIII/16 and NP-2/14, respectively). They decided to consider at the fourteenth meeting of the Conference of the Parties and the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol any potential implications of the use of digital sequence information on genetic resources for the three objectives of the Convention and for the objective of the Nagoya Protocol, respectively.
2. To assist in this consideration, the Conference of the Parties invited Parties, other Governments, indigenous peoples and local communities, and relevant organizations and stakeholders to submit views and relevant information to the Executive Secretary on the potential implications of the use of digital sequence information on genetic resources for the three objectives of the Convention (decision XIII/16, para. 2). Furthermore, such views and information were also invited to include information relevant to the Nagoya Protocol (decision NP-2/14, para. 2).
3. The Executive Secretary was requested to prepare a compilation and synthesis of the views and information submitted.
4. By notification 2017-37 of 25 April 2017, the Executive Secretary invited the submission of views and relevant information pursuant to decisions XIII/16 and NP-2/14. The list of Parties, non-Parties and organizations that submitted views and information is presented in the annex. This includes information on the acronyms used in the footnotes as well as an explanation of the submissions provided through the Commission on Genetic Resources for Food and Agriculture.
5. The full text of all submissions has been made available online.<sup>1</sup>

\* Reissued for technical reasons on 22 May 2018.

\*\* CBD/DSI/AHTEG/2018/1/1.

\*\*\* CBD/SBSTTA/22/1.

6. More than 50 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 issue but posed a significant challenge in preparing a synthesis that is as concise and easy to comprehend as possible.<sup>2</sup> To aid the reader, the document attempts to group the points from the submissions into four sections. There are overlaps between these sections, however, and points presented in one part of the document may inform considerations in another section.

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

8. The document is also complemented by an addendum (CBD/DSI/AHTEG/2018/1/2/Add.1) containing case studies and examples of the use of digital sequence information in relation to the objectives of the Convention and the Nagoya Protocol. It is also complemented by a document addresses developments and coordination with other international processes (CBD/DSI/AHTEG/2018/1/3) pursuant to paragraph 4 of decision NP-2/5.

9. 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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<sup>1</sup> <https://www.cbd.int/abs/dsi-gr/ahteg.shtml#submissions>.

<sup>2</sup> The submissions totalled approximately 340 pages.

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**I. SYNTHESIS OF VIEWS AND INFORMATION ON POTENTIAL IMPLICATIONS OF THE USE OF DIGITAL SEQUENCE INFORMATION ON GENETIC RESOURCES FOR THE CONSERVATION AND SUSTAINABLE USE OF BIOLOGICAL DIVERSITY**

**A. General considerations on digital sequence information and the conservation and sustainable use of biodiversity**

10. One region expressed the view that the three objectives of the Convention on Biological Diversity (CBD) are inextricably intertwined so that if emerging technologies undermine any one of the pillars, they undermine the whole Convention.<sup>3</sup>

11. Several submissions<sup>4</sup> agreed that digital sequence information has a critical role to play in improving our understanding of biodiversity, thereby advancing conservation and sustainable use of biodiversity. Different submissions elaborated on this point as follows:

(a) Digital sequence information plays an important role in the identification, characterization and evaluation of genetic resources, an important step towards conservation and sustainable use of biodiversity;<sup>5</sup>

(b) The recent influx of digital sequence information has provided a clear indication of how little is known about even basic biodiversity parameters such as the number of species in an ecosystem. In this light, more digital sequence information on biodiversity is needed and DNA-based technologies need to quickly become a standard tool in the biodiversity research community.<sup>6</sup>

12. Many submissions<sup>7</sup> emphasized the role of access to and free exchange of digital sequence information in research that contributes to the conservation and sustainable use of biodiversity. The obligations in Article 12 (“research and training”)<sup>8</sup> and Article 17 (“exchange of information”)<sup>9</sup> were cited in support of this perspective. A region stated that consideration of how digital sequence information may affect the objectives of the Convention and the Nagoya Protocol should be done in the light of Articles 12, 16, 17 and 18 of the Convention and Article 8(a) of the Nagoya Protocol.<sup>10</sup>

13. Submissions also provided general information on the role of digital sequence information in activities that contribute to the conservation and sustainable use of biodiversity including that:

(a) Access to digital sequence information in research projects supports the three objectives of the Convention and also contributes to national implementation of Articles 7, 9, 10, 12, 15 and 17 of the Convention as well as to the reporting requirements of Article 26;<sup>11</sup>

(i) Such research also supports the delivery of national biodiversity goals and targets and other international engagements including stewardship obligations under the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA);<sup>12</sup>

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<sup>3</sup> Africa.

<sup>4</sup> Africa; BIO-University of Guelph; German Life Sciences Association; Society for the Preservation of Natural History Collections

<sup>5</sup> European Union and Member States; group of genomics experts.

<sup>6</sup> BIO-University of Guelph.

<sup>7</sup> Japan; CGRFA – Germany; European Seed Association; German Life Sciences Association; German Research Foundation; GGBN; group of genomics experts; ICC; IFRA and IOFI; Japan Pharmaceutical Manufacturers Association; Wellcome Trust and Wellcome Sanger Institute.

<sup>8</sup> Japan Pharmaceutical Manufacturers Association.

<sup>9</sup> European Seed Association.

<sup>10</sup> European Union and Member States.

<sup>11</sup> Canada.

<sup>12</sup> Canada.

(b) It is essential for the world's scientific community to have open access to genetic sequence data as rapid and unimpeded access to such data is necessary for the science required by CBD;<sup>13</sup>

(c) The availability of biodiversity information, including digital sequence information, is important in order to meet many of the goals and targets of the Strategic Plan for Biodiversity 2011-2020;<sup>14</sup>

(d) It will not be possible to immediately halt and reverse the loss of biodiversity but strong efforts to capture and digitize genetic material is critical to preserve what remains.<sup>15</sup>

14. A number of submissions highlighted the use of digital sequence information to study genetic diversity with a view to determining conservation priorities both *in situ* and *ex situ*<sup>16</sup> and evaluating the effectiveness of *in situ* conservation measures that have already been implemented<sup>17</sup>. This included:

(a) Implementation of protected areas;<sup>18</sup>

(b) Monitoring biodiversity in specific areas to enable collection of information on variation, such as changes in specific populations or variations in environmental conditions and how organisms and populations evolve and adapt.<sup>19</sup>

15. The role of digital sequence information in the protection and management of species and populations was also highlighted. Some submissions pointed to the role of digital sequence information in understanding the genetic structure of populations or species thereby providing important information for conservation and sustainable use. This included for example:

(a) Describing and characterizing populations in order to distinguish between groups with similar morphological traits and identify their respective ecological niches.<sup>20</sup>

(b) Exploring population size and structure and estimating relationships between populations. This can be used in assessing risks to species and potential endangerment, to plan measures to minimize further genetic loss<sup>21</sup> and to monitor the survival rates of endangered species (see example 1 in addendum);<sup>22</sup>

(c) Developing strategies to preserve the genetic diversity of wild relatives of cultivars and to minimize genetic erosion;<sup>23</sup>

(d) Restoration of coral reefs: the appropriateness of candidate places for reintroduction of healthy coral can be judged by comparing the genetic composition of different coral populations;<sup>24</sup>

(e) Conservation of pollinators;<sup>25</sup>

(f) Defining population stocks for fisheries management decisions;<sup>26</sup>

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<sup>13</sup> GGBN.

<sup>14</sup> CETAF; CGIAR; German Life Sciences Association.

<sup>15</sup> Group of genomics experts.

<sup>16</sup> European Union and Member States; Switzerland; CGRFA – Brazil; CGRFA – Germany; CGIAR.

<sup>17</sup> CGRFA – ABS Task Force; European Seed Association.

<sup>18</sup> European Union and Member States.

<sup>19</sup> CGRFA – Brazil; CGIAR; European Seed Association; Japan Bioindustry Association. An example was provided whereby the unique genetic fingerprints of crop varieties can be used to establish baselines regarding farmer-held varieties, which can then be used for measuring the impact of changes in diversity over time, including as a result of interventions such as the reintroduction from *ex situ* collections of locally extinct native varieties (CGIAR).

<sup>20</sup> Switzerland.

<sup>21</sup> CGRFA – Germany.

<sup>22</sup> Japan.

<sup>23</sup> Society for the Preservation of Natural History Collections.

<sup>24</sup> Japan.

<sup>25</sup> German Life Sciences Association; GGBN; pointing to the special issue on bee pollinators published by Conservation Genetics, <https://link.springer.com/journal/10592/18/3/page/1>.

(g) Microbial communities, which are traditionally poorly understood. Digital sequence information can help to identify native, invasive and endangered species and track their dynamics; understand the role of microbes in promoting plant growth; and inform the creation and maintenance of healthy soils for sustainable productivity and ecosystem health;<sup>27</sup>

(h) Understanding threats to genetic diversity posed by environmental changes, such as those resulting from climate change, as well as the resilience and adaptability of populations all of which allow timely conservation and sustainable management measures to be taken.<sup>28</sup>

16. In contrast, other submissions were less convinced of the role of digital sequence information in conservation and sustainable use of biodiversity and expressed the following views:

(a) Digital sequence information may find some use in forestry in the distant future; however, it has a negligible impact for the conservation of biodiversity in the near future;<sup>29</sup>

(b) Undue reliance on digital sequence information as a conservation or use mechanism may undermine resolve, resources and efforts towards *in situ* conservation, which could negatively impact the work of indigenous peoples and local communities that develop, conserve and use biodiversity;<sup>30</sup>

(c) Unregulated and free access to digital sequence information could decrease the perception of the importance of maintaining and developing the resiliency of genetic resources *in situ* and within context-specific and appropriate ecological environments.<sup>31</sup>

#### **B. Role of digital sequence information in projects that contribute to the conservation and sustainable use of biodiversity**

17. Many of the submissions provided examples of different projects using digital sequence information that contribute to the conservation and sustainable use of biodiversity. This included:

(a) For trees and forests:

(i) The GenTree project to provide the European forestry sector with better knowledge, methods and tools for optimizing the management and sustainable use of forest genetic resources in Europe;<sup>32</sup>

(ii) A National Forest Information System (see example 2 in addendum);

(iii) The BioSAFE project to identify and track forest invasive pests and diseases using a genomics-based approach (see example 3 in addendum);

(iv) The response to the ash dieback outbreak in the United Kingdom in 2010 (see example 4 in addendum);

(b) For mammals:

(i) Conservation of endangered gorilla populations (see example 5 in addendum);

(ii) Managers of captive breeding programs rely on genetic sequence data to document genetic diversity thus enabling the reintroduction of stable and healthy individuals to their natural habitats.<sup>33</sup>

(c) For microorganisms:

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<sup>26</sup> GGBN.

<sup>27</sup> Group of genomics experts.

<sup>28</sup> CGRFA – Canada; CGRFA – United States; German Life Sciences Association; GGBN.

<sup>29</sup> India.

<sup>30</sup> Third World Network.

<sup>31</sup> African Centre for Biodiversity.

<sup>32</sup> CETAF; NHMUK, RBG Kew, RBG Edinburgh.

<sup>33</sup> United States.

- (i) The EcoBiomics project to characterize microbial communities (see example 6 in addendum).
- (d) For plants and fungi:
  - (i) Efforts to catalogue national plants and fungi (see example 7 in addendum).
- (e) For biodiversity for food and agriculture:
  - (i) Studying pollinator biodiversity (see example 8 in addendum);
  - (ii) Understanding gene flow related to herbicide resistance (see example 9 in addendum);
  - (iii) Studying animal breeds (see example 10 in addendum).

18. Some submissions highlighted the role of molecular characterization in contributing to *ex situ* conservation of genetic resources for food and agriculture. This can include:

(a) Allowing accurate analysis of a collection's genetic diversity (see example 11 in addendum). This can help to optimize a collection by improving understanding of its genetic representativeness, eliminating duplicates and identifying gaps where new additions may be needed;<sup>34</sup>

(b) Understanding genetic diversity within populations to identify distinct natural populations and those with increased diversity in order to develop robust *ex situ* collections. This can then help to reduce in-breeding when accessions in *ex situ* collections are used for breeding purposes (see below);<sup>35</sup>

(c) comparing representativeness among different genebanks, identifying accessions that may be at risk as they are conserved in only one place;<sup>36</sup>

(d) examining differences in diagnostic nucleotide sequences to identify unknown samples, maintain these samples genetically true-to-type, and choose the best samples for specific research or breeding purposes;<sup>37</sup>

(e) Quantifying the level of variation within and between crops to inform quality control, maintenance, distribution and use of *ex situ* collections.<sup>38</sup>

19. A number of organizations<sup>39</sup> noted results from a search in Google Scholar on DNA sequencing and conservation management. The search produced over 1,000 scientific papers published between 1 January 2016 and 1 July 2017 on a broad range of topics thus indicating the great use of DNA sequence information in implementing all the thematic areas of CBD. The organizations pointed out that researchers contributing data to these studies are located in both developed and developing countries. They also emphasized that scientific publications are not separate from implementation of CBD.

### **C. Role of digital sequence information in species identification and taxonomy, including DNA barcoding**

20. Many submissions<sup>40</sup> pointed to the important role of digital sequence information in taxonomy and that, in turn, information gained from taxonomic study is critical to conservation and sustainable use of biodiversity. Elaborations on this point included that:

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<sup>34</sup> CGRFA – Brazil; CGIAR; European Seed Association.

<sup>35</sup> CGRFA – United States; CGRFA – ABS Task Force.

<sup>36</sup> CGRFA – Brazil.

<sup>37</sup> CGRFA – United States.

<sup>38</sup> Group of genomics experts.

<sup>39</sup> CETAF; NHMUK, RBG Kew, RBG Edinburgh.

<sup>40</sup> European Union and Member States; Mexico; Switzerland; CGRFA – Canada; CETAF; GGBN; NHMUK, RBG Kew, RBG Edinburgh; Japan Bioindustry Association; Society for the Preservation of Natural History Collections.



