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# COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

## Item 5 of the Provisional Agenda

### Eighteenth Regular Session

27 September – 1 October 2021

## DIGITAL SEQUENCE INFORMATION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE: INNOVATION OPPORTUNITIES, CHALLENGES AND IMPLICATIONS

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## I. INTRODUCTION

1. The Commission on Genetic Resources for Food and Agriculture (Commission), at its Seventeenth Regular Session in 2019, took note of the *Exploratory fact-finding scoping study on “Digital Sequence Information” on genetic resources for food and agriculture* (Background Study Paper No. 68).<sup>1</sup> The study examined how “digital sequence information” (DSI) on genetic resources for food and agriculture (GRFA) is currently being used, how it might be used in the future and what the implications of its use might be for the food and agriculture sector.
2. The Commission agreed that there is a need for further review of DSI on GRFA. It agreed to address, at its next session:
  - i. the innovation opportunities DSI on GRFA offers;
  - ii. the challenges of capacity to access and make use of DSI; and
  - iii. the implications of DSI for the conservation and sustainable use of GRFA and the sharing of benefits derived from GRFA.
3. The Commission requested its intergovernmental technical working groups on animal, aquatic, forest and plant genetic resources (Working Groups) “to consider these matters with regard to existing subsector-specific examples related to conservation, sustainable use and development of genetic resources, food security and nutrition, food safety, and efforts to combat crop and animal pests and diseases”.<sup>2</sup> The Commission further noted the importance of coordination with the ongoing processes under the Convention on Biological Diversity (CBD) and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol) and the International Treaty on Plant Genetic Resources for Food and Agriculture (Treaty).
4. This document aims to contribute to the discussion on DSI by reflecting on different options to define DSI (Section II). It considers the innovation potential DSI offers by providing, by way of example, a selection of actual and potential applications of DSI related to the conservation, sustainable use and development of GRFA, which incorporates inputs and comments received from Working Groups and Commission Members (Section III) and addresses some of the factors that determine whether this potential may fully be realized (Section IV). The implications of DSI for (research and development related to) the conservation and sustainable use of GRFA and, in particular, for the sharing of benefits derived from the utilization of GRFA will depend, among other things, on the legal conditions for access and benefit-sharing (ABS) for DSI (Section V). In the light of recent developments in other fora (Section VI), the Commission may wish to identify priorities for its future work, taking into account the recommendations of its Working Groups (Section VII).

## II. TOWARDS A DEFINITION OF “DIGITAL SEQUENCE INFORMATION”

5. There is no universally agreed definition for DSI. This is reflected in relevant decisions taken under the CBD and its Nagoya Protocol and the decision taken by the Commission in 2017 to establish a new workstream on DSI. As the Commission recognized at that time, “[...] there are a multiplicity of terms that have been used in this area (including, *inter alia*, “genetic sequence data”, “genetic sequence information”, “genetic information”, “dematerialized genetic resources”, “*in silico* utilization”, etc.) and [...] further consideration is needed regarding the appropriate term or terms to be used”.<sup>3</sup>
6. The World Health Organization’s (WHO) Pandemic Influenza Preparedness (PIP) Framework does not include a definition of DSI. However, it defines “genetic sequences” as: “the order of nucleotides found in a molecule of DNA or RNA. They contain the genetic information that

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<sup>1</sup> Heinemann, J.A., Coray, D.S. & Thaler, D.S. 2018. *Exploratory fact-finding scoping study on “Digital Sequence Information” on genetic resources for food and agriculture*. Background Study Paper No. 68. Commission on Genetic Resources for Food and Agriculture. Rome, FAO. (also available at <http://www.fao.org/3/CA2359EN/ca2359en.pdf>).

<sup>2</sup> CGRFA-17/19/Report, paragraph 23.

<sup>3</sup> CGRFA-16/17/Report Rev.1, paragraph 87.

determines the biological characteristics of an organism or a virus”. In addition, the PIP Framework makes reference to “genetic sequence data”,<sup>4</sup> a term that, however, it does not further define. The revised draft text of an agreement under the United Nations Convention on the Law of the Sea on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction, issued on 18 November 2019, uses the terms “*in silico*”, “Digital Sequence Information” and “genetic sequence data” without, however, offering a definition.<sup>5</sup> The Governing Body of the Treaty has not yet decided on the official terminology for DSI/genetic sequence data and therefore decided at its last Session to use “DSI/GSD” until a new terminology has been agreed.<sup>6</sup>

7. A challenge these processes face in defining DSI or similar terms used is to decide on the scope or content of the term. While the term may be understood to embrace DNA and RNA sequences only, it could also cover amino acid sequences of proteins and/or information generated by cognitive processes applied to them or even information on the genetic resource, such as traditional knowledge or phenotypic data.<sup>7</sup>

### **Biological databases covered by *Nucleic Acid Research***

8. Background Study Paper No. 68 found that the scientific community notably does not use the term DSI and stressed that science is constantly evolving, making precise definitions potentially arbitrary or prescriptive. The authors, therefore, proposed an illustrative definition of DSI: any kind of information that could be held by any existing or future database of the type collated by the scientific journal *Nucleic Acid Research* (NAR).<sup>8</sup> NAR publishes the results of research into physical, chemical, biochemical and biological aspects of nucleic acids and proteins involved in nucleic acid metabolism and/or interactions. The first issue of each year is devoted to biological databases.<sup>9</sup>

