E

联合国粮食及农业组织 | Food and Agriculture Organization of the United Nations | Organisation des Nations Unies pour l'alimentation et l'agriculture | Продовольственная и сельскохозяйственная организация Объединенных Наций | Organización de las Naciones Unidas para la Alimentación y la Agricultura | منظمة الأغذية والزراعة للأمم المتحدة

COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

Item 7 of the Provisional Agenda

INTERGOVERNMENTAL TECHNICAL WORKING GROUP ON FOREST GENETIC RESOURCES

Seventh Session

Rome, 7–9 March 2023

DIGITAL SEQUENCE INFORMATION AND GENETIC RESOURCES FOR FOOD AND AGRICULTURE

TABLE OF CONTENTS

I. INTRODUCTION

1. The Commission on Genetic Resources for Food and Agriculture (Commission), at its Eighteenth Regular Session, took note of actual and potential applications of digital sequence information (DSI) to the conservation and sustainable use of genetic resources for food and agriculture (GRFA). It stressed 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 necssary to use DSI for research and development.[1]

2. In considering DSI, the Commission, at its last session, formulated several requests. The Commission requested the Secretary of the Commisison to:

- prepare a document reflecting key practices and experiences on how DSI is generated, stored, accessed and used for research and development related to GRFA, including relevant information on intellectual property protection;[2]
- submit a list of examples of actual and potential applications of DSI relevant to the conservation and sustainable use of GRFA to the Convention on Biological Diversity (CBD).[3]
- hold an intersessional workshop, in collaboration with relevant instruments and organizations, to raise awareness among relevant stakeholders of the role of DSI for the conservation and sustainable use of GRFA and the sharing of benefits derived from them, address the state of the art of DSI on genetic resources, present possible implications that related technologies might have for research and development related to GRFA, and consider the challenges associated with accessing and making full use of DSI;[4] and
- continue monitoring developments relevant to DSI in other fora to:
    - 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;[5]
    - contribute to the analysis of options, including access and benefit-sharing (ABS) multilateral mechanisms, discussed under the CBD, and to report back on implications for GRFA, including potential opportunities, challenges and gaps associated with the different options for consideration by the Working Groups, the ABS Expert Team and the Commission at their next sessions, for future work."[6]

3. The present document provides information on the generation, storage, access to and use of DSI for research and development related to GRFA (section II). It reports on the intersessional global workshop on DSI and GRFA held in November 2022 (section III), summarizes relevant developments in other fora (section IV) and discusses options to regulate ABS for DSI that are currently under debate (section V). At the time of writing, the 15th meeting of the Conference of the Parties to the CBD (7–19 December 2022) has not yet taken place. Relevant outcomes of this meeting will be reported to the Working Group during the session. Further information is provided in the study on *The role of digital sequence information for the conservation and sustainable use of genetic resources for food and agriculture: Opportunites and challenges.*[7]

[1] CGRFA-18/21/Report, paragraph 32.
[2] CGRFA-18/21/Report, paragraph 35.
[3] CGRFA-18/21/Report, paragraph 36.
[4] CGRFA-18/21/Report, paragraph 38.
[5] CGRFA-18/21/Report, paragraph 39.
[6] CGRFA-18/21/Report, paragraph 37
[7] CGRFA/WG-FGR-7/23/7/Inf.1.

II. THE ROLE OF DIGITAL SEQUENCE INFORMATION FOR FOOD AND AGRICULTURE

4. There is no universally agreed definition for DSI. The scope of DSI can include anything from DNA and RNA sequences, protein sequences to metabolites and other macromolecules, and may include associated information and traditional knowledge. Various attempts to reach consensus on the definition of DSI or on the terminology that should be used have so far not led to an agreement. The term "DSI" is therefore used in this document as a placeholder term for which no consensus on a replacement or precise definition exists to date.

