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BIODIVERSITY FRAMEWORK

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UPDATE OF DIGITAL SEQUENCE INFORMATION ON GENETIC RESOURCES IN RELEVANT INTERNATIONAL PROCESSES AND POLICY DEBATES

Note by the Executive Secretary

I. INTRODUCTION

1. In decision [14/20](#), paragraph 13, the Conference of the Parties requested the Executive Secretary to cooperate with other intergovernmental organizations and take their work, approaches and outcomes into consideration regarding digital sequence information on genetic resources. Decision NP-2/5 of the Conference of the Parties serving as the meeting of the Parties to the [Nagoya Protocol](#) also requested the Executive Secretary to continue to engage with relevant ongoing processes and policy debates and to collect information on current discussions on the relationship between the use of digital sequence information on genetic resources and access and benefit-sharing. The information gathered through these engagements was made available for the 2018 meeting of the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources as well as the twenty-second meeting of the Subsidiary Body on Scientific, Technical and Technological Advice.¹ The present document is an update to the overview of relevant international processes and policy debates in relation to digital sequence information on genetic resources and access and benefit-sharing.

II. RELEVANT ONGOING INTERNATIONAL PROCESSES AND POLICY DEBATES

A. Commission on Genetic Resources for Food and Agriculture

2. Following its decision of 2017 to establish a new work stream on digital sequence information on genetic resources for food and agriculture (GRFA), the [Commission on Genetic Resources for Food and Agriculture](#) considered the topic at its seventeenth regular session, held at the headquarters of the Food and Agriculture Organization of the United Nations in Rome from 18 to 22 February 2019.

3. In considering the exploratory fact-finding scoping study on “digital sequence information” on genetic resources for food and agriculture ([background study paper No. 68](#)), the Commission agreed that there was a need for further review of “DSI”. The Commission noted the importance of coordination with ongoing processes under the Convention on Biological Diversity and the Nagoya Protocol. It agreed to address, at its next session, the innovation opportunities offered by digital sequence information on genetic resources for food and agriculture, the challenges of capacity to access and make use of it and its implications for the conservation and sustainable use of GRFA and the sharing of benefits derived from GRFA. It requested its intergovernmental technical 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. The

¹ See [CBD/SBSTTA/22/INF/2/Add.2-CBD/DSI/AHTEG/2018/1/2/Add.2](#).

Commission also took note that some Members had adopted domestic measures that regulate the access to and use of “DSI” on genetic resources as part of their ABS frameworks.

4. The Commission invited countries and relevant stakeholders to provide capacity-building and funding to support access to, and the generation, analysis and sharing of, “DSI” in conservation, sustainable use and research and development of GRFA, especially in developing countries.²

5. The Commission’s intergovernmental technical working groups on animal, aquatic, forest and plant genetic resources considered “DSI” at their sessions held during the first semester of 2021 and provided guidance, in particular with regard to the actual and potential applications of DSI for the conservation and sustainable use of genetic resources in their sectors.³ The working groups recommended that the Commission request FAO to hold an intersessional workshop, in collaboration with relevant organizations and instruments, inter alia, to raise awareness among relevant stakeholders of the role of “DSI” in research and development related to genetic resources and of the challenges to access and make full use of “DSI”.

6. The working groups also recommended that the Commission request FAO to support countries in building the necessary technical, institutional and human capacity to utilize “DSI” on GRFA for research and development. Moreover, the Commission should continue monitoring developments relevant to “DSI” in other international forums.

7. In considering a draft survey of access and benefit-sharing (ABS) country measures, the Working Groups also recommended that a stand-alone document or annex to the Commission’s ABS Elements⁴ be prepared, reflecting specific examples of ABS country measures accommodating the specific features of GRFA and or traditional knowledge associated with GRFA. Several Working Groups recommended that this stand-alone document or annex also reflect measures addressing “DSI.”⁵ The Commission’s Team of Technical and Legal Experts on Access and Benefit-sharing, which held its fifth session in July 2021, recommended that the Commission consider the preparation of a document reflecting common practices and experiences with how DSI on GRFA is generated, accessed and used, for review by the Commission’s intergovernmental technical working groups and the ABS Expert Team at their next sessions.⁶

8. The Commission will consider the recommendations of its subsidiary bodies at its eighteenth regular session (27 September – 1 October 2021).

B. CGIAR Centers

9. The Consultative Group on International Agricultural Research (CGIAR) is currently in the latter stages of a system-wide reform designed to increase our efficiency and effectiveness in response to evolving global challenges. The *CGIAR 2030 Research and Innovation Strategy: Transforming Food, Land, and Water Systems in a Climate Crisis* provides an outline of the research and development priorities of CGIAR.⁷ CGIAR research will be organized under three research areas: system transformation, resilient agrifood systems, and genetic innovation. Most research and development activities working directly with genetic

² [CGRFA-17/19/Report](#), paras. 22-26.