### **The degree of biological processing and the proximity to the underlying genetic resource as a basis to distinguish groups of “digital sequence information”**

9. The Conference of the Parties (COP) to the CBD, at its Fourteenth Regular Session, noted that the term “digital sequence information” may not be the most appropriate and therefore used it as a “placeholder”. It also established a “science and policy-based process on digital sequence information on genetic resources” to, *inter alia*, “clarify the concept, including relevant terminology and scope, of digital sequence information [...]”<sup>10</sup> As part of this process, it initiated broad consultations<sup>11</sup> as well as three studies, one of which focused on the concept and scope of DSI on genetic resources and how DSI on genetic resources is currently used.<sup>12</sup> The COP also established an extended Ad Hoc Technical Expert Group (AHTEG) to, *inter alia*, develop options for operational terms and their implications to provide conceptual clarity on DSI on genetic resources.

10. Building on the study *Digital Sequence Information on Genetic Resources: Concept, Scope and Current Use*, the AHTEG considered that the degree of biological processing and the proximity to the underlying genetic resource provide a rationale to group information that may comprise DSI. The three groups considered by the AHTEG as DSI, as shown in Table 1, are cumulative (Group 2 includes all elements of Group 1, and Group 3 contains all elements of Groups 1 and 2).<sup>13</sup> Associated information, i.e. other than genetic and biochemical information, such as traditional knowledge associated with genetic resources, behavioural data and information on ecological relationships was not considered DSI. However, it is important to note that, in line with the Nagoya Protocol, ABS

<sup>4</sup> PIP Framework, see section 5.2.

<sup>5</sup> A/CONF.232/2020/3.

<sup>6</sup> IT/GB-8/19/Report, Resolution 9/2019.

<sup>7</sup> Houssen, W., Sara, R. & Jaspars, M. 2020. *Digital Sequence Information on Genetic Resources: Concept, Scope and Current Use*. CBD/DSI/AHTEG/2020/1/3. p. 31. CBD. (also available at <https://www.cbd.int/doc/c/fe9/2f90/70f037ccc5da885dfb293e88/dsi-ahteg-2020-01-03-en.pdf>).

<sup>8</sup> See See Heinemann, J.A., Coray, D.S. & Thaler, D.S. 2018. op. cit..

<sup>9</sup> <https://academic.oup.com/nar>

<sup>10</sup> Decision 14/20.

<sup>11</sup> For a synthesis of views, see CBD/DSI/AHTEG/2020/1/2.

<sup>12</sup> Houssen, W., Sara, R. & Jaspars, M. 2020. op. cit.

<sup>13</sup> CBD/DSI/AHTEG/2020/1/7, Annex I, paragraph 9.

measures in many countries provide for ABS for traditional knowledge associated with genetic resources.

11. The AHTEG also identified multiple options for terminology to describe DSI on genetic resources but did not come to definite conclusions on this matter.<sup>14</sup>

**Table 1. Clarifying the scope of “digital sequence information” on genetic resources<sup>15</sup>**

	Information related to a genetic resource			Associated information
	Genetic and biochemical information			
Group reference	<i>Group 1</i>	<i>Group 2</i>	<i>Group 3</i>	
High-level description of each group	DNA and RNA	Group 1 + proteins + epigenetic modifications	Group 2 + metabolites and other macromolecules	
Examples of granular subject matter	<ul style="list-style-type: none"> <li>• Nucleic acid sequence reads;</li> <li>• Associated data to nucleic acid reads;</li> <li>• Non-coding nucleic acid sequences;</li> <li>• Genetic mapping (for example, genotyping, microsatellite analysis, single nucleotide polymorphisms, etc.);</li> <li>• Structural annotation.</li> </ul>	<ul style="list-style-type: none"> <li>• Amino acid sequences;</li> <li>• Information on gene expression;</li> <li>• Functional annotation;</li> <li>• Epigenetic modifications (for example, methylation patterns and acetylation);</li> <li>• Molecular structures of proteins;</li> <li>• Molecular interaction networks.</li> </ul>	<ul style="list-style-type: none"> <li>• Information on the biochemical composition of a genetic resource;</li> <li>• Macromolecules (other than DNA, RNA and proteins);</li> <li>• Cellular metabolites (molecular structures).</li> </ul>	<ul style="list-style-type: none"> <li>• Traditional knowledge associated with genetic resources</li> <li>• Information associated with “digital sequence information” Groups 1, 2 and 3 (for example, biotic and abiotic factors in the environment or associated with the organism)</li> <li>• Other types of information associated with a genetic resource or its utilization.</li> </ul>

12. For each of the groups, the AHTEG identified different implications in terms of technical traceability of DSI to the source. Proximity of DSI to the underlying genetic resource and the biological process associated with the generation of the DSI determine if it is possible to technically identify or infer the genetic resource from which it is derived.<sup>16</sup> The AHTEG concluded that different sectors relied to different degrees on the different groups of DSI.

13. As the relevance of defining DSI and the implications of the definition of DSI ultimately depend on the context/purpose for which the definitions will be used, the Commission may wish to

<sup>14</sup> CBD/DSI/AHTEG/2020/1/7, Annex I, Table 2.