5. As reported to the last session of the Commission, the Ad Hoc Technical Expert Group (AHTEG) on Digital Sequence Information on Genetic Resources, established by the 14th meeting of the Conference of the Parties to the CBD, considered the possible scope of DSI compartmentalized DSI into three groups, based on the degree of biological processing and the proximity to the underlying genetic resource. Group 1 included DNA and RNA. Group 2 included, in addition to DNA and RNA, proteins and epigenetic modifications and Group 3 included, in additon to everything included in Groups 1 and 2, metabolities and other macromolecules. 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.[8]

6. Any definition of DSI carries the risk of not accommodating future technological developments. Heinemann, Coray and Thaler (2018) therefore propose that DSI, or whatever term is finally agreed, encompass "the kind of information in, or that might be added to, databases of the kind currently in use and collated by the scientific journal Nucleic *Acids Research.*"[9] *Nucleic Acids Research* (NAR) is an open-access peer-reviewed scientific journal published since 1974. In 1991, NAR started publishing as a first issue of each year an overview of biological databases.

7. Agreement on a definition of DSI will ultimately depend on the rules for access to and the sharing of benefits derived from DSI and, *vice versa*, the design of these rules will depend on what is finally considered DSI. Used in the context of GRFA, DSI on GRFA may relate 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. 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.

Relevance of DSI to food and agriculture

8. Current and potential applications of DSI show that the generation, storage, access to and use of DSI are fundamental for the characterization of all kinds of biodiversity for food and agriculture (BFA), while they are also important tools to achieve sustainable agriculture. Examples of actual and potential applications of DSI relevant to the conservation and sustainable use of GRFA, as reviewed by the Commission's intergovernmental technical working groups in 2021, clearly indicate the relevance of DSI and related technologies for all subsectors of GRFA.[10] Heinemann, Coray and Thaler (2018) did not find significant actual or potential differences in the characteristics of technologies as they are applied in the different subsectors of GRFA.

9. As requested by the Commission, the consolidated list of examples was submitted by the Secretary of the Commission to the CBD[11] to provide information on the potential future importance of DSI for characterization, conservation, sustainable use and fair and equitable benefit-sharing and its importance and potential implications for GRFA.

[8] CBD/DSI/AHTEG/2020/1/7.
[9] Background Study Paper No. 68.
[10] 9 CGRFA-18/21/8.2, paragraphs 32–35; CGRFA-18/21/9.1, paragraphs 26–30; CGRFA-18/21/10.1, paragraphs 31–39 and Appendix C; CGRFA-18/21/12.1, paragraphs 46–50.
[11] CBD/WG2020/3/INF/9.

10. As indicated in the study on *The role of digital sequence information for the conservation and sustainable use of genetic resources for food and agriculture: Opportunites and challenges*,[12] advances in DNA sequencing bring the potential to enhance food security and sustainable use of global biodiversity, benefiting the world's poorest people.[13] Numerous publications demonstrate the impact of DSI studies on research and development in the field of GRFA. Omics, a "collection of research tools and techniques that enable researchers to collect data about biological systems at a very large, or near-complete, scale",[14] include sequencing individual and community genomes (genomics, metagenomics), characterization and quantification of gene expression (transcriptomics, meta-transcriptomics), metabolite abundance (metabolomics), protein content (proteomics) and phosphorylation (phospho-proteomics). Omics technologies can drive genetic engineering, for example in plants and micro-organisms, ecosystem understanding and surveillance, and human and animal health.

11. Searches of the literature database of the Centre for Agriculture and Bioscience International (CAVI), CAB Abstracts, which contains 10.9 million records, revealed many examples of publications demonstrating the important contribution of DSI to enhanced crop production, and to the mitigation of emerging diseases and climate change. The database searches revealed a rise in the number of publications on DSI from 20 000 in 2002 to 1 180 915 in 2022 (almost 12 percent of the records). Scientific literature focusing on climate change mitigation and improved yields for the global major crops was explored. Examples found include: discovery of candidate genes for improved abiotic stress tolerance in wheat; contribution of DSI to progress understanding and manipulation of drought and heat tolerance in rice; use of DSI-based technologies to increase grain yield and starch content in maize; and DSI-assisted development of disease resistance and drought and salt tolerance in chickpea. These examples indicate that DSI is playing an increasingly important role in research towards mitigating climate change, improving crop production and reducing disease impact.

12. In summary, DSI is used extensively in all subsectors of GRFA. DSI is a routine component of nearly all research in the biological sciences. One may conclude 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 (of GRFA and non-GRFA origin) will become available.