(a) Countries have recognized a “taxonomic impediment” – the insufficient availability of taxonomic expertise and information that underpins biodiversity conservation and sustainable use;<sup>41</sup>

(b) A number of decisions of the Conference of the Parties have sought solutions to the taxonomic impediment by supporting capacity-building for the Global Taxonomy Initiative as well as the sharing of taxonomic information, including by electronic means, and through a global taxonomy information system.<sup>42</sup>

21. It was also noted<sup>43</sup> that wide availability of information on genetic composition is key to meeting a number of the goals and targets in the Strategic Plan for Biodiversity 2011-2020, including strategic goal B; strategic goal C, particularly Target 13; as well as strategic goal E, particularly Target 19. Different submissions:

(a) Suggested that target 19 should be considered a “commitment to increase the amount and quality of biodiversity relevant information and technologies as well as to make better use of it in decision making as well as to share it as widely as possible”,<sup>44</sup>

(b) Noted that the increase of DNA barcode information is mentioned in the fourth edition of the *Global Biodiversity Outlook* as a contribution to meeting Target 19;<sup>45</sup>

(c) Stated that the rapidly growing number of individuals and species being sequenced, as well as the increasing depth of genomic coverage, plays a leading role in achieving Target 19;<sup>46</sup>

(d) Expressed the view that imposing restrictions on the availability of digital sequence data will have a chilling effect on taxonomic progress, reducing the likelihood of achieving the taxonomic objectives agreed to under CBD.<sup>47</sup>

22. A number of organizations provided examples of the use of digital sequence information in taxonomy or species identification. This included its use in the identification of highly fragmented samples such as the remains of birds, bats and other animals recovered from airplane engines. These identifications are used to inform mitigation strategies at airports, targeting the practices and procedures to the unique behaviours and requirements of the most susceptible and frequently impacted animals. The identifications also aid in the design process for aircraft engines, making them less prone to damage caused by the most typically involved animals.<sup>48</sup>

23. A number of organizations referred to the advantages of using digital sequence information in identifying unknown species. These advantages included that:

(a) Digital sequence information can be used when morphological identification is difficult to achieve or not possible such as in the identification of invasive species (see section I, subsection E), morphologically cryptic species, highly similar species or microscopic organisms;<sup>49</sup>

(b) DNA-based methods of identification are cheaper than physical methods which require a high level of expertise, are slower and provide less information about diversity;<sup>50</sup>

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<sup>41</sup> CETAF; NHMUK, RBG Kew, RBG Edinburgh; Society for the Preservation of Natural History Collections.

<sup>42</sup> See decisions III/10, IV/1, V/9, VI/8, VII/9, IX/22, X/39, XI/29 and XIII/31.

<sup>43</sup> CETAF; NHMUK, RBG Kew, RBG Edinburgh; Society for the Preservation of Natural History Collections.

<sup>44</sup> CETAF; Society for the Preservation of Natural History Collections quoting the “Quick guide to the Aichi Biodiversity Targets: Knowledge improved, shared and applied”, <https://www.cbd.int/doc/strategic-plan/targets/T19-quick-guide-en.pdf>.

<sup>45</sup> CETAF.

<sup>46</sup> Society for the Preservation of Natural History Collections.

<sup>47</sup> GGBN; Society for the Preservation of Natural History Collections.

<sup>48</sup> GGBN. For other examples, see CETAF; NHMUK, RBG Kew, RBG Edinburgh.

<sup>49</sup> Canada; CGIAR; German Life Sciences Association.

<sup>50</sup> European Seed Association; Japan Bioindustry Association.

(c) DNA-based methods, particularly when using specimens already contained in collections, reduce the need for taking additional samples from wild populations.<sup>51</sup>

24. In this context, some submissions<sup>52</sup> described how species identification can be undertaken through the use of so-called environmental DNA (eDNA). It was explained that eDNA is the genetic material, in the form of fragments of DNA, extracted from environmental samples such as water, soil or air. From these samples, it is possible to obtain information on the species, populations and communities present in a given environment, for example, fishes by analyzing eDNA from sea water, animals based on eDNA from water holes, or soil organisms such as earthworms based on eDNA from soils.<sup>53</sup> Some submissions<sup>54</sup> indicated how, with this information, ecosystem conditions can be described, which has been difficult to address by conventional methods. The submissions agreed that these methods enable measures in support of conservation. (See also example 1 in the addendum.)

25. Numerous submissions<sup>55</sup> referred to DNA barcoding and the International Barcode of Life Project<sup>56</sup> hosted by the Biodiversity Institute of Ontario at the University of Guelph. The Project works to genetically “fingerprint” species, including those that have yet to be described or named.<sup>57</sup> The Biodiversity Institute of Ontario, through its Centre for Biodiversity Genomics, coordinates international efforts to maintain and expand the global reference library of DNA barcodes – the Barcode of Life Data System (BOLD)<sup>58</sup> – as an openly accessible online resource for DNA-based identification of living organisms.<sup>59</sup> The Barcode of Life database<sup>60</sup> allows researchers to identify species, a critical step for monitoring and conserving biodiversity.<sup>61</sup> (See also section II, subsection D.)

26. Some organizations<sup>62</sup> explained how use of DNA sequences for identification, classification, description, comparison and monitoring of organisms is only effective if backed by as many sequences as possible that are as easily accessible as possible. Publicly accessible DNA databases form a global taxonomic information system that is available to support taxonomic and other biodiversity research.

27. Digital sequence records linked to vouchered specimens in natural history museums are key for comparing and identifying specimens and form a huge “reference library” in the public domain.<sup>63</sup> Bioportals such as the Barcode of Life Data System and StrainInfo<sup>64</sup> that consolidate taxonomic information, sequences in public repositories and literature references were referred to as key in the conservation of biodiversity and monitoring progress towards Aichi targets 11 and 12.<sup>65</sup>

#### **D. Role of digital sequence information in plant and animal breeding**

28. The role of digital sequence information in breeding was addressed extensively in many of the submissions. Three key areas were identified: (a) contribution to understanding genetic relationships and

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<sup>51</sup> Japan; GGBN; Society for the Preservation of Natural History Collections; Japan Bioindustry Association.

<sup>52</sup> Japan; United States; CGRFA – Brazil; Japan Bioindustry Association.

<sup>53</sup> Japan Bioindustry Association.

<sup>54</sup> Japan; Japan Bioindustry Association.

<sup>55</sup> Canada; United States; BIO-University of Guelph.

<sup>56</sup> [www.ibol.org](http://www.ibol.org)

<sup>57</sup> United States.

<sup>58</sup> <http://boldsystems.org>

<sup>59</sup> Canada; BIO-University of Guelph.

<sup>60</sup> [www.barcodeoflife.org](http://www.barcodeoflife.org)

<sup>61</sup> United States.

<sup>62</sup> CETAF; NHMUK, RBG Kew, RBG Edinburgh.

<sup>63</sup> Society for the Preservation of Natural History Collections.

<sup>64</sup> <http://www.straininfo.net/>

<sup>65</sup> Society for the Preservation of Natural History Collections.

reducing in-breeding; (b) contribution to better identification and understanding of traits of interest; and (c) responding to pest and disease outbreaks. Some limitations in the role of digital sequence information in breeding were also identified.

*(a) Contributes to understanding genetic relationships and reducing in-breeding*

29. Some submissions pointed to the role of digital sequence information in understanding genetic relationships between individuals, which can contribute to reducing in-breeding. A number of examples were provided in relation to plant breeding, aquaculture and animal breeding.<sup>66</sup>

30. One organization<sup>67</sup> noted that without the ability to screen different genetic resources quickly and cost efficiently, researchers and breeders will in many cases fall back on the genetic resources whose characteristics are already well known. They indicated that working with the same genetic resources over and over again will negatively affect the genetic variation of a crop by narrowing its genetic base, which would reduce the ability of the crop to adapt and survive in a changing environment.

*(b) Contributes to better identification and understanding of traits of interest*

31. Many submissions<sup>68</sup> referred to the role of digital sequence information in identifying and understanding traits of interest for use in breeding. Such traits would include disease-, drought- and pest-resistance, product quality, nutrition enhancement, production efficiency (e.g. increasing yield, reducing input requirements) and resilience to extreme conditions.<sup>69</sup> As part of this, a number of submissions<sup>70</sup> pointed to a link between breeding and the conservation and sustainable use of biodiversity, food security, economic development and climate change adaptation, all of which contributes to achieving the Sustainable Development Goals.

32. It was also noted<sup>71</sup> that the use of digital sequence information can accelerate the breeding process. Views shared included that:

(a) Digital sequence information enables breeders to understand and use existing diversity to develop more efficient breeding strategies to reach genetic gain objectives;<sup>72</sup>

(b) When digital sequence information is linked to measured traits, it allows researchers to search repositories for genetic resources that likely exhibit the desired characteristics. In order for this to be effective, however, extensive sampling of the gene pool is required in order to have a large pool of data in which to search and this requires global collaborative efforts and the sharing of data;<sup>73</sup>

(c) Technologies and processes such as genome editing and synthetic biology have the potential to greatly reduce the amount of time for knowledge generated in the laboratory to transition into marketable products because they allow the direct modification of alleles in germplasm or breeds, thus reducing the number of breeding cycles required (see example 12 in addendum).<sup>74</sup>

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<sup>66</sup> CGRFA – United States (see examples on plant breeding and aquaculture); CGRFA – ABS Task Force (see information on animal breeding especially in sections 3 and 4 of the submission).

<sup>67</sup> European Seed Association.

<sup>68</sup> Japan; United States; CGRFA – Canada; CGRFA – Germany; CGRFA – United States; CGRFA – Prof. Sundström; CGIAR; German Life Sciences Association. For specific examples of the role of digital sequence information in identifying traits of interest in breeding and how this contributes to broader objectives see the submissions from Japan, United States and CGRFA – United States.

<sup>69</sup> CGRFA – United States.

<sup>70</sup> CGRFA – Brazil; CGRFA – Germany; CGRFA – United States; CGIAR; group of genomics experts.

<sup>71</sup> CGRFA – Brazil; CGRFA – United States; CGIAR; group of genomics experts.

<sup>72</sup> CGIAR.

<sup>73</sup> Group of genomics experts.

<sup>74</sup> CGIAR.

33. Examples of the role of models and core reference sets in plant breeding were also provided, see examples 13, 14 and 15 in the addendum.

34. One submission<sup>75</sup> explained that genomic sequence information, when coupled with phenotypic and other data, can be used to identify genotypes that are well adapted to different and changing agro-ecological conditions. They noted that when integrated into crop breeding programs, genomic sequence information is increasingly useful for achieving targeted, efficient uses of genetic diversity in sustainable agriculture. They also explained that genetic sequence information can be of use outside the formal breeding sector in farmer-led improvement programs (see example 16 in addendum.)

35. At the same time, however, the submission also noted that technological capacities to generate genomic sequence data have accelerated more quickly than capacities to enable practical use of the information. They explained that there is a lack of the phenotypic data needed to complement and interpret the digital sequence data and enable its application. Furthermore, they indicated that most traits are under complex genetic control involving multiple genes interacting in networks so a cause and effect scenario between a single gene and a given trait often cannot be readily understood.

36. They also stated that creating better crop varieties and animal breeds will not, on their own, constitute sustainable use of biodiversity or contribute to sustainable development. They explained that improved varieties and breeds must be incorporated into sustainable farming systems and this will require advances in and contributions from a broad range of sectors. They underscored that these fundamental issues significantly impact the sharing of benefits that can be generated through the use of genetic sequence information in plant and animal breeding.

(c) *Responding to pest and disease outbreaks*

37. Some submissions<sup>76</sup> pointed to the role of digital sequence information in enabling more rapid responses to outbreaks of pests and diseases including through preventive breeding actions and pathogen surveillance (see example 17 in addendum).

**E. Digital sequence information for monitoring and control purposes, including invasive species**

1. *Illegal trade: wildlife trafficking, illegal logging, seafood fraud*

38. A number of submissions indicated that digital sequence information and related technologies are becoming important tools for monitoring and control purposes and enforcement activities in areas such as wildlife trafficking, illegal logging and seafood fraud. Some of the submissions elaborated on this aspect:

(a) Quick and low-cost identification methods based on sequencing technologies provide valuable support for implementation of the Convention on International Trade in Endangered Species of Wild Fauna and Flora and control of wildlife trafficking;<sup>77</sup>

(b) Genetic sequence data can be used to identify source populations of trafficked plants and animals;<sup>78</sup>

(c) Genetic sequence data can be used to identify the species and geographic origin of timber in order to detect illegal logging and trade.<sup>79</sup> This can help to fulfil regulatory requirements such as the European Union Timber Regulation;<sup>80</sup>

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<sup>75</sup> CGIAR.

<sup>76</sup> CGRFA – Brazil; European Seed Association.

<sup>77</sup> European Union and Member States.

<sup>78</sup> United States.

<sup>79</sup> United States; CGRFA – Brazil; Japan Bioindustry Association.

<sup>80</sup> CGRFA – Germany.

(d) Genetic sequence data can be used to verify labelling of fish – both for authenticity and origin – as part of quality control and in order to combat seafood fraud, which jeopardizes the health of fish stocks, distorts legal markets and undermines sustainable fisheries;<sup>81</sup>

(e) Techniques using digital sequence information can distinguish wild species from domesticated or cultivated ones, enabling monitoring of, for example, the supply of a medicinal plant with a view to preventing overexploitation of wild populations.<sup>82</sup>

## 2. *Monitoring for invasive species*

39. Numerous submissions<sup>83</sup> pointed to digital sequence information playing an important role in identifying, monitoring and managing invasive species. Various points were made in this regard:

(a) DNA sequence information allows rapid, accurate and low-cost identification of species and can distinguish between those that are potentially invasive and those that are part of the natural ecosystem.<sup>84</sup> Early detection and identification are important as they enable an assessment of the risks posed by a non-native species and the implementation of mitigation procedures thereby significantly lower the risk of establishment of an invasive species;<sup>85</sup>

(b) Genetic sequence data can help to identify the introduction pathway of an invasive species thus contributing to the implementation of appropriate countermeasures;<sup>86</sup>

(c) For invasive species that are well established and harming native biodiversity, genetic sequence data can be used to develop counter-measures to mitigate impacts or eradicate the invaders.<sup>87</sup> This could include molecular editing tools that help reduce or eradicate an invasive species.<sup>88</sup>

(d) Research activities using digital sequence information also support other international engagements such as implementation of the International Plant Protection Convention and the World Trade Organization's Agreement on Sanitary and Phytosanitary Measures (and related regional initiatives), which aim to protect the world's cultivated and natural plant resources from the spread and introduction of plant pests while minimizing interference with the international movement of goods and people.<sup>89</sup>

40. Other submissions, however, pointed to the potential for digital sequence information to be used to modify organisms in ways that could make them invasive. This aspect is addressed in subsection F on "Biosafety risks" below.

## 3. *Role of access to databases*

41. Some submissions referred to the role of access to databases as part of the use of digital sequence information for monitoring and control purposes. In this regard, it was stated that:

(a) Publicly-accessible databases of sequence data serve as a "reference library" for comparing specimens and samples when investigating potential mislabelling of fish or wildlife trafficking, and as part of biosecurity efforts for identification of potential pests and pathogens;<sup>90</sup>

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<sup>81</sup> United States; CGRFA – Germany; Society for the Preservation of Natural History Collections. See, for example, <http://aquagene.org/>

<sup>82</sup> Japan Bioindustry Association.

<sup>83</sup> Including CGRFA – Germany. Others as indicated below.

<sup>84</sup> Canada; European Union and Member States; United States.

<sup>85</sup> Canada; United States; GGBN.

<sup>86</sup> Japan; United States.

<sup>87</sup> Canada; Japan; United States.

<sup>88</sup> United States.

<sup>89</sup> Canada; GGBN.

<sup>90</sup> GGBN.