<sup>15</sup> The table is taken from CBD/DSI/AHTEG/2020/1/7, Annex I, Table 1.

<sup>16</sup> Houssen, W., Sara R. & Jaspars, M. 2020. op. cit., p. 32.

continue using DSI as a placeholder until there is more clarity on the context in which they wish to discuss DSI and the purpose for which it should be defined.

14. The term “digital sequence information on genetic resources for food and agriculture” obviously relates to DSI derived from GRFA. However, research and development on GRFA and DSI on GRFA may well involve genetic materials and DSI from non-GRFA organisms.<sup>17</sup> Whether DSI on GRFA includes DSI from non-GRFA organisms (e.g. DSI on new traits derived from non-GRFA organisms), if used in research and development on GRFA, is an open question.

### III. OPPORTUNITIES OFFERED BY “DIGITAL SEQUENCE INFORMATION” TO CONTRIBUTE TO THE CONSERVATION AND SUSTAINABLE USE OF GENETIC RESOURCES

15. DSI plays a fundamental role in environmental and biological research, contributing to the understanding of the molecular basis of life and evolution and of the ways in which genes can potentially be modified to provide new agricultural products, therapies and cures for diseases, new energy sources and other new products. It also plays important roles in taxonomy, identifying and mitigating risks to threatened species, tracking illegal trade, identifying the geographical origin of products, and conservation management.

16. DSI on GRFA contributes to food security and nutrition as a fundamental tool for characterization of GRFA, selection and breeding, creation of new products, food safety and traceability, and management of GRFA, including the development of veterinary medicinal products, such as vaccines. DSI is an essential component of technologies used for the characterization, conservation and sustainable use of GRFA.<sup>18</sup> It underpins a wide range of technologies involved in the analysis, synthesis and presentation of DNA, RNA and other molecules involved in heritability and trait expression for reproduction, growth and health. Synthetic biology is a relatively novel discipline, which is now making it possible to analyse and synthesize molecules such as DNA, RNA, proteins and even viruses *in vitro* and *de novo* using DSI.

17. DSI allows for the generation of benefits from a genetic resource based on digitized data and information and without access to the genetic resource. Background Study Paper No. 68 did not find significant actual or potential differences in the characteristics of technologies as they are applied in the different subsectors of GRFA. It found that DSI was used extensively in all subsectors of GRFA. DSI is a routine component of nearly all research in the biological sciences. Background Study Paper No. 68 concluded that DSI on GRFA is central to product development, including the improvement of GRFA, and its importance is expected to increase, especially as an increasing amount of DSI relevant to GRFA will become available. DSI can also be used to select reproductive/vegetative material for breeding, including artificial insemination, oestrus synchronization and *in vitro* fertilization, and cloning, or to monitor or test progeny. DSI is a critical element in innovating products and processes in green (agriculture), red (healthcare and medicine) and white (industrial) biotechnologies; it is expected to play an increasingly important role in blue biotechnology (fisheries/aquaculture).

18. DSI may also contribute to the sustainable use of GRFA by facilitating the discovery and design of new vaccines, pesticides, biofertilizers and probiotics. It is used to both diagnose diseases in all forms of GRFA and to design therapeutics for treatment. It may represent a critical element in the development of new products from GRFA to increase both income security and the financial sustainability of farmers.

19. DSI contributes to species conservation. Small amounts of *DNA* collected from the water, for example, may allow scientists to identify more *species* of marine vertebrates than traditional *surveys* with nets. DSI is frequently used for identification of species and for assessing genetic diversity within and among species. It is also used to select material for genebank storage and can be used to test for viability and ensure purity over time.

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<sup>17</sup> See Heinemann, J.A., Coray, D.S. & Thaler, D.S. 2018. op. cit., p.9.

<sup>18</sup> See also CGRFA/WG-PGR-10/21/6/Inf.1.

20. DSI also plays an important role in food governance systems, including product labelling, and identification of food components, which can be important for the conservation of threatened species.

21. A selection of actual and potential applications of DSI, demonstrating its significant innovation potential, is provided in Table 2, which also reflects inputs and comments received from the Working Groups<sup>19</sup> and Commission Members.

**Table 2: Selected examples of actual and potential applications of “digital sequence information” relevant to the conservation and sustainable use of genetic resources for food and agriculture**