Generation and storage of DSI

13. DSI is primarily the product of sequencing technologies that have become faster, cheaper and more accurate in recent years.[15] Data are held in many places, in public and private databases. A significant amount of DSI is stored in an estimated 1 700 publicly accessible databases and repositories of biological and associated information worldwide. The International Nucleotide Sequence Data Collaboration (INSDC) between GenBank (United States of America), the European Nucleotide Archive (United Kingdom of Great Britain and Northern Ireland) and the DNA Data Bank (Japan) provides the key infrastructure for publicly available DSI. The three databases exchange data regularly and maintain an up-to-date copy of all published information. Little is known about private databases.

Access to public databases

14. The INSDC has a uniform data-sharing policy of free and unrestricted access to all the data records without use restrictions, licensing requirements, or fees on the distribution or use. Patented

[12] CGRFA/WG-FGR-7/23/7/Inf.1.

[13] Cowell, C., Paton, A., Borrell, J.S., Williams, C., Wilkin, P., Antonelli, A., Baker, W.J. *et al*. 2022. Uses and benefits of digital sequence information from plant genetic resources: Lessons learnt from botanical collections. *Plants People Planet*, 4: 33–43. https://doi.org/10.1002/ppp3.10216

[14] Hurgobin, B. & Lewsey, M.G. 2022. Applications of cell- and tissue-specific 'omics to improve plant productivity. *Emerging Topics in Life Sciences*, 6: 163–173. https://doi.org/10.1042/ETLS20210286

[15] Sarah, A. 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.* CBD/SBSTTA/22/INF/3. Montreal, Canada, Secretariat of the Convention on Biological Diversity.

sequences may be deposited in the INSDC. However, the INSDC will not attach statements to records that restrict access to the data, limit the use of the information in these records, or prohibit certain types of publications based on these records.[16]

Making use of DSI

15. However, unrestricted access to public databases does not mean that DSI may be used by everyone in the same way. Substantial technical, institutional and human capacity is required 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.

16. 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 public funds, such funding may not always be available and sufficient and alternative funding models may need to 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.

III. GLOBAL WORKSHOP ON DIGITAL SEQUENCE INFORMATION AND GENETIC RESOURCES FOR FOOD AND AGRICULTURE

17. As requested by the Commission, a Global Workshop on Digital Sequence Information and Genetic Resources for Food and Agriculture was held virtually on 14 and 15 November 2022. The workshop was co-organized with the CBD, the International Treaty on Plant Genetic Resources for Food and Agriculture, CABI and the CGIAR Genebank Initiative. It was attended by more than 500 participants from all regions. The workshop added an important component to a series of workshops and webinars held during the last three years on DSI, including those held by the CBD.[17] While on the first day presentations and the ensuring panel discussion centred around the role of DSI for the conservation and sustainable use of genetic resources for food and agriculture, the workshop focused on day 2 on stakeholder views regarding access to, use of and the sharing of benefits derived from DSI. On day 2, the workshop also addressed DSI in the context of indigenous data sovereignty, associated principles, frameworks and challenges.

18. The workshop raised awareness among relevant stakeholders in the food and agriculture sector of the role of DSI for the conservation and sustainable use of GRFA and the sharing of benefits derived from them. It addressed the state of use of DSI in the food and agriculture sectors and considered possible implications that related technologies might have for research and development related to GRFA. The workshop also addressed the challenges associated with accessing and making full use of DSI. Speakers and panellists seemed to agree that a global consensus on the status and exchange of DSI might be in the interest of all relevant stakeholders. The agenda of the workshop, presentations by keynote speakers and webcast links are available on the workshop webpage.[18]

[16] Arita, A. 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

[17] https://www.cbd.int/article/dsi-webinar-series-2020

[18] https://www.fao.org/cgrfa/meetings/dsi_workshop_2022/en/

IV. DEVELOPMENTS IN OTHER FORA

19. The Commission, at its last session, requested the Secretariat to continue monitoring developments relevant to DSI in other fora.[19] DSI is currently being discussed in multiple fora, including under the CBD and the Nagoya Protocol, under the United Nations Convention on the Law of the Sea, in the World Health Organization (WHO) and the World Intellectual Property Organization (WIPO).