(b) Publicly accessible databases of DNA sequence information are needed for DNA-based identification of alien species as, by definition, the species are not native to the country where they are intercepted and thus are less likely to be known to national authorities;<sup>91</sup>

(c) The more sequences available in the databases, the better the likelihood of accurate and rapid identification; and easy access to the databases is also needed for rapid identification.<sup>92</sup>

#### 4. *Other*

42. Other applications of digital sequence information for monitoring and control purposes in relation to biodiversity were also identified:

(a) Monitoring of plant and animal health;<sup>93</sup>

(b) Verification of the descent of certain breeding animals, e.g. to implement zootechnical legislation of the European Union,<sup>94</sup> as well as the authenticity of products such as products coming from specific breeds.<sup>95</sup>

### F. Biosafety risks

43. Some submissions<sup>96</sup> highlighted the possibility for digital sequence information to be used in biotechnology applications, which may pose risks to biodiversity. These risks could include synthesizing organisms or modifying organisms with synthetic genes, which when released, may become invasive. It was suggested<sup>97</sup> that this posed a novel challenge to the control of invasive alien species as synthesis of digital sequence information creates the possibility to leapfrog borders, resulting in the introduction of invasive species from within a country rather than from outside its borders.

44. The role of the gene foundry and synthesis equipment industries was pointed out<sup>98</sup> in this regard, noting that they are generally not under any obligation to consider the safety of the nucleotide sequences they are producing or risks to biodiversity, including the possibility that the sequences they produce may lead to organisms that are invasive or otherwise harmful (e.g. dangerous pathogens). It was<sup>99</sup> suggested that a report on these industries should be undertaken to inform a possible future decision of the Conference of the Parties on how these industries should be regulated to achieve the objectives of the Convention.

### G. Role of digital sequence information in substituting for “natural” products

45. Some<sup>100</sup> expressed the view that recording digital sequence information in databases is not sustainable use as such. They pointed to the examples of farmers of vanilla and vetiver where use of digital sequence information has had socio-economic and sustainable use impacts. They noted that unrestrained use of digital sequence information could economically and culturally undermine indigenous peoples and local communities thereby negatively impacting the conservation and sustainable use of biodiversity.

46. On the other hand, others<sup>101</sup> suggested that digital sequence information could support conservation and sustainable use of biodiversity if substitute products based on digital sequence

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<sup>91</sup> CETAF; GGBN; NHMUK, RBG Kew, RBG Edinburgh; Society for the Preservation of Natural History Collections.

<sup>92</sup> CETAF; GGBN; NHMUK, RBG Kew, RBG Edinburgh.

<sup>93</sup> CGRFA – Germany.

<sup>94</sup> CGRFA – Germany.

<sup>95</sup> CGRFA – ABS Task Force.

<sup>96</sup> Switzerland, Heinrich Böll Foundation; Sustainability Council of New Zealand; African Centre for Biodiversity; Third World Network.

<sup>97</sup> African Centre for Biodiversity; Heinrich Böll Foundation; Sustainability Council of New Zealand; Third World Network.

<sup>98</sup> African Centre for Biodiversity; Sustainability Council of New Zealand; Third World Network.

<sup>99</sup> Institute for Agriculture and Trade Policy.

<sup>100</sup> African Centre for Biodiversity; Third World Network.

<sup>101</sup> India; Switzerland; group of genomics experts; Personal Care Products Council.

information replace natural products, thereby reducing dependence and pressure on wild populations. In this regard, it was described<sup>102</sup> how microorganisms, such as yeasts, are engineered to produce a variety of cosmetic, food and pharmaceutical ingredients. One submission<sup>103</sup> elaborated how it was no longer necessary to source sequences from plant material; instead, new versions of sequences, specifically adapted for expression in new species, are designed and ordered from a commercial provider. Various examples were provided including artemisinin (an anti-malarial) from *Artemisia annua*, vanillin from *Vanilla planifolia* and paclitaxel from the Pacific yew tree (see example 18 in addendum). It was suggested that because the nature and source of the sequence information is known in these cases, any monetary benefit-sharing should be relatively straightforward.

#### H. Digital sequence information for public health purposes

47. Many submissions pointed to the use of digital sequence information for health purposes. Examples included:

- (a) Use of genetic information on the foot and mouth disease virus has been useful in selecting suitable vaccines in endemic areas and supplying vaccines for contingency planning for potential outbreaks in free areas;<sup>104</sup>
- (b) Responding to outbreaks of infectious diseases (see example 19 in addendum)<sup>105</sup>
  - (i) In-field rapid sequencing in molecular epidemiology and phylogenetic outbreak tracing, e.g. in Zika and Ebola outbreaks (see example 20 in addendum);<sup>106</sup>
- (c) Development of diagnostics, vaccines<sup>107</sup> and pharmaceuticals,<sup>108</sup> e.g. the development of seasonal flu vaccines depends on the availability of global epidemiological and virus sequence data;<sup>109</sup>
- (d) Monitoring drug resistance (see example 21 in addendum)<sup>110</sup> and anti-microbial resistance.<sup>111</sup>

48. A number of submissions<sup>112</sup> expressed concern that regulating digital sequence information would be detrimental to the quick sharing of information needed to address public health issues. It was noted, in particular, that, for epidemics such as Ebola and Zika, the viruses need to be sequenced quickly and the information shared without delay due to the viruses' rapid evolutionary rates if the sequence data is to be used to guide control measures.<sup>113</sup> One submission noted that additional levels of delays and bureaucracy would "make it less likely that medicines that would specifically benefit developing countries would be developed in the first place, with vaccines being particularly vulnerable in this respect."<sup>114</sup> In connection to this, it was indicated<sup>115</sup> that the use of digital sequence information for public health purposes is often for

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<sup>102</sup> Personal Care Products Council; group of genomics experts.

<sup>103</sup> Group of genomics experts.

<sup>104</sup> Japan.

<sup>105</sup> Society for Applied Microbiology; Wellcome Trust and Wellcome Sanger Institute.

<sup>106</sup> European Union and Member States; Biotechnology and Biological Sciences Research Council; Wellcome Trust and Wellcome Sanger Institute.

<sup>107</sup> BioIndustry Association.

<sup>108</sup> Biotechnology and Biological Sciences Research Council; Wellcome Trust and Wellcome Sanger Institute.

<sup>109</sup> Wellcome Trust and Wellcome Sanger Institute.

<sup>110</sup> Wellcome Trust and Wellcome Sanger Institute.

<sup>111</sup> Mexico; BioIndustry Association.

<sup>112</sup> BioIndustry Association; Biotechnology and Biological Sciences Research Council; Wellcome Trust and Wellcome Sanger Institute.

<sup>113</sup> BioIndustry Association.

<sup>114</sup> BioIndustry Association.

<sup>115</sup> Royal Society of Biology.

efforts relating to diseases, such as cholera and malaria, that disproportionately affect low- and middle-income countries.

49. Another submission<sup>116</sup> agreed that it is essential to facilitate the sharing of samples during health emergencies.

50. Another area highlighted was the use of digital sequence information in responding to influenza. The Global Influenza Surveillance and Response System – a network of public health laboratories coordinated by the World Health Organization – was described.<sup>117</sup> It was explained<sup>118</sup> that the laboratories in the System collect human and animal flu virus samples and share these samples and related digital sequence information for analysis. It was noted<sup>119</sup> that in recent years, the genetic sequence data of the viruses has become an important component of the research. The submissions stated that rapid international exchange of the viruses and their digital sequence information is particularly important because influenza viruses evolve more rapidly than many other viruses and there is always the threat of pandemic influenza,<sup>120</sup> and because the target strains for seasonal vaccines must be decided five to six months ahead of the flu season for the vaccine to be developed in time.<sup>121</sup>

51. In this context, one submission<sup>122</sup> described the role of the Global Initiative on Sharing All Influenza Data in contributing to global public health by: (1) collating an extensive repository of high-quality influenza data; (2) facilitating the rapid sharing of potentially pandemic virus information during recent outbreaks; (3) supporting the World Health Organization's biannual seasonal flu vaccine strain selection process; (4) developing informal mechanisms for conflict resolution around the sharing of virus data; and (5) building greater trust with several countries key to global pandemic preparedness. (See example 22 in addendum as well as section II, subsections E and F for more information.)

## **II. SYNTHESIS OF VIEWS AND INFORMATION ON POTENTIAL IMPLICATIONS OF THE USE OF DIGITAL SEQUENCE INFORMATION ON FAIR AND EQUITABLE BENEFIT-SHARING**

### **A. Potential impacts of digital sequence information on access and benefit-sharing, prior informed consent and mutually agreed terms**

52. Several Parties and organizations expressed the view that digital sequence information could undermine access and benefit-sharing, prior informed consent (PIC) and mutually agreed terms (MAT) as follows:

(a) If the Convention and its Parties do not update their approaches to ABS to account for the potential for digital sequence information to be used without benefit-sharing, the third objective of the Convention will be undermined with serious consequences for CBD as a whole;

(i) Gene segments, genes and even entire organisms of high economic value (e.g. vaccine viruses) are now synthesized from digital sequence information that may be exchanged electronically without requiring access to an organism;<sup>123</sup>

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<sup>116</sup> Mexico.

<sup>117</sup> GISAID; Wellcome Trust and Wellcome Sanger Institute.

<sup>118</sup> Wellcome Trust and Wellcome Sanger Institute.

<sup>119</sup> GISAID.

<sup>120</sup> GISAID.

<sup>121</sup> Wellcome Trust and Wellcome Sanger Institute.

<sup>122</sup> GISAID.

<sup>123</sup> Third World Network.



(b) “Digital-to-biological” converters enable the use of sequence data to recreate organisms anywhere and this technology poses challenges to the first and third objectives of the Convention;<sup>124</sup> (see also section I, subsection F.)

(c) Utilization of natural information instead of the genetic resource itself potentially undermines benefit-sharing;<sup>125</sup>

(d) The emergence of digital sequence information gives rise to the possibility that genetic resources can be accessed without prior informed consent and in the absence of a benefit-sharing agreement thereby undermining the third objective of the Convention as well as the objective of the Protocol;<sup>126</sup>

(i) Current benefit-sharing regimes may be rendered redundant and the central imperative of the Protocol to prevent misappropriation of genetic resources would be eroded;<sup>127</sup>

(ii) The ability to transfer sequence data through digital means will circumvent the ABS requirements of the Nagoya Protocol;<sup>128</sup>

(e) Digital sequence information raises the possibility of accessing the value of genetic resources of Parties without asking for authorization and without obtaining PIC and MAT, which could facilitate wrongful access;<sup>129</sup>

(f) Excluding the use of genetic information (digital or otherwise) from the mechanisms of the Nagoya Protocol – which seeks to operationalize the third objective of the Convention – would compromise the purpose and principles of the Protocol, especially in megadiverse and developing countries;<sup>130</sup>

(g) Online databases are frequently used to find organisms (including microorganisms) that contain matching genetic sequences<sup>131</sup> (for more information on conserved sequences, see subsection H):

(i) This could lead to a situation where a user interested in a genetic sequence from an organism from one particular country could search a database to find a similar sequence from a different country with less restrictive ABS measures;<sup>132</sup>

(ii) Treating all digital sequence information equally under the Nagoya Protocol, regardless of origin, could help to mitigate this risk but could impinge on the sovereign rights of Parties.<sup>133</sup> (See also section II, subsection I.)

## **B. Regulation of digital sequence information through prior informed consent and mutually agreed terms for access to genetic resources**

53. Some Parties<sup>134</sup> and a number of organizations<sup>135</sup> agreed that Parties granting access to genetic resources already have the right – through their procedures on prior informed consent and mutually agreed

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<sup>124</sup> Heinrich Böll Foundation.

<sup>125</sup> Africa.

<sup>126</sup> African Centre for Biodiversity.

<sup>127</sup> African Centre for Biodiversity.

<sup>128</sup> Institute for Agriculture and Trade Policy.

<sup>129</sup> Mexico.

<sup>130</sup> Brazil.

<sup>131</sup> Society for Applied Microbiology.

<sup>132</sup> BioIndustry Association; NHMUK, RBG Kew, RBG Edinburgh; Society for Applied Microbiology.

<sup>133</sup> Society for Applied Microbiology.

<sup>134</sup> European Union and Member States; Mexico; Switzerland.

<sup>135</sup> German Life Sciences Association; German Research Foundation; ICC; IFPMA; Institute for Agriculture and Trade Policy; Japan Bioindustry Association; Personal Care Products Council.

terms – to address DNA sequencing and information sharing. Two organizations<sup>136</sup> felt that this approach was preferable to a general determination that digital sequence information is in the scope of the Protocol, as using PIC and MAT could allow digital sequence information to be addressed on a case-by-case basis where relevant and necessary. Another organization<sup>137</sup> indicated that sequence data and genomic information based on utilization of genetic resources are typically generated under agreements between providers and users.

54. At the same time, however, these submissions were not necessarily in favour of digital sequence information being addressed through PIC and MAT either, with the following points being noted:

(a) For countries that do decide to use their national law to regulate use of digital sequence information, they would need to balance the possible benefits of this policy with the potential for benefit-sharing to be compromised and the challenges it would pose to the special considerations in Article 8 of the Protocol;<sup>138</sup>

(b) Widespread exercise of this right was likely to result in a sharp reduction in information being made available to public databases<sup>139</sup> and could result in deposits being rejected by collection holders because standard protocols for validating material at its entry involve sequencing;<sup>140</sup>

(c) Restrictions on sequencing of genetic resources and publication of digital sequence information could result in a reduction in biodiversity research especially in those countries where these restrictions have been introduced thereby reducing the information available to these countries.<sup>141</sup>

55. A region<sup>142</sup> also indicated that care is needed to avoid disproportionate restrictions that impede research due to decreased accessibility of information. Overall, they were concerned that regulating digital sequence information could restrict the development of knowledge needed for the conservation and sustainable use of biodiversity, possibly limiting attainment of the three objectives of the Convention.

56. In highlighting the role of mutually agreed terms, one organization<sup>143</sup> felt that current emphasis should be on implementation of the Protocol rather than creating legal uncertainty by expanding its scope (see also the discussion under section IV, subsection D.)

57. Another organization<sup>144</sup> considered the particular case of microorganisms. They explained that sequence data from microorganisms is generated or described on a large scale, with varying degrees of complexity and at an increasing rate. They were of the view that it would be unfeasible to enter into benefit-sharing arrangements each time digital sequence information is generated.

58. Another organization<sup>145</sup> supported that all digital sequence information generated from organisms should be provided alongside full provenance details under an appropriate material transfer agreement which provides relevant information on PIC and MAT. They suggested that in databases, this provenance information should be included as metadata alongside the sequence data to ensure transparency and traceability and they referred to existing best practice guidance in this regard<sup>146</sup> (see also subsection F

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<sup>136</sup> German Life Sciences Association; Personal Care Products Council.

<sup>137</sup> CETAF.

<sup>138</sup> German Life Sciences Association.

<sup>139</sup> IFPMA.

<sup>140</sup> European Union and Member States.

<sup>141</sup> European Union and Member States; CETAF.

<sup>142</sup> European Union and Member States.

<sup>143</sup> ICC.

<sup>144</sup> Society for Applied Microbiology.

<sup>145</sup> Society for Applied Microbiology.