<b>Common to all genetic resources</b>
<ul style="list-style-type: none"> <li>• DSI is used to accurately identify and understand genetic relationships between species from all over the world. For example, databases such as the Barcode of Life (<a href="https://ibol.org/">https://ibol.org/</a>) allow researchers to identify species, which allows for monitoring and conservation of biological diversity.</li> <li>• DSI is also used for disease diagnosis and prevention, for management of breeding programmes and for avoiding the further loss of genetic diversity between and within species. For example, researchers can use DSI to identify, understand and mitigate factors that threaten a wide range of populations of vulnerable species.</li> <li>• DSI is used for monitoring <i>in situ</i> conservation programmes and for the development and optimization of <i>ex situ</i> collections, sampling strategies and evaluation of collections.</li> </ul>
<b>Animal genetic resources</b>
<p><i>Characterization:</i></p> <ul style="list-style-type: none"> <li>• Use of DSI has facilitated improvements to the molecular characterization of breeds and contributed to the identification of genomic regions associated with both production traits and adaptive traits, such as heat tolerance and disease resistance, and to identify the variations responsible for numerous genetic defects.</li> </ul> <p><i>Sustainable use:</i></p> <ul style="list-style-type: none"> <li>• DSI allows the maintenance of genetic variability within populations for sustainable use of animal genetic resources. Different methods have been developed to manage inbreeding while increasing genetic gain.</li> <li>• It can be used to advance discovery and development of new livestock breeds, with enhanced outcomes for sustainable and resilient livestock systems and food security.</li> <li>• DSI can improve the rapid understanding of traits of interest for adaptation to new breeding conditions, particularly in the context of climate change, such as adaptability to high altitudes and increasing tolerance to high ambient temperatures and humidity.</li> <li>• DSI is useful for disease diagnosis and prevention.</li> <li>• Genomic selection, where genome-wide markers are used for predicting the breeding value of individual animals, is widely used in commercial breeding programmes.</li> <li>• For DSI of the rumen biome and its use in management of animal genetic resources, several significant metagenomic surveys of the rumen microbiome have been completed, creating DSI that is applied to the dual challenges of increasing feed efficiency and reducing greenhouse gas emissions.</li> </ul> <p><i>Conservation:</i></p> <ul style="list-style-type: none"> <li>• DSI contributes to the conservation of threatened species, such as endangered breeds or pollinators, contributing to improved food security and is therefore critical in preventing further loss of threatened and endangered species as well as in studying diversity.</li> </ul>

<sup>19</sup> CGRFA-18/21/8.2, paragraphs 32–35; CGRFA-18/21/9.1, paragraphs 26–30; CGRFA-18/21/10.1, paragraphs 31–39 & *Appendix C*; CGRFA-18/21/12.1, paragraphs 46–50.

- DSI allows cryoconservation to be improved by comparing the genotypes of animals with stored material to those of animals in live populations, followed by targeted collection of underrepresented diversity.
- Genomic analysis allows for the evaluation of long-term *in situ* conservation programmes. By genomic analysis, information about breed history and about genetic diversity within and between breeds or populations is available for mating plans.

### **Aquatic genetic resources**

#### *Characterization:*

- DSI is used to characterize genes and identify genetic sequences, for the study of population genetics and for stock assessment.

#### *Sustainable use:*

- In aquatic genetic resources for food and agriculture DSI is most relevant for molecular markers, for example barcodes, “omics” and biotechnologies for disease diagnosis, and pedigree assignment in breeding programmes.
- DSI contributes to reproductive technologies and detection of hybrids, and disease diagnosis and prevention.
- DSI can improve access to markets and consumer confidence in supply chains through traceability and identifying product substitution, and supporting product labelling and certification schemes.

#### *Conservation:*

- DNA barcoding based on DSI has been used to support conservation of species, including those that might be illegally traded.
- DSI is used to support restoration of degraded coral reefs through transplantation, where the appropriateness of candidate places can be judged to reintroduce healthy coral by comparing DSI (genetic compositions) of different coral populations.

### **Forest genetic resources**

#### *Characterization:*

- DSI is used for species, subspecies and hybrid identification; it assists in understanding phylogenetical information of species and population origin and profile; understanding of pleiotropic effect of gene expression and morphological diversity; accelerating knowledge on heritability, ecophysiology and biology of forest tree species.

#### *Sustainable use and management:*

- DSI is contributing to the assembly of breeding populations in newly developed and advanced breeding programmes, as well as to selecting genetic material for storage or micropropagation.
- With the help of bioinformatics tools, DSI can give insight to the genetic make-up of individuals and populations, making real-time selection possible for progeny and breeding programmes; it has powerful potential for the breeding of forest trees as well as enhancing the productivity of plantation forests and judicious control of pest infestation.
- DSI has enabled the so-called “breeding-without-breeding” approach, which allows designing tree breeding programmes with affordable costs in many countries. This approach relies on DSI in the form of complete pedigree information from a subset of offsprings.
- Technologies that rely on DSI assist to identify the species and geographic origin of wood in order to detect illegal logging and trade.

#### *Conservation:*

- Being an integral part of sustainable forest management, the conservation of forest genetic resources needs accurate information on genetic diversity among individuals and tree populations. Through barcoding and other fingerprint marker-based technologies coupled with DSI, better conservation strategies can be designed and implemented. DSI is also contributing to a more accurate delineation of species taxonomy.
- DSI can assist in maintenance of genetic diversity through the development of robust *ex situ* collections of at-risk species by identifying distinct natural populations and those with high diversity.

- DSI used in predictive genomics may help in the conservation of trees by identifying the environment suited to the genotype and by providing information for assisted migration.
- DSI can support complex biostatistics calculation of individual and population genetic diversity, targeting landscapes and areas of superior individuals important for further selection and conservation measures.
- Accumulated DSI enables comparison of large numbers of individuals and populations of the same and related species in order to identify the current distribution area and project changes to it due to climate change.

### Plant genetic resources

#### *Characterization:*

- Increasingly, various types of molecular markers – usually developed based on DSI – are used either alone or as complements to morphological traits to identify and/or analyse heritable variations in germplasm accessions.
- The continuing development and use of next generation sequencing increase significantly the throughput for the generation of DSI, which coupled with the significantly reduced costs and time for molecular assays, including whole genome sequencing, is resulting in the increasing use of genotyping by sequencing (or GBS) to analyze the variations, i.e. characterize, germplasm accessions. A widespread use of GBS will enhance significantly the efficiency of genebank operations as duplicate accessions would be identified reliably and removed from the holdings.