Convention on Biological Diversity/ Nagoya Protocol

20. The Conference of the Parties (COP) to the CBD, at its Thirteenth Meeting, and the COP serving as the meeting of the Parties to the Nagoya Protocol (COP-MOP) at its Second Meeting adopted decisions on "DSI" that recognized the need for a coordinated and non-duplicative approach on this matter under the CBD and the Nagoya Protocol.[20] Contracting Parties agreed on a process to facilitate consideration of this matter, including: consultations with governments, indigenous peoples and local communities and relevant organizations and stakeholders;[21] the preparation of a fact-finding and scoping study to clarify terminology and concepts and to assess the extent and the terms and conditions of the use of "DSI" in the context of the CBD and the Nagoya Protocol;[22] and the establishment of an hoc technical expert group to consider, inter alia, the technical scope and legal and scientific implications of existing terminology related to "DSI".[23]

21. At its Fourteenth Meeting, the COP considered potential implications of the use of DSI for the three objectives of the CBD and committed to working towards resolving this divergence of views among Parties regarding benefit-sharing from the use of DSI.[24] The COP put in place a process, comprising the submission of views and information by Parties,[25] the commissioning of four studies[26] and the convening of an AHTEG.[27] The COP-MOP, at its Third Meeting, welcomed the process put in place by the COP. It was decided that the outcomes of the AHTEG be considered by the Open-ended Working Group on the Post-2020 Global Biodiversity Framework (OEWG), which should make recommendations to the COP, at its Fifteenth Meeting, on how to address DSI in the context of the Post-2020 Global Biodiversity Framework, and submit its outcomes to COP-MOP at its Fourth Meeting.

22. The OEWG considered DSI during the first (virtual) part of its third meeting in August 2021 and during the second part of the third meeting, held in Geneva in March 2022. It adopted a recommendation on DSI on genetic resources, which also included an annex with a draft decision for consideration by the COP and a recommendation to COP-MOP to consider the recommendation of the

[19] CGRFA-18/21/Report, paragraphs 37 and 39.
[20] Decisions CBD COP XIII/16 and NP-2/14.
[21] See *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* (CBD/SBSTTA/22/INF/2 & CBD/DSI/AHTEG/2018/1/2/Add.1).
[22] See *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* (CBD/DSI/AHTEG/2018/1/3).
[23] See Report of the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources (CBD/SBSTTA/22/INF/4).
[24] CBD COP Decision 14/20.
[25] *Compilation of views and information on digital sequence information on genetic resources submitted pursuant to paragraphs 9 and 10 of decision 14/20* (CBD/DSI/AHTEG/2020/1/INF/1)
[26] See *Synthesis of views and information related to digital sequence information on genetic resources* (CBD/DSI/AHTEG/2020/1/2); *Digital sequence information on genetic resources: concept, scope and current use* (CBD/DSI/AHTEG/2020/1/3); *Combined study on digital sequence information in public and private databases and traceability* (CBD/DSI/AHTEG/2020/1/4); *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).
[27] *Report of the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources* (CBD/DSI/AHTEG/2020/1/7).

OEWG as well as any decision prepared by the Fifteenth Meeting of the COP.[28] At its fourth meeting held in June 2022, the OEWG continued its consideration of the draft COP decision on DSI and adopted a recommendation with elements for a draft decision by the COP; it also decided to hold a fifth meeting in December 2022.[29] The outcome of the fifth meeting of the OEWG and the fifteenth meeting of the COP will be reported during the meeting of the Working Group.

23. At the first part of the third meeting of the OEWG, the Co-Chairs of the OEWG together with the Executive Secretary of the CBD also established an informal co-chairs' advisory group on DSI on genetic resources (IAG). The IAG held five virtual meetings between September and November 2021 and undertook an assessment of consequences of possible policy approaches, options or modalities for benefit-sharing arising from the utilization of DSI on genetic resources, and identified areas of potential convergence and areas of divergence as well as areas of additional work on DSI.[30] At the second part of its third meeting, the OEWG requested the IAG to be extended by representatives of the scientific research community, the private sector, civil society organizations, and databases dealing with DSI on genetic resources, and to continue its work on the assessment of consequences of potential policy approaches, options or modalities for benefit-sharing arising out of the utilization of DSI on genetic resources. The IAG held eight virtual meetings and continued its work on the assessment of consequences of potential policy approaches, options or modalities for benefit-sharing.[31] Following the fourth meeting of the OEWG, the IAG held five virtual meetings to assess the proposed policy options using a matrix with pre-agreed criteria.[32] Key results of these consultations are discussed below, in section V.