<sup>146</sup> For reference, see the Global Genome Biodiversity Network (GGBN) Best Practice Guidance for ABS - [https://absch.cbd.int/api/v2013/documents/A68FE827-FF28-39B4-34C3-1AC435B0500A/attachments/GGBN%20Guidance%20\\_Best\\_Practice\\_June\\_2015-Final.pdf](https://absch.cbd.int/api/v2013/documents/A68FE827-FF28-39B4-34C3-1AC435B0500A/attachments/GGBN%20Guidance%20_Best_Practice_June_2015-Final.pdf)

below and example 30 in addendum). Another organization<sup>147</sup> agreed that, if a provider sets conditions on digital sequence information when granting access to a genetic resource, these conditions need to be observed and also transmitted when digital sequence information is shared with a database. They indicated, however, that the nucleotide databases do not currently offer the possibility to do this and they expressed doubt that the managers of databases would be willing to consider such an option (but see subsection F below).

**C. Regulation of digital sequence information through prior informed consent and mutually agreed terms for access to the information itself**

59. Some submissions addressed the possibility of using PIC and MAT to regulate access to the information itself. Views expressed in this regard included:

(a) “In the absence of physical access, the applicability of PIC and MAT for bilateral transfer between the provider and the user needs to be customized to the nature of digital access, the elements of which would require careful consideration”;<sup>148</sup>

(b) A country has the right to control access to digital sequence information but this should not be to the extent that it impedes science;<sup>149</sup>

(c) Regulating access to information through PIC and MAT would create excessive burdens on users as it would potentially mean that anyone seeking to access and use of information in a databank, or perhaps even in a journal, would need to obtain the consent of the provider of the genetic resources and potentially need to pay for such access and use;<sup>150</sup>

(d) Requiring PIC and MAT on the use of publicly available digital sequence information would make the utilization of this information extremely difficult, particularly where bulk digital sequence information is needed for comparison purposes;<sup>151</sup>

(i) The administrative burden that would result would be particularly challenging for academic and public institutions<sup>152</sup> and would delay or even prevent scientific research;<sup>153</sup> (See also section IV, subsection D.)

(e) If it were necessary to reach an agreement with a providing country before any sequence was accessed on a database then the system would fail;<sup>154</sup>

(f) If ABS obligations applied to digital sequence information, the amount of data to be regulated would quickly become unmanageable;<sup>155</sup>

(g) Regulation of digital sequence information by Parties to CBD would simply create the incentive to move research and development to non-Parties, which would undermine the objective of benefit-sharing.<sup>156</sup>

60. A number of organizations<sup>157</sup> noted that, unlike many biological samples, information can be reused indefinitely. They considered that, if digital sequence information were subject to PIC and MAT, the situation would become increasingly complex with multiple benefit-sharing agreements “for any given

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<sup>147</sup> German Research Foundation.

<sup>148</sup> India.

<sup>149</sup> Society for Applied Microbiology.

<sup>150</sup> IFPMA; IFRA and IOFI; Royal Society of Biology.

<sup>151</sup> German Life Sciences Association; Personal Care Products Council.

<sup>152</sup> ICC; Royal Society of Biology.

<sup>153</sup> German Life Sciences Association.

<sup>154</sup> CETAF; NHMUK, RBG Kew, RBG Edinburgh.

<sup>155</sup> IFPMA.

<sup>156</sup> IFPMA.

<sup>157</sup> IFPMA, IFRA and IOFI; German Life Sciences Association; Royal Society of Biology.

genetic sequence, which would be attached to the sequence forever, with each further transfer requiring additional permission and documentation resulting in long term and increasing litigation burden, financial and time delays to research and innovation.”

61. Other organizations<sup>158</sup> noted that research using digital sequence information often involves combining, editing and refining large amounts of information originating from many sources. One suggested<sup>159</sup> that this would create challenges for identifying the country of origin (see also subsection H below). Another suggested<sup>160</sup> that the administrative burden of negotiating a myriad of ABS agreements in such a situation would be significant and the utility dubious when the value of any one piece of information that contributed to the whole was minimal. They also referred to situations where the final product has a sequence that represents an “average” of all input sequences meaning it is virtually impossible to determine the relative value of each individual input sequence (see example 23 in addendum.)

62. A region<sup>161</sup> expressed the view that providers would be forced to use PIC and MAT to control utilization of natural information if such utilization was bypassing compliance measures. (See section II, subsection H and section IV, subsection B for further elaboration.)

#### **D. Benefit-sharing through technology transfer and capacity-building**

63. Some submissions noted that there is a digital divide between developing and developed countries in the context of digital sequence information<sup>162</sup> and that the emerging technologies linked to digital sequence information threaten to widen existing technology and capacity gaps.<sup>163</sup> Views included that:

- (a) This would undermine efforts for conservation and sustainable use;<sup>164</sup>
- (b) Technology transfer, partnerships and collaboration, information exchange and capacity development are needed to ensure that new genomic technologies are used in ways that contribute to sustainable development and generate benefits for developing countries;<sup>165</sup>
  - (i) Different provisions in the Convention and the Protocol refer to technology transfer, capacity-building and information exchange, e.g. Article 17 of the Convention, paragraphs 2(f), (b) and (j) of the Annex to the Protocol;<sup>166</sup>
  - (ii) Restrictions on the use of digital sequence information would run counter to these provisions;<sup>167</sup>
- (c) More efforts are needed to support researchers from developing countries to generate and publish digital sequence information from their national genetic resources.<sup>168</sup>

64. A number of examples were provided of projects to increase capacity in developing countries to use genomic technologies. This included training on DNA barcoding for rapid identification of invasive alien species<sup>169</sup> (see section I, subsection C) as well as examples 24 to 28 in the addendum.

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<sup>158</sup> BioIndustry Association; ICC.

<sup>159</sup> BioIndustry Association.

<sup>160</sup> ICC.

<sup>161</sup> Africa.

<sup>162</sup> Group of genomics experts.

<sup>163</sup> Africa, CGIAR.

<sup>164</sup> Africa.

<sup>165</sup> Africa, CGIAR; Group of genomics experts; NHMUK, RBG Kew, RBG Edinburgh.

<sup>166</sup> CGRFA – ABS Task Force; CGIAR; Group of genomics experts.

<sup>167</sup> CGRFA – ABS Task Force.

<sup>168</sup> BIO-University of Guelph.

### **E. Benefit-sharing and the public availability and sharing of digital sequence information**

65. A number of submissions<sup>170</sup> emphasized the role of sharing digital sequence information, particularly through publicly accessible databases<sup>171</sup> or in journals, as a contribution to benefit-sharing or as necessary in order to achieve fair and equitable benefit-sharing. For example:

(a) Continued access to digital sequence information that is already publicly available is consistent with a range of requirements in the Convention including Articles 12, 13, 15, 16, 17, 18 and 19 and accordingly, should be understood as benefit-sharing;<sup>172</sup>

(b) Different benefits result from public availability of digital sequence information, including some from the list of monetary and non-monetary benefits in the annex to the Protocol such as collaboration (paragraph 2(b)); admittance to databases (paragraph 2(e)); and access to scientific information relevant to conservation and sustainable use (paragraph 2(k)).<sup>173</sup>

66. A number of submissions<sup>174</sup> underlined the importance of scientific collaborations as a benefit stemming from the sharing of digital sequence information. Different submissions elaborated on this point:

(a) Examples of cooperative projects included the Spinach Genome Sequencing Consortium, the Centre for BioSystems Genomics and the International Wheat Genome Sequencing Consortium;<sup>175</sup>

(b) Cooperation and collaboration contributes to achieving different commitments in the Convention including Article 10(e) and Article 12;<sup>176</sup>

(c) Including digital sequence information in the scope of the Protocol would create difficulties for international research cooperation, resulting in a decrease in training and capacity-building for scientists from developing countries.<sup>177</sup>

67. Some organizations<sup>178</sup> expressed the view that rather than focusing on ways to restrict and control access to digital sequence information, the emphasis should instead be on finding legally robust means for free and unrestricted data sharing. As part of this:

(a) It may be necessary to consider restrictions on privatization or proprietization of genetic resources and associated information by the private sector, particularly where this may lead to unfair or inequitable benefit-sharing or may hamper scientific enquiry;<sup>179</sup>

(b) Benefit-sharing from digital sequence information should be on a global basis for the common good, along the lines of Aichi Target 19;

(i) This will require a common set of technical standards (discussed further in subsection F, “digital sequence information, databases and benefit-sharing”).<sup>180</sup>

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<sup>169</sup> Canada; BIO-University of Guelph; NHMUK, RBG Kew, RBG Edinburgh. This training is a collaborative effort between the Biodiversity Institute of Ontario and the CBD Secretariat, see <https://www.cbd.int/gti/training.shtml>.

<sup>170</sup> Canada; United States; CGRFA – United States; CETAF; LGC Group; ICC; IFPMA.

<sup>171</sup> Examples of such databases referred to in the submissions included: the databases in the International Nucleotide Sequence Database Collaboration, Ensembl, Genesys, Gramene, GrainGenes, GRIN Global, TreeGenes and SoyBase. See submissions from: United States; CGRFA – Canada; CGRFA – United States; CGIAR.

<sup>172</sup> ICC; IFPMA.

<sup>173</sup> European Union and Member States; CGIAR; European Seed Association.

<sup>174</sup> United States; CGRFA – Germany; CGRFA – ABS Task Force; group of genomics experts; Wellcome Trust and Wellcome Sanger Institute.

<sup>175</sup> European Seed Association.

<sup>176</sup> European Seed Association; German Life Sciences Association.

<sup>177</sup> BIO-University of Guelph; German Life Sciences Association; Wellcome Trust and Wellcome Sanger Institute.

<sup>178</sup> BIO-University of Guelph; CETAF; GGBN.

<sup>179</sup> BIO-University of Guelph.

<sup>180</sup> CETAF.

68. A number of policy rationales were cited in support of public accessibility of digital sequence information as a form of benefit-sharing. These were as follows:

- (a) Results from publicly funded research should be publicly available;<sup>181</sup>
- (b) Knowledge assets should be governed as a global public good;<sup>182</sup>
  - (i) Once a sequence is publicly published, the information is available for the benefit of humanity;<sup>183</sup>
  - (ii) The development of an open body of scientific information in genomics reflects the belief that longer-term societal benefits will come from harvesting the whole, not by hoarding the parts;<sup>184</sup>
    - this model should be particularly advantageous to developing countries, which could otherwise be priced out of access to knowledge (see also section IV, subsection D);
  - (iii) A background study prepared for the third meeting of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing had proposed that genomes and proteomes could usefully be seen as global public goods given that they may extend beyond individual jurisdictions and across generations;<sup>185</sup>
- (c) Efficiencies;<sup>186</sup>
  - (i) Sharing DSI helps to ensure the efficient use of limited funds, human resources as well as the genetic resources themselves by avoiding duplication of efforts and expenditures;
  - (ii) Sharing contributes to faster advancement of human knowledge and technological developments being made available more rapidly;<sup>187</sup>
  - (iii) Regulating access to and sharing of digital sequence information would likely lead to a significant reduction in the sharing of data and would have negative impacts on research, development and innovation, hindering activity to further CBD and Nagoya Protocol objectives;<sup>188</sup>
- (d) Digital sequence information provided to databases by researchers from around the world should be publicly available;<sup>189</sup>
- (e) Single sequences have less value than a collection of sequences as collections enable comparisons to identify differences and understand the functions of different genes;<sup>190</sup>
- (f) The value of digital sequence information is increased by sharing;
  - (i) It enables searches and comparisons across data sets and analyses of large data samples, increasing statistical robustness;<sup>191</sup>

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<sup>181</sup> CGRFA – Canada; Biotechnology and Biological Sciences Research Council; BIO-University of Guelph; German Research Foundation; CGRFA – Prof. Sundström.

<sup>182</sup> CGRFA – Germany; CGRFA – Prof. Sundström.

<sup>183</sup> LGC Group.

<sup>184</sup> Group of genomics experts.

<sup>185</sup> CGRFA – ABS Task Force citing UNEP/CBD/WG-ABS/3/INF/4.

<sup>186</sup> CGRFA-Brazil, United States, European Seed Association, Royal Society of Biology, group of genomics experts.

<sup>187</sup> CGRFA – Brazil.

<sup>188</sup> United States.

<sup>189</sup> BIO-University of Guelph.

<sup>190</sup> Group of genomics experts.

<sup>191</sup> CGRFA – Brazil; Group of genomics experts; IFPMA; Personal Care Products Council; Royal Society of Biology.

- (ii) Separating data into individual silos would contribute to a “tragedy of the anti-commons”, diminishing the value of individual data items and the number of people who can access them, which, in turn, would reduce the potential for productive use of the resource;<sup>192</sup>
- fraud;<sup>193</sup> (g) Shared data improve research reproducibility and help to build trust and combat scientific
- (i) Digital sequence information included in non-open access databases could generate mistrust towards the scientific community as this has been seen as a starting point for biopiracy;<sup>194</sup>
- (ii) Without sharing, there would be no libraries available to do identification and quality control of research results;<sup>195</sup>
- (iii) Digital sequence information is used in laboratories to verify that a result is as expected;<sup>196</sup>
- (iv) Enhances traceability of utilized genetic resources.<sup>197</sup>
- (h) Access to data that would not otherwise be available through a bilateral approach, e.g. information about non-endemic species (see section I, subsection E);<sup>198</sup>
- (i) Data sharing contributes to the global research commons;<sup>199</sup>
- (i) Data sharing can widen the research community and become part of a common infrastructure available for use by a range of new actors who can challenge the monopolies of powerful incumbents;<sup>200</sup>
- (ii) Keeping digital sequence information out of the scope of ABS legislation creates a level playing field among researchers;<sup>201</sup>
- The more administrative requirements are imposed on the use of sequence information, the more it will only be those researchers with the funds and resources to comply who will be able to benefit from such sequence information;
- (iii) Publicly available sequences that have been purposefully placed in the public domain for the benefit of humanity should not be regulated by the Nagoya Protocol;<sup>202</sup>
- Publicly available sequence information is very important for both basic and commercial research;<sup>203</sup>
  - Publication and sharing of digital sequence information prevents its privatization (including through patents) and individual profiting;<sup>204</sup>

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<sup>192</sup> Group of genomics experts.

<sup>193</sup> Society for the Preservation of Natural History Collections; group of genomics experts.

<sup>194</sup> Mexico.

<sup>195</sup> Canada.

<sup>196</sup> BioIndustry Association.

<sup>197</sup> Society for the Preservation of Natural History Collections.

<sup>198</sup> CETAF; NHMUK, RBG Kew, RBG Edinburgh.

<sup>199</sup> CGRFA – Prof. Sundström; CGIAR.

<sup>200</sup> Group of genomics experts.

<sup>201</sup> European Seed Association.

<sup>202</sup> German Research Foundation; Japan Pharmaceutical Manufacturers Association; LGC Group.

<sup>203</sup> German Research Foundation; LGC Group.

<sup>204</sup> LGC Group; group of genomics experts; IFRA and IOFI.