#### *Sustainable use:*

- Based on DSI, the sequences of DNA or even a new organism that perform novel functions are created from scratch; this increasingly growing interdisciplinary endeavor is known as synthetic biology.
- Molecular markers are used to establish the identity of crop varieties.
- Molecular markers are used for disease diagnosis in molecular epidemiology and help to trace the origin and evolution of pathogens.
- Access to DSI provides nowadays a fundamental basis for plant research and crop enhancement. DSI can be used to advance the development of new crop varieties, with enhanced outcomes for food security especially for production of drought- and pest-resistant crops, crops that require fewer inputs of water or fertilizers, and crops altered for enhanced nutritional and economic value. Use of DSI has enabled researchers to rapidly identify markers for genes associated with drought tolerance in sorghum, maize, wheat and other crops.
- DSI also underpins marker-assisted selection in genomics-assisted breeding programmes.
- Continued access to DSI promotes research and development efforts to increase the sustainable use of plant genetic diversity, as well as understanding gene flow and pest management.

#### *Conservation:*

- DSI is critical for preventing further loss of threatened and endangered species. Conservation of plant genetic resources for food and agriculture tends to include increasing amounts of molecular characterization data, such as in the DNA Barcode of Life initiative, or “local” initiatives such as the sequencing of genomes of an entire botanical garden.

*Note:* A previous version of this table has been produced based on examples taken from the literature below. The table has been revised in the light of comments and inputs received from the Commission’s Working Groups and Commission Members. CGRFA-17/19/4/Inf.1; Heinemann, J.A., Coray, D.S. & Thaler, D.S. 2018. op. cit.; Lidder, P. & Sonnino, A. 2011. *Biotechnologies for the management of genetic resources for food and agriculture*. Background Study Paper No. 52. Commission on Genetic Resources for Food and Agriculture. Rome, FAO. (also available at <http://www.fao.org/docrep/meeting/022/mb387e.pdf>); Clarke, R. 2010. *Private food safety standards: their role in food safety regulation and their impact*. Rome, FAO. (also available at <http://www.fao.org/docrep/016/ap236e/ap236e.pdf>); Sultana, S., Ali, M.E., Hossain, M.A.M., Asing, Naquiah, N. & Zaidul, I.S.M. 2018. Universal mini COI barcode for the identification of fish species in processed products. *Food Res. Internat.*, 105: 19–28; El-Kassaby, Y.A., Cappa, E.P., Liewlaksaneeyanawin, C., Klápště, J. & Lstibůrek, M. 2011. Breeding without breeding: is a complete pedigree necessary for efficient Breeding? *PLoS One*, 6: e25737; Liu, H., Wei, J., Yang, T., Mu, W., Song,

B., Yang T., Fu, Y. *et al.* 2019. Molecular digitization of a botanical garden: high-depth whole genome sequencing of 689 vascular plant species from the Ruili Botanical Garden. *Gigascience*, 8(4). 10.1093/gigascience/giz007; Halewood M., Lopez Noriega I., Ellis D., Roa C., Rouard M. & Sackville Hamilton R. 2018. Using genomic sequence information to increase conservation and sustainable use of crop diversity and benefit-sharing. *Biopreserv. Biobank*. 16: 368–376. 10.1089/bio.2018.0043; Laird, S.A. & Wynberg, R.P. 2018. *A fact-finding and scoping study on digital sequence information on genetic resources in the context of the Convention on Biological Diversity and the Nagoya Protocol*. 77 pp. (also available at <https://www.cbd.int/doc/c/e95a/4ddd/4baea2ec772be28edcd10358/dsi-ahteg-2018-01-03-en.pdf>); Spindel, J.E. & McCouch, S.R. 2016. When more is better: how data sharing would accelerate genomic selection of crop plants. *New Phytol.*, 212, 814–826. doi: 10.1111/nph.14174; Halewood, M., Chiurugwi, T., Sackville Hamilton, R., Kurtz, B., Marden, E., Welch, E., Michiels, F. *et al.* (2018). Plant genetic resources for food and agriculture: opportunities and challenges emerging from the science and information technology revolution. *New Phytol.*, 217: 1407–1419. doi: 10.1111/nph.14993.

#### IV. CAPACITY TO ACCESS AND MAKE USE OF DIGITAL SEQUENCE INFORMATION

22. The importance of having access and being able to make use of DSI can hardly be overstated. The life sciences depend on the availability of the complete DSI datasets from different sources to compare with and understand new DSI.<sup>20</sup>

23. Many factors determine the capacity to access and make use of DSI. A significant amount of DSI is currently stored in an estimated worldwide 1 700 publicly accessible databases and repositories of biological and associated information. The databases include the DNA Data Bank of Japan at the National Institute of Genetics, the European Nucleotide Archive at the European Molecular Biology Laboratory's European Bioinformatics Institute and GenBank at the National Center for Biotechnology Information, United States of America. The three databases form the International Nucleotide Sequence Database Collaboration (INSDC), which is the core infrastructure for sharing DSI connecting scientific databases and platforms. Little is known about DSI databases in the private sector.