³ [CGRFA-18/21/8.2](#), paras. 32-35; [CGRFA-18/21/9.1](#), paras. 26-30; [CGRFA-18/21/10.1](#), paras. 31-36; [CGRFA-18/21/12.1](#), paras. 46-50.

⁴ FAO. 2019. [ABS Elements: Elements to Facilitate Domestic Implementation of Access and Benefit-Sharing for Different Subsectors of Genetic Resources for Food and Agriculture with Explanatory Notes](#). Rome. 84 pp. Licence: CC BY-NC-SA 3.0 IGO. (also available at <http://www.fao.org/3/ca5088en/ca5088en.pdf>).

⁵ [CGRFA-18/21/8.2](#), para. 29; [CGRFA-18/21/10.1](#), para. 33; [CGRFA-18/21/12.1](#), para. 41.

⁶ [CGRFA-18/21/4.1](#), para. 31.

⁷ Available at <https://cgspace.cgiar.org/bitstream/handle/10568/110918/OneCGIAR-Strategy.pdf>

resources and associated genomic information (or DSI) will take place under genetic innovation research areas, which includes the CGIAR genebanks and breeding programmes.⁸

10. CGIAR Centers and research programmes are increasingly making use of technological advances to generate and analyse genetic sequence data as part of their research and development programmes, with a view to contributing to the conservation and sustainable use of genetic resources as well as benefit-sharing. In 2018, CGIAR submitted a report⁹ describing these uses of DSI to the Secretariat, which then incorporated the information into a note submitted to the Ad Hoc Technical Expert Group on Digital Sequence Information;¹ CGIAR will submit an update to that report in 2022. Meanwhile, CGIAR encourages interested delegates to visit the interactive CGIAR Results Dashboard,¹⁰ where it is possible to search for peer reviewed publications to which CGIAR scientists have contributed that involve the generation and use of DSI.

11. In November 2020, the CGIAR System Board approved the CGIAR Research Ethics Code as a cross-CGIAR Policy.¹¹ The purpose of the Code is to ensure that clear, achievable and relevant standards of ethical conduct apply to all CGIAR Research. Section 4.3 of the code sets out mandatory ethical standards applicable to CGIAR research involving modern biotechnology, and includes considerations related to the management of intellectual property rights over biotechnologies and the evaluation of socio-economic impacts from the use of modern biotechnologies. As a complementary resource, CGIAR has adopted two accompanying Q&A documents related to the use of genetic engineering and genome editing technologies in CGIAR Centers and research programmes.¹²

12. CGIAR genebanks have used the Plant Treaty's Global Information System on Plant Genetic Resources for Food and Agriculture (GLIS)¹³ to mint digital object identifiers (GLIS DOIs) for more than 850,000 accessions of materials held in genebanks. These GLIS DOIs are globally unique digital identifiers that facilitate the documentation and discovery of PGRFA and associated information, including DSI. Appropriately referenced in third party information systems and scientific literature, any digital information can be made accessible to GLIS through GLIS DOIs. An increasing number of scientific publications by CGIAR scientists include the DOIs linking information to the PGRFA used in those studies. Use of GLIS DOIs is voluntary but is viewed as critical for adding value to conserved, available PGRFA and, ultimately, to be able to generate and share benefits from the sustainable use of those resources. In addition to obtaining and using GLIS-DOIs for materials in their genebanks, one CGIAR Center, IRRI, has already minted DOIs for some derived breeding materials, and another, ICRISAT, is piloting a system for minting DOIs for Centers' breeding materials. Another Center, CIMMYT, is developing software to provide an interface between GRIN-global¹⁴ (a genebank information management system), EasySMTA¹⁵ (an online tool for generating standard material transfer agreements and reporting to the Plant Treaty's governing body), and DOI registration in the GLIS.

13. CGIAR representatives participated in the meeting of the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources held in March 2020. CGIAR scientists are also following and

⁸ More information concerning the CGIAR portfolio of research and development activities is available at <https://www.cgiar.org/news-events/news/cgiar-announces-new-portfolio-to-transform-food-land-and-water-systems-in-a-climate-crisis/>

⁹ The report is available in English (<https://www.cbd.int/abs/DSI-views/CGIAR-DSI-en.pdf>), French (<https://www.cbd.int/abs/DSI-views/CGIAR-DSI-fr.pdf>), and Spanish (<https://www.cbd.int/abs/DSI-views/CGIAR-DSI-es.pdf>).