- Regulating access to such information would frustrate the CBD objectives of promoting cooperation in scientific advances and technology transfer;<sup>205</sup>
  - Imposing any terms or conditions on the sharing of digital sequence information via publicly accessible databases would undermine their value and sustainability;<sup>206</sup>
- (iv) If digital sequence information were not shared, it would impede the developing global resource that is already being used by Parties.<sup>207</sup>

69. Some analogies were made to discussions and work undertaken in the context of human genetic resources where, after an initial period when access to data was restricted, it was recognized that free public access was desirable.<sup>208</sup>

70. At the same time, however, one submission<sup>209</sup> pointed to three challenges to the sharing of data, particularly in the context of viruses: (a) scientists may hesitate to share data on lethal viruses because they are concerned about other researchers using this data to publish scholarly articles more quickly than they themselves are able to – meaning that their scientific contributions would not be properly acknowledged and recognized; (b) Governments may be concerned about negative economic ramifications if they are identified as the source country for an international outbreak and they may also wish to retain ownership over any intellectual property potentially residing in such data and – particularly for low- and middle-income countries – will wish to ensure that they can secure access to new vaccines or medicines developed on the basis of that cooperation; and (c) there are practical obstacles in terms of who will actually provide the international leadership, legitimacy, coordination, and funding needed for sustaining the material infrastructures essential for collecting, curating, and distributing such virus data. (See also subsection F below for information on efforts to address these challenges.)

71. One organization<sup>210</sup> expressed the view that unregulated and free access to sequences may harm communities and decrease the perception of the importance of maintaining and developing the resiliency of the genetic resources in situ and within context specific and appropriate ecological environments.

#### **F. Digital sequence information, databases and benefit-sharing**

72. Three organizations addressed the role of repositories (including databases, microbial collections, botanical gardens, academic institutions and others) in benefit-sharing. Points raised included:

(a) That the CBD should explore how these repositories could require users to agree to benefit-sharing as a precondition of access to digital sequence information;<sup>211</sup>

- (i) This could include consideration of the development of provisions for user agreements, such as click wrap terms and conditions, for databases and recommendations on how databases should be required to implement them;
- (ii) At the same time, however, not every use of digital sequence information in a database would incur a benefit-sharing obligation, so appropriate triggers would also need to be identified.<sup>212</sup>

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<sup>205</sup> Intellectual Property Owners Association.

<sup>206</sup> Wellcome Trust and Wellcome Sanger Institute.

<sup>207</sup> CETAF; NHMUK, RBG Kew, RBG Edinburgh.

<sup>208</sup> Royal Society of Biology. See also the references to the Bermuda Principles and the Fort Lauderdale Agreement in the submissions from BIO-University of Guelph and group of genomics experts.

<sup>209</sup> GISAID.

<sup>210</sup> African Centre for Biodiversity.

<sup>211</sup> African Centre for Biodiversity, Heinrich Böll Foundation, Third World Network.

<sup>212</sup> Third World Network.



73. A number of submissions provided information on technical standards for databases that could assist in maintaining easy access to data while also contributing to benefit-sharing and implementation of the Protocol. Examples included:

(a) The databases of the International Nucleotide Sequence Data Collaboration, the Global Biodiversity Information Facility (GBIF) and the Barcode of Life Database;

(i) It was noted that GBIF explicitly operates within an intellectual property rights framework (see example 29 in addendum);<sup>213</sup>

(b) Work being undertaken to establish links between stored samples and sequence accession numbers in databases (see example 30 in addendum);<sup>214</sup>

(c) The development of a data standard to facilitate sharing of factual information about a sample (including permit information and access conditions) in a consistent and open manner in order to fulfil the requirements of the Protocol (see example 30 in addendum);<sup>215</sup>

(i) It was proposed that this data standard become the global biodiversity data exchange standard for fulfilling the requirements of the Protocol;<sup>216</sup>

(d) The development of a tool that enables tracking of parent and offspring use of samples with the objective to ensure that by the end of 2020, all samples created since the ratification of the Protocol will provide permit information (see example 30 in addendum.)

74. Other organizations<sup>217</sup> noted that for most countries, the content in databases is available at zero cost so researchers from anywhere can freely access and use the information, including in support of the conservation and sustainable use of biodiversity.

75. One submission<sup>218</sup> described the approach taken by the Global Initiative on Sharing All Influenza Data (GISAID). It was explained that the Initiative has been designed to overcome some of the challenges associated with the international sharing of virus data (see section I, subsection H). This included issues of transparency and equity of data sharing and it was felt that these would likely remain unresolved if data archives with anonymous access to data were used. The submission explained that the approach taken instead was to try to provide data contributors with additional protections and assurances about how their data would be used. The result was the development of a data access agreement, which:

retained the principle of a publicly accessible database – meaning that any natural person (whether scientist or not) could obtain credentials to access data in GISAID, predicated upon a one-time positive verification of the individual's identity, and agreement to the terms of the [data access agreement], which license the use of data in GISAID. This process of positively identifying the contributors and users of data differs from the anonymous access afforded to public domain archives (like Genbank), but provides GISAID with the mechanism for enforcement, and makes users adhere to the rules set forth in the [data access agreement]. Further benefits of this system are that it makes it easier for scientists to discover and properly acknowledge those who contributed the data and to also assist with any biosecurity considerations that could potentially arise around the use of some such data.

(See example 22 in addendum.)

76. The submission stated that the Initiative has a successful track record in the sharing of influenza data and that there is now widely perceived merit in the Initiative's formula for balancing control versus

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<sup>213</sup> CETAF.

<sup>214</sup> GGBN.

<sup>215</sup> CETAF; GGBN.

<sup>216</sup> GGBN.

<sup>217</sup> CETAF; NHMUK, RBG Kew, RBG Edinburgh; Japan Bioindustry Association.

<sup>218</sup> GISAID.

openness and for reconciling the competing imperatives of science, public health and business. It was suggested that the experience of the Initiative may serve as a useful blueprint for other diseases and global challenges that depend on the international sharing of sensitive data and demonstrates how innovative solutions to global challenges can be found when lessons are creatively applied from one issue area to another and that such cross-sectoral learning should be encouraged.

### **G. Benefits shared from use of digital sequence information**

77. Many submissions pointed to benefits that are already shared from the use of digital sequence information. (Indeed, much of the views and information synthesized in previous sections, e.g. section I, subsections B, C, D, E and H and section II, subsections D and E, could also be considered as benefits from the use of digital sequence information.)

78. One organization<sup>219</sup> identified a number of benefits associated with the use of genomic sequence information by its research centres:

- (a) Farmers' improved access to technologies;
- (b) Food and livelihood security benefits (further to paragraph 2(o) in the annex to the Nagoya Protocol);
- (c) Enhanced institutional capacities of developing country research organizations;
- (d) Shared research results;
- (e) Local, national and regional economic development, including through the availability of improved plant varieties (which also generate benefits for the farmers who use them).

79. They suggested that, given the relatively newness of the technologies, there are not yet many examples that start with the generation of raw sequence data and end with released cultivars and breeds adopted by farmers. They did, however, provide the example of a project to develop a fortified variety of maize (see example 31 in addendum).

### **H. Monitoring and compliance measures**

80. One region<sup>220</sup> expressed the view that utilization of natural information instead of the genetic resource could bypass compliance measures as existing user measures will not lead to a monitoring of the utilization of sequence information in the country where utilization occurs. They suggested that this could lead to the situation where providers will be forced to use their national measures through PIC and MAT to control such utilization and ensure appropriate benefit-sharing (see also subsection C above). They foresaw that this could place undue restrictions on utilization of natural information, which would be counter-productive for achieving the objectives of the Convention. They were of the view that, accordingly, the focus should be on designing measures to ensure fair and equitable benefit-sharing as with such measures, the need for controlling access would decrease and monitoring compliance would be facilitated. This was linked to their suggestion that Article 10 of the Nagoya Protocol might help Parties arrive at beneficial solutions (see subsection I below as well as section IV, subsection B).

81. One Government (in a submission via an inter-governmental organization)<sup>221</sup> noted the importance of traceability for countries granting access to genetic resources in order to achieve full implementation of benefit-sharing in the context of utilization of digital sequence information. This Government also suggested that traceability is similarly fundamental for "user countries" in order to demonstrate the existence of a complete legal framework to institutions that may be interested in investing in research in those countries.

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<sup>219</sup> CGIAR.

<sup>220</sup> Africa.

<sup>221</sup> CGRFA – Brazil.

82. One organization<sup>222</sup> stated that natural history collections anchor all associated information with specimens and, by linking permits, agreements and other metadata to their specimens, there is increased transparency regarding origins and use.

83. Several submissions addressed the linkages between databases and monitoring of digital sequence information (see also subsection F above). Different points that were noted included that:

(a) Although genetic sequence databases require the provision of different pieces of information regarding submitted sequences, in many cases, the data needed for traceability is not mandatory, making precise determination of the source of the information difficult;<sup>223</sup>

(b) Given that information needed for traceability can be made available in public databases, traceability is feasible but not yet mandatory. For example, for the Barcode of Life database, traceability is essential as the objective is to identify species so the deposit of a voucher specimen in an indexed herbarium or museum is required;<sup>224</sup>

(c) Information on the origin, providers or sovereign rights holders of the initial genetic resource related to digital sequence information are usually not available in databases making it unclear how compliance with the principles of the Nagoya Protocol could be ensured;<sup>225</sup>

(d) Once rules for the use of digital sequence information are established in the context of the Convention and the Nagoya Protocol, it will be necessary to establish mechanisms to ensure that the genetic databases require standardized information necessary for the traceability of submitted sequences. Furthermore, a different approach will be needed for sequences already in databases as well as for sequences whose traceability is not possible;<sup>226</sup>

(e) Databases that contain information on novel engineered sequences should describe the geographical origin of the genetic components of the sequences. Ensuring traceability will enable subsequent users to enter into new ABS agreements, as necessary.<sup>227</sup>

84. A Party<sup>228</sup> also suggested that mutually agreed terms could be used to establish traceability requirements when sequencing information is deposited in databases and that databases could also serve as checkpoints in the context of Article 17 of the Nagoya Protocol. They were of the view that, if this were the case, it could potentially facilitate the establishment of prior art for the analysis of patent applications, inhibit misappropriation, create mutual trust among all stakeholders and make traceability possible.

85. Many submissions identified challenges to the traceability and monitoring of digital sequence information.<sup>229</sup> Of these submissions, most<sup>230</sup> were of the view that these challenges underlined why there should not be ABS obligations on digital sequence information.

86. These challenges were:

(a) Difficulties in identifying geographic- and species-origin of sequences:

(i) Many genes are shared between even distantly related species and may not differ substantially in function or sequence composition. These are known as conserved genes or conserved sequences;<sup>231</sup>

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<sup>222</sup> Society for the Preservation of Natural History Collections.

<sup>223</sup> Brazil.

<sup>224</sup> CGRFA – Brazil.

<sup>225</sup> IFRA and IOFI.

<sup>226</sup> Mexico; CGRFA – Brazil.

<sup>227</sup> Society for Applied Microbiology.

<sup>228</sup> Mexico. See also section II, sub-section B.

<sup>229</sup> Mexico, CGRFA – Brazil, CGRFA – Prof. Sundström, ICC, Intellectual Property Owners Association, IFRA and IOFI, German Life Sciences Association.

<sup>230</sup> ICC, Intellectual Property Owners Association, IFRA and IOFI, German Life Sciences Association.

- For example: “the genes that determine reproductive organ identity i.e. stamen- and carpel-identity are highly conserved within all flowering plants, and it is in principal possible to move those genes between species without changing either form or function of the flower”;<sup>232</sup>
- (ii) Microorganisms present a particular challenge given their ubiquitous nature, the ease with which they cross borders without human intervention and the prevalence of conserved genes between different species;<sup>233</sup>
- (iii) The effect of conserved genes is to make the identification of the origin of a sequence – both geographically and in terms of the species of the organism<sup>234</sup> – difficult or impossible;
- (iv) Even if information on the origin of a sequence were available, it would be nearly impossible to verify the accuracy of the information and could lead to legal disagreements;<sup>235</sup>
- (v) Data may be derived from multiple organisms so may not have a single origin (see also subsection C above).<sup>236</sup> Examples included:
  - A case study on the development of a consensus protein (see example 23 in addendum);<sup>237</sup>
  - Using codon optimization to change the original sequence to one that expresses better in particular bacteria: “If the final sequence differs from the original sequence, it cannot be regarded solely as the genetic property of an originator country”;<sup>238</sup>
- (vi) For sequence data derived from multiple organisms, this could lead to requirements for multilateral arrangements for utilization, potentially slowing the pace of research until an agreement is reached;<sup>239</sup>
- (b) Continuous changes to genomes and taxonomy:
  - (i) Changes in taxonomic status are common, which would create challenges for traceability;<sup>240</sup>
  - (ii) Tracking digital sequences is particularly problematic in the case of microorganisms, including due to their rapid evolution;<sup>241</sup>
  - (iii) Genetic sequence data are not permanent and would change over time as the sequences are modified by random mutations;<sup>242</sup>
- (c) Difficulties in controlling information:

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<sup>231</sup> CGRFA – Brazil; CGRFA – Prof. Sundström; Biotechnology and Biological Sciences Research Council; German Life Sciences Association; ICC; IFRA and IOFI; Royal Society of Biology; Society for Applied Microbiology.

<sup>232</sup> CGRFA – Prof. Sundström.

<sup>233</sup> German Life Sciences Association; Royal Society of Biology; Society for Applied Microbiology.

<sup>234</sup> The difficulty in identifying the original species a sequence as a result of conserved sequences was also expressed as the concept of the species not being relevant at the level of the gene (CGRFA- Prof. Sundström). Indeed, some DNA research, which seeks to identify molecular markers associated with defense and resistance (abiotic, biotic) genes or adaptation does not need, a priori, the correct species identification (CGRFA – Brazil). See also the discussion of the conservation of gene sequences in the submission from a group of genomic experts.

<sup>235</sup> Intellectual Property Owners Association; Society for Applied Microbiology.

<sup>236</sup> LGC Group, Society for Applied Microbiology.

<sup>237</sup> ICC.

<sup>238</sup> BioIndustry Association.

<sup>239</sup> Society for Applied Microbiology.

<sup>240</sup> CGRFA – Brazil.

<sup>241</sup> CGRFA – Brazil.

<sup>242</sup> CGRFA – Canada.