24. Most scientific journals require that data underlying the results presented in a scientific article are made available in an open access repository before submission of the manuscript. The INSDC, which has a policy of open access, therefore serves as a unique registry of all publicly available DSI.<sup>21</sup>

25. However, public availability of DSI does not mean that DSI is accessible for everyone in the same way. Substantial technical, institutional and human capacity is required to be able to access and make full use of the innovation potential of DSI. Though at varying degrees and depending on the status of technological development, many developing countries lack access to the necessary technical infrastructure, financial and human resources to fully exploit the potential DSI offers. Circumstances that may impact access to and use of DSI include shortage of trained bioinformaticians and limited computational expertise, educational and training opportunities, and scientific collaborations but also factors such as the lack of computing infrastructures, reliable electricity and high-speed Internet. To facilitate the use of DSI for research and development in developing countries, there is therefore a need to build or develop capacity, to support technology transfer, research collaborations and partnerships, to strengthen the scientific infrastructure and to make the necessary funds available.

26. Closely linked to the challenge of technical, institutional and human capacity required to access and make use of DSI are the challenges of storage, distribution and analysis tools. Given the exponential growth of genomic data, the infrastructure for the storage and distribution of DSI may well change in the future. While the cost of this infrastructure is currently predominantly met by

<sup>20</sup> Oldham, P. 2020. *Digital Sequence Information - Technical Aspects*. (also available at [https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Final\\_Report\\_technical\\_aspects\\_of\\_DSI.pdf](https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Final_Report_technical_aspects_of_DSI.pdf)); Scholz, A.H., Hillebrand, U., Freitag, J., Cancio, I. *et al.* 2020. *Finding compromise on ABS & DSI in the CBD: Requirements & policy ideas from a scientific perspective*. WiLDSI. (available at [https://www.dsmz.de/fileadmin/user\\_upload/Collection\\_allg/Final\\_WiLDSI\\_White\\_Paper\\_Oct7\\_2020.pdf](https://www.dsmz.de/fileadmin/user_upload/Collection_allg/Final_WiLDSI_White_Paper_Oct7_2020.pdf))

<sup>21</sup> Arita, M., Karsch-Mizrachi, I. & Cochrane, G. on behalf of the International Nucleotide Sequence Database Collaboration. 2021. The international nucleotide sequence database collaboration. *Nucleic Acids Research*, 49(D1): D121–D124. <https://doi.org/10.1093/nar/gkaa967>

public funds, such funding may not always be available and sufficient and alternative funding models may be considered. Such models could restrict access to DSI. However, they could also provide sustainable funding for the life science infrastructure without restricting access to DSI, take into account equity considerations and even provide the framework for benefit-sharing arrangements, for example through subscription fees, data deposit and access or membership fees.

## V. IMPLICATIONS OF DIGITAL SEQUENCE INFORMATION FOR ACCESS AND BENEFIT-SHARING

27. Given its scientific and economic significance, it is not surprising that DSI has raised the question if existing ABS measures for genetic resources address DSI adequately or, should this not be the case, if new rules should be established for access to DSI and the sharing of benefits derived from it.

28. Most ABS measures might allow to address DSI as part of the agreement on mutually agreed terms (MAT) that are negotiated when genetic resources are made available for research and development. Whether DSI extracted from a genetic resource qualifies by itself as a “genetic resource” is subject to controversy and ultimately a question of law. Currently, treatment of DSI by domestic ABS measures varies from country to country. ABS measures of some countries, according to a recent study, seem to require prior informed consent (PIC) and MAT before DSI may be accessed. These countries basically treat access to and the sharing of benefits derived from DSI like access to genetic resources and the sharing of benefits derived from them. Other countries, though not restricting access to DSI, require that benefits derived from the utilization of DSI are shared. Another group of countries requires neither PIC, nor benefit-sharing for the use of DSI.<sup>22</sup> Thus, currently countries take different approaches to addressing DSI within their ABS measures, which ultimately could also affect the implementation and effects of ABS measures for the use and exchange of genetic resources, including GRFA.

29. Between the two antipodes, treatment of DSI as a “genetic resource” for the purpose of ABS, on the one hand, and no ABS for DSI, on the other, multiple access to and the utilization of DSI are currently under discussion. Options include, but are not limited to:

- i. an agreement on the sharing of benefits derived from DSI based on standard MAT that are either nationally or internationally agreed;
- ii. the introduction of a pay-per-use or membership fee-based system for the use of DSI;
- iii. the establishment of a micro-levy, a small fee users of DSI and/or acquirers of relevant equipment for genomic research would have to pay; or
- iv. voluntary sharing of benefits for the use of DSI.