International Treaty on Plant Genetic Resources for Food and Agriculture

24. The Governing Body of the Treaty, at its Seventh Session, considered DSI in the context of the Draft Multi-Year Programme of Work for 2018–2025. It decided to consider at its Eighth Session the potential implications of the use of DSI on genetic resources for the objectives of the Treaty, and to consider it for inclusion in its Multi-Year Programme of Work at that meeting.

25. At its Eighth Session, the Governing Body adopted Resolution 13/2019 on the Multi-Year Programme of Work through which, among other matters, it requested the Secretary to inform the Governing Body at the Ninth Session of the state of discussions and outcomes of the related processes in the CBD and in the Commission, as they relate to the potential implications of the use of DSI on genetic resources for the objectives of the International Treaty. The Governing Body also included DSI in the Multi-Year Programme of Work of the Governing Body for the Ninth and Tenth sessions.

26. At its Ninth Session, the Governing Body took note of the latest deliberations of the CBD OEWG on DSI and requested the Secretary to continue following the discussions on DSI/genetic sequence data (GSD) 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 work. It encouraged Parties to the CBD, in their consideration of potential decisions on a solution for fair and equitable benefit-sharing from the use of DSI on genetic resources, to bear in mind the need for implementation of the International Treaty and of the CBD and its Nagoya Protocol to be mutually supportive. It also requested the Secretary to invite Contracting Parties and stakeholders to provide information about their capacity-building needs for accessing and using DSI/GSD and to share their experiences in this regard. The Governing Body further called on Contracting Parties and other donors with the capacity to do so to promote the provision of financial resources and technical assistance to reduce the existing gap on capacity regarding DSI/GSD between developed and developing countries.[33]

[28] Recommendation WG2020-3/2.
[29] Recommendation WG2020-4/2.
[30] CBD/WG2020/3/INF/8.
[31] CBD/WG2020/4/INF/4.
[32] CBD/WG2020/5/INF/1.
[33] IT/GB/9/22/Report, Resolution 16/2022.

27. In deciding to resume the process for enhancing the functioning of the Multilateral System, the Governing Body further requested the Co-chairs of the re-established Ad Hoc Open-ended Working Group to Enhance the Functioning of the Multilateral System of Access and Benefit-sharing to accord early attention to the issue of DSI. [34] The Governing Body further requested the Secretary of the International Treaty to include the possible impact of DSI/GSD on Farmers' Rights as set out in Article 9 of the International Treaty, in the assessment of DSI/GSD foreseen in the Multi-Year Programme of Work.[35]

World Health Organization

28. The outbreak of the COVID-19 pandemic brought renewed attention to the issue of sharing of human pathogens, including related DSI.

29. The Pandemic influenza preparedness framework for the sharing of influenza viruses and access to vaccines and other benefits (PIP Framework),[36] adopted in 2011 by the World Health Assembly (WHA), aims to improve pandemic influenza preparedness and response and strengthen the protection against pandemic influenza, with the objective of creating a fair, transparent, equitable, efficient and effective system for, on an equal footing, sharing of influenza viruses with human pandemic potential and access to vaccines and sharing of the benefits. However, while the PIP Framework makes reference to "genetic sequence data"[37] and encourages all countries to share these data in a rapid, timely and systematic manner,[38] genetic sequence data are not included in the definition of PIP Biological Materials. The benefit-sharing regime applicable under the PIP Framework to PIP Biological Materials does therefore not fully include genetic sequence data. An independent expert group established in 2015 by the Director-General of WHO, while noting that the principles of the Framework remained as relevant as they were in 2011, concluded that "there are key issues that must urgently be addressed for the PIP Framework to remain relevant, including the issue of how GSD [genetic sequence data] should be handled under the PIP Framework."[39]

30. WHO, in response to Decision WHA72(13), developed an all-stakeholder survey on current human pathogen-sharing practices and arrangements, the implementation of access and benefit-sharing measures, as well as the potential public health outcomes and other implications. The report on the implementation of Decision WHA72(13) indicates, among other issues, 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 the 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."[40] The WHA considered the report on the implementation of Decision WHA72(13) in May 2021.