- (i) There are inherent difficulties in monitoring digital information in contrast to physical genetic resources;<sup>243</sup>
- (ii) monitoring use of publicly available databases is complex;<sup>244</sup>
- (iii) How could sequence information have a chain of custody and be securely tracked.<sup>245</sup> They stated that none of the proposals so far for monitoring and tracing digital sequence information provided a perfect solution.<sup>246</sup>
- (d) Digital sequence information already publicly available:
  - (i) Concerns regarding digital sequence information that is already available in public databases and for which there is no information on the country of origin;<sup>247</sup>
  - (ii) Potential users may be expected to identify the country of origin of information when the digital sequence information has been created from long-standing, readily available data for which no country of origin information exists;<sup>248</sup>
- (e) Excessive burdens would arise from monitoring digital sequence information:
  - (i) Imposing ABS requirements on digital sequence information would be unworkable for both users and Governments because compliance, monitoring and checking would be extremely burdensome or even impossible to achieve;<sup>249</sup>
    - Such an approach would cause enormous transaction costs that would negatively affect research in all countries and scientists in provider countries will suffer first and foremost;<sup>250</sup>
    - The burden would be particularly challenging for small- and medium-sized enterprises that lack the resources to meet compliance requirements;<sup>251</sup>
- (f) How to handle synthetic sequences and digital sequence information created by accident.<sup>252</sup>

87. In contrast to these challenges, however, one organization<sup>253</sup> stated that databases that contain information on novel engineered sequences should describe the geographical origin of the genetic components of the sequences. They indicated that ensuring traceability will enable subsequent users to enter into new ABS agreements, as necessary.

88. Another submission<sup>254</sup> suggested that given the role of DNA sequences in identifying populations and species, such information can aid in identifying the origin of a sample when sequences obtained by different groups from different countries are made publicly available in databases and articles.

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<sup>243</sup> Intellectual Property Owners Association.

<sup>244</sup> LGC Group.

<sup>245</sup> German Life Sciences Association.

<sup>246</sup> They referred to the contract model, the copyright and database rights model and cited Lawson, C. and Rourke, M. 2016. *Open Access DNA, RNA and Amino Acid Sequences: The Consequences and Solutions for the International Regulation of Access and Benefit-Sharing*. Griffith Law School Research Paper No. 16-12, Griffith University Law School, Australia. 5 October.

<sup>247</sup> BioIndustry Association.

<sup>248</sup> IFPMA.

<sup>249</sup> ICC; German Life Sciences Association; IFRA and IOFI.

<sup>250</sup> German Life Sciences Association.

<sup>251</sup> BioIndustry Association.

<sup>252</sup> BioIndustry Association; Biotechnology and Biological Sciences Research Council; IFPMA; LGC Group. Two examples were provided: a genetic sequence is synthesized and assembled de novo by artificial means (gene synthesis or DNA printing) but then an identical sequence is subsequently found in nature, or the synthetic sequence leads to a protein identical to one found in a genetic resource (BioIndustry Association; Biotechnology and Biological Sciences Research Council).

<sup>253</sup> Society for Applied Microbiology.

<sup>254</sup> CGRFA – Brazil.

89. An organization<sup>255</sup> pointed to the use of digital object identifiers for plant genetic resources as a means of ensuring that research results, including genomic research, are associated with and traceable to the genetic resources conserved by its genebanks and made available to the international community.

### **I. Digital sequence information and multilateral benefit-sharing**

90. One region<sup>256</sup> and one Party<sup>257</sup> pointed to Article 10 of the Nagoya Protocol (“global multilateral benefit-sharing mechanism”) as a possible means for addressing fair and equitable benefit-sharing in relation to digital sequence information. In the context of Article 10, another Party<sup>258</sup> suggested that further analysis is needed on how benefit-sharing should be carried out in cases of (a) access to multiple genetic resources, including cases in which the genetic information was obtained from genetic databases, and may come from different species or regions, and (b) use of conserved sequences, since these sequences can be found in hundreds or even thousands of different species, which makes traceability difficult. (See also subsection H above.)

91. Some organizations<sup>259</sup> suggested that the existing public databases can be considered as a global multilateral benefit-sharing mechanism. It was indicated that:

(a) The non-monetary benefits arising from access to this information have been called for over many years in decisions of the Conference of the Parties, and their delivery supports the Aichi Biodiversity targets.<sup>260</sup>

(b) The development of a global taxonomy information system has been called for by the Conference of the Parties and might be considered a global multilateral benefit-sharing mechanism.<sup>261</sup>

(c) Scientific research has always operated on a multilateral benefit-sharing model (even if it has not been termed as such)<sup>262</sup> – the information is shared openly and any Party can obtain what it needs.<sup>263</sup>

(d) No Party has the capacity to manage information on all of its biota or the information itself, so all must rely on information generated and held elsewhere.<sup>264</sup>

92. Some submissions<sup>265</sup> considered the possibility of setting up a new multilateral system to manage access to and use of digital sequence information. Different challenges were identified with this approach:

(a) The ability to manage the very large volume of information and transactions, including the application of conditions and monitoring sequence information;

(b) Loss of input from researchers following a move to a different database model from the current approach;

(c) Sustainable funding;

(d) Whether it would be effective in addressing non-compliance and concerns about “data piracy”,<sup>266</sup>

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<sup>255</sup> CGIAR.

<sup>256</sup> Africa.

<sup>257</sup> Mexico.

<sup>258</sup> Brazil.

<sup>259</sup> CETAF; NHMUK, RBG Kew, RBG Edinburgh; GGBN.

<sup>260</sup> CETAF; NHMUK, RBG Kew, RBG Edinburgh.

<sup>261</sup> NHMUK, RBG Kew, RBG Edinburgh. See also section I, subsection C.

<sup>262</sup> NHMUK, RBG Kew, RBG Edinburgh.

<sup>263</sup> CETAF.

<sup>264</sup> CETAF; NHMUK, RBG Kew, RBG Edinburgh.

<sup>265</sup> BIO-University of Guelph; CETAF.

<sup>266</sup> BIO-University of Guelph; CETAF.

(e) Potential to hinder the compilation of data and information, thereby delaying non-monetary benefits,<sup>267</sup> and create unnecessary barriers to science, particularly basic science.<sup>268</sup>

93. Instead of setting up a new multilateral system to manage digital sequence information, it was suggested<sup>269</sup> that it could be possible to extend current standard data exchange systems to include permit information (see subsection F above).

94. Other submissions discussed the option of charging a fee for access to digital sequence information in databases, perhaps in the form of a subscription<sup>270</sup> or a small charge for accessing any sequence.<sup>271</sup> The funds could then be shared on a multilateral basis. Views expressed included that:

- (a) This would not be very feasible to set up and maintain;<sup>272</sup>
- (b) It would add a significant financial burden on users of digital sequence information, especially those accessing large numbers of sequences;<sup>273</sup>
- (c) It would discourage basic research as researchers would be expected to pay a fee even where there was no expectation of a financial return;<sup>274</sup>
- (d) The isolated value of the information accessed may be limited as each database search is not generating financial returns;<sup>275</sup>
- (e) The financial and administrative costs to users and database managers of imposing even a very small fee for reading a sequence would outweigh the benefits generated.<sup>276</sup>

### III. TERMINOLOGY

#### A. Types of information that may be included in digital sequence information and descriptions of what digital sequence information is or might be

95. Different submissions offered different descriptions of what digital sequence information might be. The details of these descriptions are as follows:

- (a) Genetic sequence information is the way in which the base pairs of DNA and RNA are structured in an organism. Digital sequence information may include any information derived from the nucleotide or amino acid sequences, gene locations, genetic maps, artificial chromosome maps, localization details, functional expression details, genome sequences and its annotations, and applied aspects in decoding the sequence information;<sup>277</sup>
- (b) Digital sequence data includes standardized DNA-fingerprints or barcodes, DNA sequences and full genome sequencing;<sup>278</sup>
- (c) Digital sequence information is, in general terms, the information that originates from the analysis of the data contained in a digital file with a precise order of nucleotides, amino acids or molecular

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<sup>267</sup> Society for the Preservation of Natural History Collections.

<sup>268</sup> BIO-University of Guelph; CETAF.

<sup>269</sup> CETAF.

<sup>270</sup> Society for Applied Microbiology.

<sup>271</sup> IFPMA.

<sup>272</sup> IFPMA; Society for Applied Microbiology.

<sup>273</sup> IFPMA; Society for Applied Microbiology.

<sup>274</sup> IFPMA; Society for Applied Microbiology.

<sup>275</sup> CETAF; IFPMA; NHMUK, RBG Kew, RBG Edinburgh; Society for Applied Microbiology.

<sup>276</sup> CETAF; NHMUK, RBG Kew, RBG Edinburgh.

<sup>277</sup> India.

<sup>278</sup> Society for the Preservation of Natural History Collections.

structure of proteins. The sequence of nucleotides or amino acids forms nucleic acid molecules, DNA and RNA, and proteins, whose main function is the storage and transmission of genetic information;<sup>279</sup>

- (i) Digital sequence information can be obtained by sequencing the DNA of organisms, through inference by reverse translation of amino acid sequences or fabricated through simulations and computer programs. In the first two cases they are called natural sequences and in the third case synthetic sequences;<sup>280</sup>
- (d) Digital sequence information should be understood to include sequences of DNA and RNA in all their forms as well as the sequences of amino acids and accompanying characterization information;<sup>281</sup>
  - (i) Hereditary material of an organism is not just DNA but in some cases, is RNA.
  - (ii) Amino acid sequences are also valuable as they can be used to replicate and modify natural compounds and in the design of biological systems.
- (e) Digital sequence information on genetic resources is “electronically held sequence information which represents the biological composition of “genetic material” as defined under the Convention.”<sup>282</sup> There is a broad range of types and quality of sequence information relating to genetic resources that may be stored and/or transmitted digitally. Different types of sequence information include DNA, RNA and protein sequences as well as information on epigenetic factors such as methylation and glycosylation sites. The quality of information can range from raw sequence data through to fully annotated, characterized and codon optimized sequences complete with information on relationships to other sequences, including from multiple source organisms;
- (f) Digital sequence information on genetic resources is data contained in a digital registry on the biomolecules, such as the DNA, RNA and proteins that should have gone through an ABS process;<sup>283</sup>
- (g) Digital sequence information is broad in scope and does not encompass a single type of data. Researchers use DNA sequence data with different qualities such as:
  - (i) DNA “barcodes” - short stretches of DNA with sequences that are conserved enough to find and yet diverse enough to allow researchers to identify what organism they are from;
  - (ii) Gene sequences - sequences that include the start and stop instructions and all the necessary DNA codons to create a gene product e.g. a protein;
  - (iii) Regulatory DNA - stretches of DNA that do not code for proteins but instead have effects on e.g. the processing of genes;
  - (iv) Whole genomes - the complete genome sequence of an organism. As each organism is unique, there may be standard or consensus (compiled from multiple, even thousands) genome sequences;<sup>284</sup>
- (h) The primary types of digital sequence information are single nucleotide polymorphisms and whole genome sequence information;<sup>285</sup>
  - (i) Discussion on digital sequence information should include not only DNA information but also the sequences that allow or lead to derivatives of genetic resources through the tools of new “-omics” techniques;<sup>286</sup>

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<sup>279</sup> Brazil.

<sup>280</sup> CGRFA – Brazil.

<sup>281</sup> African Centre for Biodiversity; Institute for Agriculture and Trade Policy; Sustainability Council of New Zealand; Third World Network.

<sup>282</sup> Australia.

<sup>283</sup> Ecuador.

<sup>284</sup> BioIndustry Association.

<sup>285</sup> CGRFA – ABS Task Force.



(j) Digital sequence information should be treated as “information associated” with the species. The benefits associated with it should be addressed in a similar fashion to traditional knowledge associated with genetic resources in the scope of the CBD;<sup>287</sup>

(k) Digital sequence information is information which has been deduced from a living organism in the same way, as for example the phyllotaxis, inflorescence, taxonomic classification, or even the colouring of the flower;

(i) In an analogy, a chemical structure cannot be considered as a physical compound which can be weighed or used for tests, it is merely a scheme of how atoms are connected to each other. The invention of e.g. a chemist, who designs a route to synthesize such a physical compound is clearly distinct from the chemical structure as such a process is an invention/creation on its own;<sup>288</sup>

(l) “Digital sequence information on genetic resources” is interpreted as “digital sequence information derived from genetic resources” as this addresses the question of “whether digital [DNA] sequence information should become the purview of the Nagoya Protocol in the same way as it currently governs the transfer and utilization of *genetic resources*.”<sup>289</sup>

(m) Sequence data is analytically derived information, or data that describe the order of nucleotides in DNA or RNA in genetic material;<sup>290</sup>

(n) Digital sequence information is simply data that results from research on a genetic resource.<sup>291</sup>

96. Some submissions examined the meaning of “digital sequence information” or “digital sequence information on genetic resources” and proposed alternative terminology.

97. In order to avoid a situation whereby biodiversity policy is overtaken by technological developments, one region<sup>292</sup> favoured the use of a “neutral and wide term like ‘natural information’” although they were open to discussing the possibility that different types of natural information might be subject to different governance regimes. They noted that “digital” may become obsolete if current modes for encoding information are overtaken by new developments. They stated that the relevant point is the information itself, the fact of storage and worldwide accessibility and modes of reconstitution and utilization.

98. The region suggested that the word “genetic” tends to obscure developments in other relevant “-omics” such as proteomics and metabolomics. They expressed the view that the definition of “utilization of genetic resources” in the Nagoya Protocol refers not only to genetic molecules (namely DNA and RNA) but also to any naturally occurring component contained in the biological material, including proteins, metabolites and others. Along similar lines, they suggested that “sequence” could be understood as only referring to nucleic acid sequences, as their view was that the definition of “utilization of genetic resources” covers the information contained in any natural substance described through the sequence of, for example, nucleic acids in DNA, amino acids in proteins or atoms in biochemical compounds”. They stated that it is crucial to apply the term “digital sequence information” in a way that fully recognizes and incorporates the definitions of the Convention and the Nagoya Protocol.

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<sup>286</sup> Mexico.

<sup>287</sup> CGRFA – India.

<sup>288</sup> IFRA and IOFI.

<sup>289</sup> BIO-University of Guelph.

<sup>290</sup> GGBN.

<sup>291</sup> Personal Care Products Council.

<sup>292</sup> Africa.

99. An organization identified what it considered to be a number of flaws with the words “digital”, “sequence” and “information” in this context:<sup>293</sup>

(a) “Digital”: implies that anything not digital is not included in the discussions. “So, a sequence which is first accessed through the print medium would not be within the scope of ‘digital sequence information on genetic resources’”;

(b) “Sequence”: does not cover expressions of natural information – such as molecular structures, biomimicry and animal behaviour – other than nucleic acids and amino acids;

(c) “Information”: without a modifier of either “natural” or “artificial” does not identify the provenance of the sequence and so extends to information which could be artificial in origin (see also section II, subsection H).

The organization was also concerned that “digital sequence information on genetic resources” creates opportunities for lawful avoidance of ABS. In the light of all this, they advocated the use of the term “natural information” and suggested that analysis in the academic literature demonstrates how this could achieve conservation and sustainable use of biodiversity through access and benefit-sharing.