30. Benefits could either be shared bilaterally or be pooled in and disbursed through a multilateral mechanism; they could be established dependent on or irrespective of the (extent of) use of DSI or the geographical origin of the original gene sequence. Benefit-sharing could be mandatory or voluntary, monetary and/or non-monetary.<sup>23</sup>

31. Depending on the option chosen, ABS for DSI may have different implications, including with regard to transaction costs, the need to trace the country of origin of the original genetic resource, the user-friendliness of the system and, ultimately, the characterization, conservation and sustainable use of genetic resources, including GRFA. While the options to address DSI and their implications resemble to quite some extent previous discussions on ABS for genetic resources, regulating ABS for DSI faces an additional challenge, which is to avoid a “two-tier DSI/genetic resources bureaucracy”<sup>24</sup>

<sup>22</sup> Bagley, M., Karger, E., Ruiz Muller, M., Perron-Welch, F. & Thambisetty, S. 2020. *Fact-finding Study on How Domestic Measures Address Benefit-sharing Arising from Commercial and Non-commercial Use of Digital Sequence Information on Genetic Resources and Address the Use of Digital Sequence Information on Genetic Resources for Research and Development*. CBD/DSI/AHTEG/2020/1/5. CBD. (also available at <https://www.cbd.int/doc/c/428d/017b/1b0c60b47af50c81a1a34d52/dsi-ahteg-2020-01-05-en.pdf>).

<sup>23</sup> For an overview of these and other options, see: <https://www.cbd.int/abs/DSI-webinar/Dsi-Webinar3-Policy-options.pdf>

<sup>24</sup> Scholz, A.H., Hillebrand, U., Freitag, J., Cancio, I. *et al.* 2020. *op. cit.*

that could develop if ABS for DSI is addressed through additional, rather than existing, legal, administrative or policy measures.

## VI. DEVELOPMENTS IN OTHER FORA

32. As noted by the Commission at its last Session, it is important to coordinate any work on DSI with ongoing processes in other fora.<sup>25</sup>

33. The **COP to the CBD** at its fourteenth meeting considered potential implications of the use of DSI on genetic resources for the three objectives of the CBD and adopted decision 14/20. Furthermore, the COP serving as the meeting of the Parties to the **Nagoya Protocol** at its third meeting also considered potential implications for the objective of the Nagoya Protocol and adopted decision NP-3/12. In decision 14/20, the COP, among other issues, noted that, as there was a divergence of views among Parties regarding benefit-sharing from the use of DSI, Parties committed to working towards resolving this divergence through a science- and policy-based process. The decision noted the importance of DSI for scientific research, both commercial and non-commercial, but also the disparity in capacity to access, use and benefit from the use of DSI.

34. The process put in place included the commissioning of a number of studies by the Executive Secretary,<sup>26</sup> and the convening of the extended Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources (see above, paragraphs 9–12).<sup>27</sup> At the request of the Co-Chairs of the Open-ended Working Group on the Post-2020 Global Biodiversity Framework, the Secretariat also organized a series of webinars on DSI.<sup>28</sup> The Open-ended Working Group on the Post-2020 Global Biodiversity Framework is to consider the outcomes of the extended Ad Hoc Technical Expert Group, to make recommendations to the COP on how to address DSI in the context of the Post-2020 Global Biodiversity Framework, and to submit its outcomes to the COP serving as the meeting of the Parties to the Nagoya Protocol at its fourth meeting.<sup>29</sup> The first part of the third meeting of the Open-ended Working Group will be held virtually from 23 August to 3 September 2021.<sup>30</sup>

35. The Governing Body of the **Treaty**, at its eighth session, in November 2019, included DSI in its Multi-Year Programme of Work.<sup>31</sup> The Governing Body: (i) noted the work being done on DSI in the framework of the CBD and the Commission; (b) requested the Secretary to continue following the discussions in other fora and to continue coordinating with the secretariats of the CBD and the Commission in any related activities in order to ensure coherence and avoid duplication of efforts; and (c) requested the Secretary to inform the Governing Body at its ninth session of the state of discussions and outcomes.

36. At its ninth session (9–15 May 2022), the Governing Body will consider the status of the science-based process on DSI of the CBD, and the discussions of the Commission on DSI in relation to plant genetic resources for food and agriculture (PGRFA). At its tenth session, the Governing Body will again consider the potential implications of the use of DSI on PGRFA for the objectives of the International Treaty. In addition to the rolling review in the Multi-Year Programme of Work, DSI is also under consideration in the context of the Global Information System (GLIS) under Article 17 of the Treaty.

37. DSI is also being considered in the context of the discussions of the Intergovernmental Conference on an international legally binding instrument under the **United Nations Convention on the Law of the Sea** on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction. Part II of the revised draft text of an agreement prepared by the President for consideration at the Conference's fourth session addresses marine genetic resources, including questions on the sharing of benefits. As mentioned above, the revised draft text uses the terms "*in*

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<sup>25</sup> CGRFA-17/19/Report, paragraph 24.

<sup>26</sup> CBD/DSI/AHTEG/2020/1/3; CBD/DSI/AHTEG/2020/1/4; CBD/DSI/AHTEG/2020/1/5.

<sup>27</sup> CBD/DSI/AHTEG/2020/1/7.

<sup>28</sup> <https://www.cbd.int/article/dsi-webinar-series-2020>

<sup>29</sup> CBD/COP/DEC/14/20, paragraph 12; CBD/NP/MOP/DEC/3/12, paragraphs 2–3.

<sup>30</sup> <https://www.cbd.int/meetings/WG2020-03>

<sup>31</sup> Resolution 13/2019.

*silico*”, “Digital Sequence Information” and “genetic sequence data” without, however, offering a definition.<sup>32</sup> The fourth session of the Intergovernmental Conference has been postponed to 2022.