¹⁰ <https://www.cgiar.org/food-security-impact/results-dashboard/>

¹¹ The CGIAR Ethics Code is available at <https://cgspace.cgiar.org/bitstream/handle/10568/113003/CGIAR-Research-Ethics-Code-Approved-3Nov2020.pdf?sequence=1&isAllowed=y>.

¹² The two documents on questions and answers about genetic engineering and genome editing can be accessed at <https://cgspace.cgiar.org/handle/10568/113825> and <https://cgspace.cgiar.org/handle/10568/113824>

¹³ <https://ssl.fao.org/glis/>

¹⁴ <https://www.grin-global.org/>

¹⁵ <https://mls.planttreaty.org/itt/>

contributing to several other intergovernmental and “informal” dialogues related to the international governance of DSI. For example, in July 2021, CGIAR Scientists moderated regional consultative dialogues with scientists and policymakers in Asia and the South Pacific, and North America and Europe that were hosted by the DSI Scientific Network.¹⁶

14. CGIAR previously made submissions to the Governing Body of the Plant Treaty and the Ad Hoc Open Ended Working Group to Enhance the Functioning of the Multilateral System of Access and Benefit-sharing (WG-EFMLS) concerning the possibility of adopting a subscription system – as part of the multilateral system - whereby benefits associated with the use of both plant genetic resources and related genomic information could be equitably shared without creating barriers to the availability and use of such information for agricultural research and developments. While the negotiations of the WG-EFMLS were suspended by the Governing Body in 2019, CGIAR is hopeful that some resolution to outstanding tensions concerning DSI derived from PGRFA can eventually be forged by taking advantage of the basic architecture of the Plant Treaty’s multilateral system, given that it was developed to reflect the needs (and opportunities for benefit sharing) in the agricultural research and development sector. Clearly efforts and developments under the Plant Treaty and Convention on Biological Diversity need to be complementary and mutually supportive, so dynamic communication and facilitation between the two bodies is critical.

15. The Secretariat of the Convention on Biological Diversity and the Secretariat of the Plant Treaty are making contributions to a project that is being implemented by the Alliance of Bioversity International and CIAT and the Plant Genetic Resource Centre of the Southern African Development Community (SADC), and is focussing on the creation of a subregional network to promote the conservation and sustainable use of crop wild relatives and associated benefit-sharing. Project partners will be considering options for the mutually supportive implementation of the Nagoya Protocol and the Plant Treaty and developing agreements on how DSI can be generated and used, and benefits shared, in the context of that project.

C. International Treaty on Plant Genetic Resources for Food and Agriculture

16. Following the submission of information by Contracting Parties and other stakeholders on the impact of DSI on the objectives of the International Treaty, the Governing Body of the International Treaty, at its eighth session, in November 2019, included DSI in the Multi-Year Programme of Work of the Governing Body (see Resolution [13/2019](#)). Specifically, the Governing Body:

(a) Noted the work being done on “digital sequence information” in the framework of the Convention on Biological Diversity and the Commission on Genetic Resources for Food and Agriculture (CGRFA);

(b) Requested the Secretary to continue following the discussions in other forums and to continue coordinating with the secretariats of the Convention on Biological Diversity and the CGRFA in any related activities in order to ensure coherence and avoid duplication of efforts;

(c) Further requested the Secretary to inform the Governing Body at its ninth session of the state of discussions and outcomes.

17. In the Multi-Year Programme of Work, DSI is an item for the upcoming Ninth and the subsequent Tenth Sessions of the Governing Body. At its ninth session, the Governing Body will consider the status of the science-based process on ‘DSI’ of the Convention on Biological Diversity, and the discussions of the CGRFA on ‘DSI’ in relation to PGRFA. It will also consider additional inputs from Contracting Parties and the updates by the Secretary on the Convention on Biological Diversity and CGRFA processes. At its tenth session, the Governing Body will again consider the potential implications of the use of “digital sequence information” on PGRFA for the objectives of the International Treaty.

18. In addition to the rolling review in the Multi-Year Programme of Work, DSI are also under consideration in the context of the Global Information System (GLIS) under Article 17 of the Plant Treaty.