100. Two Governments<sup>294</sup> preferred the term “genetic sequence data”. Reasons included that:

(a) The word “genetic” was necessary to distinguish from other types of sequences;<sup>295</sup>

(b) That “data” was more accurate as it can be codified and is transmissible, which is the case for genetic sequences but not always the case for information;<sup>296</sup>

(c) The word “digital” was not necessary as the fact that the sequences can be stored or conveyed digitally is of secondary importance;<sup>297</sup>

(d) Genetic sequence data is data that describes the order in which nucleotides are situated in a chain relative to one another in DNA or RNA molecules contained in genetic material of actual or potential value.<sup>298</sup>

## **B. Other comments on terminology**

101. Some organizations<sup>299</sup> suggested that the rationale for seeking to bring digital sequence information into the scope of the Nagoya Protocol could also apply to other information concerning a genetic resource, such as the chemical structures of compounds found within it. They stated that this could mean that anyone accessing a journal article containing information about a genetic resource or its components would be obliged to obtain content to use or perhaps even reference that information, which they felt would make the public domain subject to regulation.

102. Another organization<sup>300</sup> indicated that sequence data must be broadly defined because it is not necessary to synthesize an entire genome in order for the data to be useful and profitable. They explained that individual genes synthesized from data and inserted into living organisms can be of enormous commercial value, particularly in industrial and medical applications.

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<sup>293</sup> Peruvian Society of Environmental Law. Views on “genetic resources” are addressed below.

<sup>294</sup> United States, CGRFA – Canada.

<sup>295</sup> CGRFA – Canada.

<sup>296</sup> CGRFA – Canada.

<sup>297</sup> CGRFA – Canada.

<sup>298</sup> United States.

<sup>299</sup> IFPMA; IFRA and IOFI.

<sup>300</sup> African Centre for Biodiversity.

#### IV. DIGITAL SEQUENCE INFORMATION AND THE SCOPE OF THE CONVENTION AND THE NAGOYA PROTOCOL

103. Many of the submissions examined definitions in the Convention and the Protocol in considering whether or not digital sequence information can be or should be within the scope of these instruments. These relevant definitions are as follows:

(a) “Genetic material” means any material of plant, animal, microbial or other origin containing functional units of heredity (Convention, Article 2);

(b) “Genetic resources” means genetic material of actual or potential value (Convention, Article 2);<sup>301</sup>

(c) “Utilization of genetic resources” means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention (Nagoya Protocol, Article 2(c));

(d) “Derivative” means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity (Nagoya Protocol, Article 2(e)).

##### A. Digital sequence information and the definitions of “genetic resources” and “genetic material”

104. A number of Parties were of the view that digital sequence information is included in the definitions of “genetic resources” and “genetic material” in the Convention. In general, this perspective may be summarized as understanding these terms to include both the tangible and intangible components, i.e. the physical material as well as the actual or potential value it contains in the form of information.<sup>302</sup> Some of the submissions elaborated further as follows:

(a) The term “material” should not be confused with “matter” as the former can include the information associated with a genetic resource. Dictionary definitions of these words make this contrast clear:

(i) “Material” can be defined as “information or ideas for use in creating a book or other work”;

(ii) “Matter” is a “physical substance in general, as distinct from mind and spirit; (In physics) that occupies space and possesses rest mass, especially as distinct from energy”;<sup>303</sup>

(b) The phrase “or other origin” included in the definition of “genetic material” includes digital information obtained from the sequencing of such material meaning that “functional units of heredity” can be contained in non-biological material;<sup>304</sup>

(i) The essence of a “functional unit” is its ability to convey the information necessary to encode the hereditary trait and there is no known way of transmitting information except through material means.<sup>305</sup>

105. Some organizations<sup>306</sup> suggested that there should be a clarification under the Convention that sequence data be considered the equivalent of biological material. Reasons for this included:

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<sup>301</sup> It should be noted that the terms defined in Article 2 of the Convention also apply to the Protocol, see Article 2 of the Protocol.

<sup>302</sup> India, Mexico.

<sup>303</sup> Brazil, quoting the Oxford English Dictionary.

<sup>304</sup> Africa; Mexico.

<sup>305</sup> Africa.

<sup>306</sup> African Centre for Biodiversity; Heinrich Böll Foundation; Institute for Agriculture and Trade Policy; Third World Network.

(a) For users of digital sequence information to, in general, be subject to the same benefit-sharing obligations as users of the biological materials that are the source of the information;<sup>307</sup>

(b) Because sequence data are derived directly or indirectly from physical material;<sup>308</sup>

(c) Because without such a clarification, technological developments in sequencing and synthetic biology will undermine the Convention, and its third objective in particular, and facilitate biopiracy (see also section II, subsection A).<sup>309</sup>

106. One organization<sup>310</sup> expressed the view that there must also be agreement to take measures at the national level to ensure that ABS measures apply to sequence data while another organization<sup>311</sup> suggested that there should be guidance on how to implement the Protocol in a manner that treats digital sequence information as equivalent to physical material.

107. In contrast, a number of submissions<sup>312</sup> stated that the definitions of “genetic material” and “genetic resources” refer to tangible or physical material while digital sequence information is intangible or abstract and so not covered by these definitions.

108. Additional submissions provided more detail or explanation of why they considered digital sequence information not to be part of the definitions of “genetic resources” and “genetic material”:

(a) Information does not contain “functional units of heredity” or genes as required by definition of genetic material.<sup>313</sup>

(b) Access to information is not equivalent to access to genetic resources within the meaning of the CBD and the Nagoya Protocol;<sup>314</sup>

(c) Genetic resources contain functional units of heredity but functional units of heredity are not themselves genetic resources and even less so, the sequences within these functional units. Genetic sequence data do not and cannot contain functional units of heredity like DNA. Furthermore, provisions in the CBD regarding conserving genetic resources do not apply to strands of DNA;<sup>315</sup>

(d) There is a distinction between genetic materials and the information describing them<sup>316</sup> or analytically inferred from them.<sup>317</sup> It is essential that this distinction be maintained;<sup>318</sup>

(e) “Genetic resources” refers to tangible genetic material that must physically contain genes. Accordingly, intangible digital sequence information cannot constitute a genetic resource.<sup>319</sup>

109. An organization<sup>320</sup> expressed the view that “genetic resources” should not have been classified as “material” in the use of terms set out in Article 2 of the Convention. They stated that “digital sequence information on genetic resources” preserves this mistake and allows natural information to be transmitted by media that are not genetic material, thereby lawfully avoiding ABS.

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<sup>307</sup> Third World Network.

<sup>308</sup> Institute for Agriculture and Trade Policy.

<sup>309</sup> Heinrich Böll Foundation.

<sup>310</sup> African Centre for Biodiversity.

<sup>311</sup> Institute for Agriculture and Trade Policy.

<sup>312</sup> Switzerland; Enzyme Technical Association; European Seed Association; German Life Sciences Association; IFRA and IOFI; Japan Bioindustry Association; Japan Pharmaceutical Manufacturers Association.

<sup>313</sup> Australia.

<sup>314</sup> European Union and Member States; CGRFA – Germany.

<sup>315</sup> CGRFA – Canada.

<sup>316</sup> United States.

<sup>317</sup> GGBN; Society for the Preservation of Natural History Collections.

<sup>318</sup> United States; GGBN.

<sup>319</sup> ICC.

<sup>320</sup> Peruvian Society of Environmental Law.

## B. Digital sequence information, utilization and derivatives

110. Some Parties<sup>321</sup> expressed the view that the generation of digital sequence information through sequencing activities constitutes “utilization of genetic resources” as defined in the Nagoya Protocol. Accordingly, relevant ABS obligations of the Nagoya Protocol should<sup>322</sup> or may<sup>323</sup> apply. Some submissions elaborated on this perspective:

(a) The non-exhaustive list of different uses of genetic resources developed by the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches during the negotiation of the Protocol formed the basis of the definition of “utilization of genetic resources” and the list expressly referred to the synthesis of DNA segments;<sup>324</sup>

(b) This matter is already considered settled in the national ABS measures of one country whereby research utilizing genetic information obtained *in silico* can be freely carried out but registration is required at the time of the publication of results, application for a patent or before introduction of a product on the market;<sup>325</sup>

(c) The Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol should take a decision to agree on a further specification of the term “utilization” as part of the understanding that sequence data is equivalent to physical material.<sup>326</sup>

111. A region<sup>327</sup> expressed the view that utilization of natural information is within the scope of the Convention and the Protocol and that the outcome of the discussions on this issue should be to clarify that utilization of naturally occurring information is equivalent to utilization of genetic resources. At the same time, however, they recognized that trying to control access to natural information is likely to be difficult and to produce sub-optimal outcomes. They advocated finding creative ways to guarantee benefit-sharing in order for open access and sharing of natural information to flourish with its associated positive outcomes. This was linked to their suggestion that the global multilateral benefit-sharing mechanism foreseen in Article 10 of the Protocol might help in finding a solution (see also section II, subsection I).

112. One organization<sup>328</sup> was of the view that digital sequence information is an expression of a genetic resource and therefore should, in principle, be subject to ABS requirements. They identified a number of considerations for including digital sequence information in the scope of the Protocol, namely that basic research leading to descriptive knowledge should not be considered utilization but subsequent use of published digital sequence information for the development of a product or tool should be part of utilization and would trigger the need for an ABS agreement between the user and provider. They also stated that the publication of digital sequence information in the form of a description of a genetic resource in a publicly available database should be sufficient to satisfy benefit-sharing requirements.

113. On the other hand, a number of organizations<sup>329</sup> argued that basic research leading to descriptive knowledge should not be regarded as utilization and so should not lead to obligations under the Nagoya Protocol nor should digital sequence information be considered a derivative of a genetic resource. Elaborations on this view included:

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<sup>321</sup> Brazil, India, Mexico, Switzerland.

<sup>322</sup> Brazil, India, Mexico.

<sup>323</sup> Switzerland.

<sup>324</sup> India, referring to document UNEP/CBD/WG-ABS/7/2: <https://www.cbd.int/doc/meetings/abs/absgte-01/official/absgte-01-abswg-07-02-en.pdf>

<sup>325</sup> Brazil.

<sup>326</sup> Institute for Agriculture and Trade Policy.

<sup>327</sup> Africa.

<sup>328</sup> Society for Applied Microbiology.

<sup>329</sup> IFRA and IOFI; Personal Care Products Council.

(a) That digital sequence information can be accessed and utilized without accessing or utilizing the genetic resource “much in the same way that a synthetic compound based on structural information from a scientific journal does not require access to a genetic resource or its derivative”,<sup>330</sup>

(b) Simple comparisons of sequence data for non-commercial use cannot be considered “utilization”,<sup>331</sup>

(c) Expanding the definition of “utilization of genetic resources” to include digital sequence information would create legal uncertainty, which would be contrary to the aims behind the negotiation of the Protocol to create legal certainty for access to genetic resources and to provide for compliance mechanisms based on this certainty;<sup>332</sup>

(d) While natural biodiversity may provide inspiration in research and development that uses digital sequence information, value is created by computational and experimental means that relies on human intervention.<sup>333</sup> A number of examples were provided in this regard:

(i) The development of a consensus protein (see example 23 in addendum);<sup>334</sup>

(ii) Designing organisms and novel sequences to produce an ingredient or novel molecule;<sup>335</sup>

(iii) In these cases, no individual sequence contributes more than another – all sequences are equal and together serve as inspiration for a final, human-designed sequence.<sup>336</sup>

### **C. Consideration of digital sequence information in the negotiations of the Protocol**

114. A number of submissions were of the view that this issue had been addressed during the negotiations that led to the adoption of the Nagoya Protocol and the conclusion or understanding from the negotiations was that digital sequence information is not in the scope of the Protocol.<sup>337</sup>

115. One organization<sup>338</sup> referred to discussions by a technical expert group during the negotiations of the Protocol which acknowledged that cells and other “parts of organisms” might contain DNA or RNA – the functional units of heredity, and that any renegotiation of the terms would be impractical. In this light, the organization was of the view that digital sequence information does not and cannot contain such functional units of heredity.

### **D. Potential impacts from including digital sequence information in the scope of the Convention and the Protocol**

116. Many submissions<sup>339</sup> were of the view that digital sequence information should not be part of the scope of the Convention and the Nagoya Protocol. Some expanded upon this view and stated that digital sequence information should not be in the scope of the Protocol included because it would:

(a) Harm research supporting conservation and sustainable use of biodiversity and the objectives of the Convention and the Protocol;<sup>340</sup>

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<sup>330</sup> Personal Care Products Council.

<sup>331</sup> GGBN.

<sup>332</sup> ICC.

<sup>333</sup> ICC; group of genomics experts; Personal Care Products Council.

<sup>334</sup> ICC.

<sup>335</sup> Group of genomics experts; Personal Care Products Council. It was explained that designing novel sequences is used both to produce novel products, such as ingredients for industry (e.g. novel fragrances) and also to produce libraries of novel drug candidates for functional screens (group of genomics experts).

<sup>336</sup> Group of genomics experts.

<sup>337</sup> Australia; German Life Sciences Association; ICC; IFPMA; Japan Pharmaceutical Manufacturers Association.

<sup>338</sup> Intellectual Property Owners Association referring to document UNEP/CBD/WG-ABS/7/2:  
<https://www.cbd.int/doc/meetings/abs/absgte-01/official/absgte-01-abswg-07-02-en.pdf>

<sup>339</sup> BIO-University of Guelph; GGBN; Royal Society of Biology; Wellcome Trust and Wellcome Sanger Institute.

- (i) Digital sequence information is being used increasingly in efforts to advance the conservation and sustainable use of biodiversity and easy and rapid access to and use of the information is essential in this regard. Keeping digital sequence information outside the scope will maximize advancement of the objectives of the Convention<sup>341</sup>, whereas creating new rules would erect barriers that would impede research, hinder conservation and sustainable use and run counter to requirements in the Convention to take into account the needs of developing countries;<sup>342</sup>
  - (ii) The consequences could be particularly detrimental to “provider countries” with high levels of biodiversity because the legal uncertainty and barriers to access to and use of digital sequence information would deter research projects being undertaken in those countries and would reduce the amount of information available on their biodiversity;<sup>343</sup>
  - (iii) Restricting access to digital sequence information would be contrary to decisions of the Conference of the Parties to the Convention which have repeatedly called for greater access to information of many types, including genetic information;<sup>344</sup>
  - (iv) Including digital sequence information in the scope of the Protocol would create enormous implementation challenges for both developed and developing countries that could make the system unworkable. This would hamper research and development and sustainable use, contrary to the objectives of the Convention and the Protocol;<sup>345</sup>
- (b) Harm research leading to new developments that would contribute to conservation and sustainable use;
- (i) Restrictions on the use of digital sequence information would be particularly harmful for research and development related to genetic resources for food and agriculture and plant and animal breeding efforts in support of sustainable, environmentally friendly food production;<sup>346</sup>
  - (ii) Research on orphan crops and less productive and profitable market segments and agro-ecologies would suffer from the complexities and uncertainties created if ABS were extended to digital sequence information;<sup>347</sup>
  - (iii) There would be even less innovation addressing the needs of resource-poor farmers;<sup>348</sup>

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<sup>340</sup> Canada; CGRFA – Canada; Biotechnology and Biological Sciences Research Council; CETAF; European Seed Association; German Life Sciences Association; German Research Foundation; ICC; NHMUK, RBG Kew, RBG Edinburgh; Society for the Preservation of Natural History Collections.