38. In response to decision WHA72(13), the **World Health Organization**, in collaboration with various partners and stakeholders, developed an all-stakeholder survey on current human pathogen-sharing practices and arrangements and implementation of access and benefit-sharing measures, as well as opinions on the public health implications of both, in collaboration with the Secretariat of the CBD and in consultation with various international organizations.

39. The report on the implementation of decision WHA72(13) indicates, among other things, that “[t]imely sharing of pathogens, their genetic sequence data and relevant metadata is of paramount importance in enabling early identification, sound risk assessment, initiation of evidence-based interventions and the subsequent development and deployment of countermeasures such as diagnostics, vaccines and therapeutics.” It also reports that “[n]early all responses [to a WHO survey] indicated that genetic sequence data should be differentiated from physical sample sharing, noting that benefit to public health is linked to the ability to share sequences almost instantaneously across the world at no cost.”<sup>33</sup> The World Health Assembly considered the report on the implementation of decision WHA72(13) in May 2021.

40. DSI is also being considered in the context of intellectual property rights. The use of DSI was discussed in the context of patent disclosure requirements for genetic resources and traditional knowledge in the **Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore of the World Intellectual Property Organization (WIPO)**. It was also referred to in relation to database search systems for information associated with genetic resources in the context of patent examination, which are addressed in the draft “consolidated document relating to intellectual property and genetic resources”.<sup>34</sup>

## VII. OPTIONS FOR FUTURE WORK

41. There is a clear need to support countries in building the technical, institutional and human capacity necessary to utilize DSI on GRFA for research and development.<sup>35</sup>

42. Given the ongoing discussions on DSI in other fora, it seems pertinent for the Commission and its Working Groups to continue monitoring relevant developments in these fora, to reflect upon the implications of these developments for the access to, use of and the sharing of benefits derived from GRFA and to identify, as appropriate, key aspects that should be taken into consideration in addressing DSI as used in the agri-food sector.<sup>36</sup>

43. There is still a lack of awareness of the significant and increasingly important role DSI may play for research and development and for the sharing of benefits, in the food and agriculture sector. The policy implications of DSI and their impact on the use and exchange of GRFA are still largely unexplored and have not been considered in any depth by the Commission. The Commission may therefore wish to request the Secretary to explore how DSI is generated, accessed and used, and analyse the impact existing access and benefit-sharing measures for DSI have on research and development in the agri-food sector.<sup>37</sup>

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<sup>32</sup> A/CONF.232/2020/3.

<sup>33</sup> EB148/21.

<sup>34</sup> WIPO/GRTKF/IC/35/4.

<sup>35</sup> CGRFA-18/21/8.2, paragraph 34; CGRFA-18/21/9.1, paragraph 28; CGRFA-18/21/10.1, paragraph 35; CGRFA-18/21/12.1, paragraph 49.

<sup>36</sup> CGRFA-18/21/8.2, paragraph 35; CGRFA-18/21/9.1, paragraph 30; CGRFA-18/21/10.1, paragraph 36; CGRFA-18/21/12.1, paragraph 50.

<sup>37</sup> CGRFA-18/21/8.2, paragraph 35; CGRFA-18/21/9.1, paragraph 27; CGRFA-18/21/10.1, paragraph 33; CGRFA-18/21/12.1, paragraphs 47.

44. The Commission may wish to recommend that an intersessional workshop be held, in collaboration with relevant instruments and organizations, to raise the awareness of relevant stakeholders of the role of DSI for research and development related to GRFA.<sup>38</sup>

### VIII. GUIDANCE SOUGHT

45. The Commission may wish to:

- i. take note of the actual and potential applications of DSI relevant to the conservation and sustainable use of genetic resources for food and agriculture, as indicated in Table 2 of the document; and
- ii. stress the innovation opportunities DSI offers for research and development related to GRFA as well as the challenges many countries face in developing the technical, institutional and human capacity necessary to use DSI for research and development.

46. The Commission may further wish to:

- i. request FAO to support countries in building the technical, institutional and human capacity necessary to utilize DSI for research on and development related to GRFA;
- ii. request the Secretary to prepare a document reflecting common practices and experiences with how DSI is generated, accessed and used in research and development related to GRFA, for review by the Working Groups and the ABS Expert Team at their next sessions;
- iii. request the Secretary to analyse the observed impact of existing national measures for, or approaches to, access and benefit-sharing for DSI on research and development related to GRFA, for review by the Working Groups, the ABS Expert Team and the Commission;
- iv. request the Secretary to hold an intersessional workshop, in collaboration with relevant instruments and organizations, to raise awareness of relevant stakeholders of the role of DSI for research and development related to GRFA, address the state of the art of DSI on genetic resources, present possible implications related technologies might have on research and development related to GRFA, and consider the challenges for accessing and making full use of DSI; and
- v. request the Secretary to continue monitoring developments relevant to DSI in other fora, and consider the implications of these developments for access to, use of and the sharing of benefits derived from GRFA, with a view to identifying, as appropriate, key aspects that should be taken into consideration in addressing DSI and in creating an enabling environment for, and facilitating access to, GRFA as well as to building capacity to generate, use, share and access data for the conservation, development and sustainable use of GRFA.

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<sup>38</sup> CGRFA-18/21/8.2, paragraph 34; CGRFA-18/21/9.1, paragraph 29; CGRFA-18/21/10.1, paragraph 34; CGRFA-18/21/12.1, paragraphs 48.