31. The sharing of genetic sequence data may also play a significant role in the negotiations of a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response, which the second special session of the WHA initiated in December 2021.[41]

[34] IT/GB/9/22/Report, Resolution 3/2022.
[35] IT/GB/9/22/Report, Resolution 7/2022.
[36] WHO. 2011. Pandemic influenza preparedness framework for the sharing of influenza viruses and access to vaccines and other benefits.
[37] "Genetic sequences" means the order of nucleotides found in a molecule of DNA or RNA. They contain the genetic information that determines the biological characteristics of an organism or a virus (PIP Framework, section 4.2).
[38] PIP Framework, section 5.2.1.
[39] PIP Framework Review Group. 2016. Review of the Pandemic Influenza Preparedness Framework, Report by the Director General. Geneva: World Health Organization, p.13.
[40] EB148/21.
[41] SSA2(5).

32. The WHA established an intergovernmental negotiating body (the "INB") and decided that the INB first identify the substantive elements of the instrument and then begin the development of a working draft to be presented, on the basis of progress achieved, for the consideration of the INB at its second meeting. The working draft, presented to the second session of the INB, held in July 2022, underscores in its Preamble "the importance to promote early, safe, transparent and rapid sharing of samples and genetic sequence data of pathogens, taking into account relevant national and international laws, regulations, obligations and frameworks, including, as appropriate, the International Health Regulations (2005), the Convention on Biological Diversity and the Nagoya Protocol, and the Pandemic Influenza Preparedness Framework".[42]

33. The working draft, furthermore, refers to "measures to ensure access and benefit sharing, which would include, but not be limited to: rapid, regular and timely sharing of pathogens and genomic sequences through a standardized real-time global platform; and timely access to affordable, safe and effective pandemic response products, including diagnostics, vaccines, personal protective equipment and therapeutics." It also considers "measures to establish a comprehensive system for access and benefit sharing, including but not limited to, consistency with relevant elements of the Convention on Biodiversity and its Nagoya Protocol, by building upon or adapting mechanisms and/or principles contained in existing or previous instruments" and "measures to promote and facilitate recognition of the system as a specialized comprehensive system for access and benefit sharing system, at the national level".[43]

34. The INB, at its second session, considered the working draft "as a good basis to facilitate the discussions" and agreed that the instrument should be legally binding and contain both legally binding as well as non-legally binding elements.[44]

United Nations Convention on the Law of the Sea

35. 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.

36. The *Further 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*[45] of 1 June 2022 refers to DSI in various provisions, including those on the use of terms, application, transmission of information to the clearinghouse mechanism, fair and equitable benefit-sharing, and monitoring and transparency.

37. The further revised draft text was reviewed and further revised during the fifth session of the Intergovernmental Conference. On 21 August 2022 a "refreshed text"[46] was developed and on 26 August 2022 a "further revised text".[47] These documents, which are not publicly available are, according to the President of the Intergovernmental Conference, "not necessarily reflective of agreement on all issues of the package, but they do reflect a direction in which a substantial number of delegations were content to proceed, incorporating significant compromises on key issues".[48]

38. The fifth session of the Intergovernmental Conference in August 2022 was unable to conclude the negotiations of the instrument. The President of the Intergovernmental Conference therefore suspended the conference, which will be resumed in the near future.

World Intellectual Property Organization

[42] A/INB/2/3.
[43] Ibid.
[44] A/INB/2/5.
[45] A/CONF.232/2022/5.
[46] A/CONF.232/2022/CRP.12 and A/CONF.232/2022/CRP.12/ Add.1.
[47] A/CONF.232/2022/CRP.13 and A/CONF.232/2022/CRP.13/Add.1.
[48] A/CONF.232/2022/9.

39. 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 (IGC) of the World Intellectual Property Organization (WIPO).