<sup>341</sup> European Seed Association.

<sup>342</sup> United States; European Seed Association; German Life Sciences Association; GGBN; Intellectual Property Owners Association; ICC.

<sup>343</sup> BIO-University of Guelph; Biotechnology and Biological Sciences Research Council; CETAF; German Research Foundation.

<sup>344</sup> CETAF.

<sup>345</sup> CGRFA – Germany; Enzyme Technical Association; Japan Pharmaceutical Manufacturers Association; Personal Care Products Council; Royal Society of Biology.

<sup>346</sup> CGRFA – ABS Task Force.

<sup>347</sup> European Seed Association; Royal Society of Biology.

<sup>348</sup> European Seed Association. One example was the development of submergence-tolerant rice as an innovation for resource-poor farmers, which had been enabled by systematic characterization of genetic resources and use of digital sequence information but may not have been realized had ABS applied to the information (European Seed Association). Another example related how research on an under-researched crop (important to several national economies) had been hindered because of commercial and political concerns around sharing of the digital sequence information that had already been generated (Royal Society of Biology).

- (iv) Potential for tools using digital sequence information to accelerate the breeding process and reduce the resources required to be restricted if the information were subject to ABS requirements;<sup>349</sup>
  - This would slow down the availability of new varieties adapted to new challenges such as emerging diseases;
  - There could be a need to screen many more genetic resources to identify suitable breeding candidates and this screening would need to be performed through field trials (rather than molecular methods), which would require more time and space;
- (v) Applying ABS obligations to digital sequence information would hinder achievement of the Sustainable Development Goals;<sup>350</sup>
- (c) Harm research and development leading to progress in other areas such as the life sciences and biotechnology;
  - (i) Open access and the advances it enables would be undermined if digital sequence information were included in the scope of the Convention and the Protocol as it would either significantly restrict the data available in publicly available databanks or introduce excessive obligations that would deter users;<sup>351</sup>
  - (ii) Economic compensation for the application of digital sequence information in the public domain is not the intended objective of the Convention and the Protocol but rather hinders application of this information towards scientific and technological development;<sup>352</sup>
  - (iii) Without the sharing of digital sequence information, research on biodiversity would be paralyzed, especially on microbial life, and thus have a ripple effect up to industry;<sup>353</sup>
- (d) Harm benefit-sharing;<sup>354</sup>
  - (i) Including: non-monetary benefits resulting from international cooperation in such areas as taxonomy, conservation genomics, human health and climate change adaptation; student exchange programmes involving publication of research findings including digital sequence information; and access to information in order to answer questions related to identification, protection of biodiversity or sustainable use;<sup>355</sup>
  - (ii) Publication of sequence data is now a prerequisite for scientific publication so if countries restrict publication of this data, scientists will stop researching the biodiversity of these countries, which would result in a loss of non-monetary benefits for these countries;<sup>356</sup> (See also section II, subsection B.)

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<sup>349</sup> European Seed Association.

<sup>350</sup> European Seed Association.

<sup>351</sup> Japan Bioindustry Association; IFPMA; Royal Society of Biology; IFRA and IOFI.

<sup>352</sup> Japan Pharmaceutical Manufacturers Association.

<sup>353</sup> Canada.

<sup>354</sup> Biotechnology and Biological Sciences Research Council; CETAF; CGRFA – ABS Task Force; GGBN; NHMUK, RBG Kew, RBG Edinburgh; German Life Sciences Association.

<sup>355</sup> CGRFA – ABS Task Force; GGBN.

<sup>356</sup> CETAF; NHMUK, RBG Kew, RBG Edinburgh.



- (iii) Non-monetary benefits could be harmed in the process of trying to obtain monetary benefits<sup>357</sup> and monetary benefits may be relatively small but the costs for the international research community could be very large;<sup>358</sup>
- (e) Create legal uncertainty;<sup>359</sup>
  - (i) Legal uncertainty would impede scientific research for conservation and sustainable use of biodiversity<sup>360</sup> and for innovation<sup>361</sup>, which would result in a substantial loss of socio-economic benefits for society as a whole;
  - (f) Create additional bureaucratic hurdles and excessive burdens to research and development which would delay scientific progress and innovation<sup>362</sup> and have negative impacts on conservation, sustainable use and benefit-sharing.<sup>363</sup>

117. A number of other reasons were also provided as to why digital sequence information should not be in the scope of the Convention or the Protocol:

- (a) Genetic sequence data are not genetic resources so they should not be treated as if they were;<sup>364</sup>
- (b) It is not appropriate to try to force sequence data into the scope of the Protocol when it was not designed for this purpose;<sup>365</sup>
- (c) Putting new requirements on the use of digital sequence information that is publicly available would constitute retroactivity;<sup>366</sup>
- (d) It would be contrary to the special considerations identified in Article 8 of the Protocol;<sup>367</sup>
- (e) It avoids the risk of conserving the wrong materials.<sup>368</sup>

118. Additional perspectives on why digital sequence information should not be included in the scope of the Protocol are also presented in the preceding sections (see in particular section II, subsection C). Perspectives on why digital sequence information should be in the scope of the Convention and the Protocol are largely addressed in section II, subsection A.

#### **E. Other views on scope**

119. A number of other organizations, while not supporting the inclusion of digital sequence information in the scope of the Convention and the Protocol, identified some considerations that should be taken into account if it was nonetheless determined that digital sequence information is in the scope, including that:

- (a) There should be an exemption for academic utilization;<sup>369</sup>

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<sup>357</sup> ICC; German Life Sciences Association.

<sup>358</sup> German Life Sciences Association.

<sup>359</sup> Enzyme Technical Association; ICC; BioIndustry Association; Japan Pharmaceutical Manufacturers Association; Royal Society of Biology.

<sup>360</sup> ICC; German Life Sciences Association; German Research Foundation.

<sup>361</sup> ICC.

<sup>362</sup> Personal Care Products Council.

<sup>363</sup> European Seed Association; ICC; Royal Society of Biology.

<sup>364</sup> CGRFA – Canada.

<sup>365</sup> IFPMA.

<sup>366</sup> Intellectual Property Owners Association; ICC.

<sup>367</sup> German Life Sciences Association.

<sup>368</sup> European Seed Association.

<sup>369</sup> Biotechnology and Biological Sciences Research Council.

(b) Countries should consider the benefits of open access to data when designing access measures;<sup>370</sup>

(c) The approach should ensure harmonization of national systems of implementation in order not to disrupt business activities;<sup>371</sup>

(d) This should not be applied retroactively;<sup>372</sup> rather a future date should be agreed that allows sufficient time to consider all the practical aspects of enforcement and compliance for digital sequence information.<sup>373</sup>

120. One organization indicated that any approach to include digital sequence information in the scope of the Protocol must begin with agreement on accurate and reliable terminology, which they felt would be very challenging to achieve.<sup>374</sup> Another organization<sup>375</sup> suggested that careful consideration is needed for digital sequence information to be included in the scope of the Protocol and clear guidance would be required on when the Protocol would apply.

121. For those who do not think that digital sequence information is already part of the Protocol, some suggested<sup>376</sup> that the focus at this point in time should be put in place the frameworks, infrastructure and practices necessary to implement the Protocol and reach its goals rather than expanding the scope of the Protocol. Views expressed included the following:

(a) Concerns about lack of benefit-sharing from utilization of genetic resources would be resolved once the required measures are in place;<sup>377</sup>

(b) Any decision to expand the scope of the Protocol must be based on clear evidence that the current system is failing to achieve its objectives and that incorporation of digital sequence information would help to resolve this and there is no such evidence to date;<sup>378</sup>

(c) Changing the terms and concepts of the Protocol would cause significant legal uncertainty for both Governments and users who have already invested significant efforts on implementation of the Protocol;<sup>379</sup>

(d) A stock-taking is needed of the impacts of the Protocol on access, benefit-sharing and biodiversity research before there should be any consideration of changing its scope;<sup>380</sup>

(e) Countries granting access to genetic resources have been successfully countering alleged biopiracy around the world thus demonstrating that the CBD is functioning in principle. The risks and costs may not justify extending the CBD to cover digital sequence information.<sup>381</sup>

122. For others, the issue of scope was unclear. Points expressed included that:

(a) The implications of digital sequence information for the Convention and the Protocol are difficult to assess because there is no common understanding of what constitutes “digital sequence information”;<sup>382</sup>

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<sup>370</sup> Ibid.

<sup>371</sup> IFRA and IOFI.

<sup>372</sup> IFPMA.

<sup>373</sup> Biotechnology and Biological Sciences Research Council.

<sup>374</sup> German Life Sciences Association.

<sup>375</sup> Society for Applied Microbiology.

<sup>376</sup> ICC.

<sup>377</sup> BioIndustry Association; IFPMA.

<sup>378</sup> BioIndustry Association; IFPMA.

<sup>379</sup> ICC.

<sup>380</sup> ICC; BIO-University of Guelph.

<sup>381</sup> CETAF.

<sup>382</sup> Switzerland.

(b) It will be important to consult with researchers about the types of data or uses of the data in considering whether digital sequence information should be included in the scope;<sup>383</sup>

(c) The implications of digital sequence information were still unknown for some as the process of implementation of the Protocol has just begun.<sup>384</sup>

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<sup>383</sup> BioIndustry Association.

<sup>384</sup> CGRFA – Ecuador.

*Annex*

**LIST OF SUBMISSIONS**

As described above, by notification 2017-37 of 25 April 2017, the Executive Secretary invited the submission of views and relevant information pursuant to decision XIII/16, paragraph 2 and decision NP-2/14, paragraph 2.

The submissions received by the Secretariat in response are listed below. The full text of all submissions has been made available online.<sup>385</sup>

<b>CBD Parties</b>	<b>CBD non-Parties</b>
Argentina	United States of America
Australia	
Belarus	
Brazil	
Canada	
Ecuador	
Ethiopia	
Ethiopia on behalf of the African Group	
European Union and its Member States	
India	
Japan	
Mexico	
Switzerland	
Venezuela	
<b>Organizations</b>	
African Centre for Biodiversity	International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
Biodiversity Institute of Ontario, University of Guelph (BIO-University of Guelph)	International Fragrance Association and the International Organization of the Flavor Industry (IFRA and IOFI)
BioIndustry Association	International Treaty on Plant Genetic Resources for Food and Agriculture
Biotechnology and Biological Sciences Research Council	Japan Bioindustry Association

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<sup>385</sup> <https://www.cbd.int/abs/dsi-gr/ahteg.shtml#submissions>.

<b>CBD Parties</b>	<b>CBD non-Parties</b>
Centre for Agriculture and Biosciences International (CABI)	Japan Pharmaceutical Manufacturers Association
Commission on Genetic Resources for Food and Agriculture ( <i>see below for more information on the submissions from the Commission</i> )	LGC Group
Consultative Group on International Agriculture Research (CGIAR)	Natural History Museum, Royal Botanic Gardens Kew and Royal Botanic Garden Edinburgh (NHMUK, RBG Kew, RBG Edinburgh)
ABS Core Group, Consortium of European Taxonomic Facilities (CETAF)	Personal Care Products Council
Enzyme Technical Association	Peruvian Society of Environmental Law
German Research Foundation	Royal Society of Biology
European Seed Association	Society for Applied Microbiology
German Life Sciences Association	Society for the Preservation of Natural History Collections
Global Genome Biodiversity Network (GGBN)	submission from a group of genomics experts
Global Initiative on Sharing All Influenza Data (GISAID)	Sustainability Council of New Zealand
Heinrich Böll Foundation	United Nations Office of Legal Affairs, Division for Ocean Affairs and the Law of the Sea
Intellectual Property Owners Association	Third World Network
Institute for Agriculture and Trade Policy	University of Edinburgh
International Chamber of Commerce (ICC)	Wellcome Trust and Wellcome Sanger Institute

*Additional information on the submissions received from the Secretary of the Commission on Genetic Resources for Food and Agriculture*

At its sixteenth session, the Commission on Genetic Resources for Food and Agriculture established a new work stream on digital sequence information on genetic resources for food and agriculture (GRFA) (for more detail, see document CBD/DSI/AHTEG/2018/1/3). As part of this, the Commission requested its Secretary to invite members of the Commission to submit information on the use of digital sequence information on GRFA and potential implications for the conservation and sustainable use of GRFA, including exchange and ABS, and to submit this information to the Executive Secretary of the Convention on Biological Diversity as a contribution to the process established in decision XIII/16.

In this regard, the Secretary of the Commission transmitted five documents to the Executive Secretary of the CBD. In some cases, these documents included submissions from more than one Government and/or organization. For ease of reference, the table below:

- (a) Presents the list of the Governments and organizations that made submissions via the Commission;

- (b) Indicates in which of the documents sent by the Commission the submission may be found, as reflected on the CBD web page with the list of all submissions;
- (c) Provides the short form by which the submission is referred to in the synthesis above.

<b>Government/organization</b>	<b>Link to document received from Secretary of the Commission</b>	<b>Short form used in synthesis</b>
Brazil	<a href="#">Commission on Genetic Resources for Food and Agriculture (Part 1)</a>	CGRFA – Brazil
Canada	<a href="#">Commission on Genetic Resources for Food and Agriculture (Part 2)</a>	CGRFA – Canada
Ecuador	<a href="#">Commission on Genetic Resources for Food and Agriculture (Part 4)</a>	CGRFA – Ecuador
Germany	<a href="#">Commission on Genetic Resources for Food and Agriculture (Part 1)</a>	CGRFA – Germany
India	<a href="#">Commission on Genetic Resources for Food and Agriculture (Part 5)</a>	CGRFA – India
United States of America	<a href="#">Commission on Genetic Resources for Food and Agriculture (Part 1)</a>	CGRFA – United States of America
ABS Task Force of the European Regional Focal Point on Animal Genetic Resources	<a href="#">Commission on Genetic Resources for Food and Agriculture (Part 3)</a>	CGRFA – ABS Task Force
African Centre for Biodiversity	<a href="#">Commission on Genetic Resources for Food and Agriculture (Part 1)</a>	Not referred to in the synthesis as the text corresponded to submission sent directly to the CBD Secretariat
CABI	<a href="#">Commission on Genetic Resources for Food and Agriculture (Part 1)</a>	Not referred to in the synthesis as the text corresponded to submission sent directly to the CBD Secretariat
Institute for Agriculture and Trade Policy	<a href="#">Commission on Genetic Resources for Food and Agriculture (Part 1)</a>	Not referred to in the synthesis as the text corresponded to submission sent directly to the CBD Secretariat

<b>Government/organization</b>	<b>Link to document received from Secretary of the Commission</b>	<b>Short form used in synthesis</b>
Third World Network	<a href="#">Commission on Genetic Resources for Food and Agriculture (Part 1)</a>	Not referred to in the synthesis as the text corresponded to submission sent directly to the CBD Secretariat
Associate Professor Jens Sundström, Faculty Professor Pär Ingvarsson, Department of Plant Biology, Swedish University of Agricultural Sciences	<a href="#">Commission on Genetic Resources for Food and Agriculture (Part 1)</a>	CGRFA – Prof. Sundström

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