40. Since the Commission's last session, the IGC met in February/March 2022 (IGC-42) and May/June 2022 (IGC-43) to undertake negotiations on genetic resources with a focus on addressing unresolved issues and considering options for a legal instrument. Both sessions made considerable progress and achieved significant convergence around the Chair's Text of a Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources[49] as a "focused, effective, and balanced basis for further engagement".[50]

41. The central provision of the Chair's Text would require Contracting Parties to the international legal instrument to make the disclosure of the country of origin mandatory where a patent application is "[materially or directly] based on" genetic resources or associated traditional knowledge. "[Materially/Directly] based on" is proposed to mean that the genetic resources and/or associated traditional knowledge "must have been necessary or material to the development of the claimed invention, and that the claimed invention must depend on the specific properties of the genetic resources and/or associated traditional knowledge". Whether physical access by the inventor to the genetic resource will be required or access to DSI be sufficient to trigger the disclosure requirement are still open and contentious questions.

42. The WIPO General Assembly decided in July 2022 to convene a Diplomatic Conference to conclude an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources. The Diplomatic Conference will be based on the Chair's Text and any other contributions by Member States and be held no later than 2024.

43. The WIPO General Assembly further agreed to convene in the second half of 2023 a Preparatory Committee, to establish the necessary modalities of the Diplomatic Conference. The Preparatory Committee will consider at this time, the draft Rules of Procedure to be presented for adoption to the Diplomatic Conference, the list of invitees to participate in the conference, and the text of the draft letters of invitation, as well as any other document or organizational questions relating to the Diplomatic Conference. The Preparatory Committee will also approve the basic proposal for the administrative and final provisions of the international legal instrument.[51]

V. REGULATING ACCESS AND BENEFIT-SHARING FOR DIGITAL SEQUENCE INFORMATION ON GENETIC RESOURCES

44. Currently, very few countries seem to require prior informed consent (PIC) and mutually agreed terms (MAT) where access is sought to DSI only (rather than to the physical genetic resource).[52] Some countries, while not restricting access to DSI, require that benefits derived from DSI obtained from their genetic resources are shared. There is a concern that in the absence of a global agreement on ABS for DSI, an increasing number of countries could adopt domestic ABS measures for DSI.

45. At the global level, consultations held over the past five years, in particular under the CBD, have generated various options to regulate ABS for DSI. Based on the outcomes of the Co-leads' last

[49] WIPO/GRTKF/IC/43/5.
[50] WO/GA/55/12 Prov., paragraph 309.
[51] WO/GA/55/12 Prov., paragraph 309.
[52] *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).

report on the work of the IAG[53] established under the CBD, at least eleven options, including suboptions may be distinguished:

(1)	Option 0	Status quo
(2)	Option 1	DSI is treated like genetic resources, where country PIC and MAT apply
(3)	Option 2.1	DSI requires a country MAT but no PIC
(4)	Option 2.2	DSI requires a global standardized MAT and no PIC
(5)	Option 3.1	DSI access requires payment
(6)	Option 3.2.a	Payment/levy on services and products as inputs to research
(7)	Option 3.2.b	Bonds and labels linked to voluntary contributions
(8)	Option 3.2.c	Levy on products from the use of DSI
(9)	Option 4	Enhanced technological and scientific collaboration and capacity-building
(10)	Option 5	No benefits are shared from the use of DSI
(11)	Option 6	1 percent levy on retail sales of products using biodiversity (the African proposal)[54]

46. The IAG assessed these options in a matrix approach against the criteria given in Table 1 and most of its members thought that options 3.2b, 3.2c and 6 should be further considered (or identified a need for further information). Option 4 had the most favourable scores in the matrix and all members of the IAG considered that it should be considered further, at least as part of a solution in combination with another option or options. It is, of course, important to note that not all criteria have the same weight and a meaningful assessment of the different options against criteria does not just require a common understanding of or even consensus on the criteria, but also on their relative weight.

47. The criteria listed in Table 1 are generic. While the "potential to contribute to the conservation and sustainable use of biodiversity" (A.5) is one of the criteria against which the IAG assessed the different options, none of the criteria reflect the special nature of genetic resources for food and agriculture, their distinctive features and problems needing distinctive solutions. On the other hand, the list of criteria requires "coherence with other fora considering DSI" (D.18) which signals openness to take into account considerations relevant to the treatment of DSI in other sectors.

Table 1: List of criteria and sub-criteria:
A. Effective in achieving goals
1. Potential to deliver predictable monetary benefits
2. Potential to deliver predictable non-monetary benefits
3. Access to public databases remains open
4. Does not hinder research and innovation
5. Potential to contribute to the conservation and sustainable use of biodiversity
B. Efficient and feasible to implement
6. Technically feasible
7. Legally feasible
8. Legally clear and certain to implement
9. Administratively simple
10. Implementable within the next two years
11. Enables distinction between commercial and non-commercial use of DSI
12. Cost of set-up and implementation is reasonable/minimal
C. Enables good governance
13. Easy to understand by providers and users
14. Easily enforceable by providers
15. Ease of compliance for users
16. Does NOT result in jurisdiction shopping
17. Facilitates the sharing of benefits with Indigenous Peoples and Local Communities
D. Coherent and adaptable

[53] *Co-leads' report on the work of the Informal Co-Chairs' Advisory Group on digital sequence information on genetic resources since the fourth meeting of the Open-ended Working Group on the Post-2020 Global Biodiversity Framework* (CBD/WG2020/5/INF/1).
[54] CBD/WG2020/5/3, p.3.

18. Coherence with other fora considering DSI 19. Agile and adaptable to future technological and scientific development

Source: CBD/WG2020/5/3

48. Current discussions on DSI centre around two different models: a multilateral approach and the so-called hybrid approach. The two approaches have in common that they would not restrict access to DSI. However, the use of DSI would require benefit-sharing. Under the multilateral approach, benefits, generated, for example, through a levy on products from the use of DSI, would be deposited in a global fund that would also be open for voluntary contributions from all sources. Under the hybrid approach, benefit-sharing modalities would have to be negotiated with the country of origin of the genetic resource from which the DSI was obtained, provided the country of origin is known. Where DSI from genetic resources of several countries is used, benefits would have to be shared through a multilateral mechanism with the countries of origin of the genetic resources from which the DSI was obtained. Where no country of origin of the genetic resource from which the DSI has been obtained can be identified, benefits would have to be deposited, like under the multilateral approach, in a global fund. For both approaches criteria for the disbursement of funds deposited in the global fund would have to be established.

49. Relatively little attention has been given so far to the relationship between existing ABS measures built on the freedom of contract principle and a multilateral or hybrid open access DSI regime that would apply to the DSI obtained from genetic resources. The co-existence of these different regimes would imply that access to and the use of the same genetic information would be governed by different benefit-sharing regimes, depending on the form in which the genetic information is accessed.

50. Not sufficient attention has been given to the "sector-blindness" of DSI, which may make it difficult to address DSI as a sector-specific phenomenon given that scientists use DSI independent of whether it has been originally accessed for a specific purpose or use in a specific sector. DSI derived from genetic resources, other than GRFA, may be relevant to research on and development of GRFA. Future discussions on DSI in the different fora will show how these complex issues may be addressed while retaining open access to DSI and ensuring that benefits derived from DSI are fairly and equitably shared.

VI. GUIDANCE SOUGHT

51. The Working Group may wish to:

(i) take note of the information provided in this document and of the study on *The role of Digital Sequence Information in the conservation and sustainable use of genetic resources for food and agriculture: opportunities and challenges;*

(ii) recommend that the Commission request the Secretariat to

a. invite Members to submit information on domestic access and benefit-sharing measures applying to DSI and their actual or potential implications for the conservation and sustainable use of GRFA, including exchange, access to and the fair and equitable sharing of the benefits arising from their use, and to compile this information, for the information of the Commission;

b. continue monitoring developments regarding DSI in other fora, with a view to consider their potential implications, including potential opportunities and challenges for the Commission and its Members;

c. report regularly on these developments, including, as appropriate, prior to the next regular session of the Commission, for example through webinars; and

d. continue to hold virtual open-ended workshops on DSI, as appropriate, with a view to inform Commission Members and observers on recent technological and policy developments related to DSI.