¹⁶ See https://www.dsmz.de/fileadmin/user_upload/Presse/DSI/DSI_Scientific_Network_Asia_Pacific_Webinar_Flyer.pdf and https://www.dsmz.de/fileadmin/user_upload/Presse/DSI/DSI_-_North_America_Europe_Flyer.pdf

At its Eighth Session, the Governing Body thanked the stakeholders and users who submitted information on the application of digital object identifiers (DOIs) to digital sequence information/genetic sequence data (DSI/GSD) and requested the Scientific Advisory Committee (SAC) on the GLIS to continue considering scientific and technical issues of relevance to DSI/GSD and national legislation, as appropriate.¹ At its meeting in April 2021, the SAC noted that the information provided on DSI developments in other forums was helpful and advised the Secretariat to continue monitoring these relevant processes and informing the Committee. It also stressed that the forum for discussing DSI/GSD in relation to PGRFA and benefit-sharing should be the International Treaty through its Governing Body.

19. In the current intersessional period, the Secretariat of the International Treaty collaborated with the FAO Legal Office on a study on agricultural data policy and management, which has been commissioned to the Global Open Data for Agriculture and Nutrition Initiative (GODAN) and the University of Ottawa. The study under preparation is intended to develop knowledge and insights into existing legal and policy structures of agricultural data ownership, control and management, including intellectual property rights, and, in particular, addresses the case of the International Treaty.

D. 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

20. In its resolution [69/292](#), the General Assembly decided to develop an international legally binding instrument on the conservation and sustainable use of marine biodiversity of areas beyond national jurisdiction under the United Nations Convention on the Law of the Sea. To that end, the General Assembly also decided to establish a preparatory committee to make substantive recommendations to the General Assembly on the elements of a draft text of an international legally binding instrument under the Convention on the Law of the Sea.

21. Following the completion of the work of the preparatory committee in 2017, the General Assembly adopted resolution [72/249](#) 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. In the resolution, the General Assembly decided to convene a conference to elaborate the text of such an instrument, with a view to developing that instrument as soon as possible.

22. Marine genetic resources, including the sharing of benefits, have been central to the discussions of the Conference, which is addressing the topics identified in the package agreed in 2011, namely the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction, in particular, together and as a whole, marine genetic resources, including questions on the sharing of benefits, measures such as area-based management tools, including marine protected areas, environmental impact assessments and capacity-building and the transfer of marine technology. Cross-cutting issues, such as institutional arrangements and dispute settlement, have also been addressed by the Conference. The first session of the Conference was convened in 2018 and the second and third sessions in 2019. At the third session, delegations began text-based negotiations on the basis of a draft text of an agreement developed by the President of the Conference ([A/CONF.232/2019/6](#)). The fourth session of the Conference, which was scheduled to be held in August 2021 pursuant to General Assembly resolution [75/239](#), was further postponed by the General Assembly to the earliest possible available date in 2022, preferably during the first half of the year. It will consider a revised draft text of an agreement ([A/CONF.232/2020/3](#)). Part II of the revised draft text is entirely dedicated to marine genetic resources, including questions on the sharing of benefits, and contains provisions on, inter alia, access to marine genetic resources of areas beyond national jurisdiction, access to traditional knowledge of indigenous peoples and local communities associated with marine genetic resources of areas beyond national jurisdiction, sharing of benefits, including modalities for such sharing, and monitoring. As reflected in the various President's documents and compilations of proposals prepared in the context of the Conference, different views have been expressed on whether access to and benefit-sharing from genetic resources in silico, digital sequence data, genetic sequence data or digital sequence information would be included in the agreement, with different views also expressed on terminology.

E. World Health Organization

23. Timely 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. Establishing mechanisms for fair and equitable sharing of the benefits arising from the utilization of the concerned resources has become a central element of ensuring expedited pathogen sharing.

24. In May 2019, the Seventy-second World Health Assembly adopted two decisions concerning the public health implications of the Nagoya Protocol. These actions were taken months before the emergence of the virus that causes COVID-19, the spread of which has highlighted the importance of rapid pathogen sharing in the context of public health emergencies. Given the global impact of the COVID-19 epidemic, this report includes a section that focuses specifically on cooperation across countries in sharing the SARS-CoV-2 virus and the SARS-CoV-2 genetic sequence data, and the WHO COVID-19 Reference Laboratory Network.

25. In its decision [WHA72\(12\), the World Health Assembly](#) focused on two aspects of influenza virus sharing and associated public health considerations: influenza virus sharing through the Global Influenza Surveillance and Response System (GISRS),¹⁷ on the one hand, and the treatment of influenza virus sharing in existing relevant legislation and regulatory measures, including those implementing the Nagoya Protocol,¹⁸ on the other. In implementing decision WHA72(12), WHO gathered data from GISRS and non-GISRS laboratories (including private sector entities) to better understand the challenges, opportunities and implications for public health associated with influenza virus sharing, including identifying specific instances in which influenza virus sharing was hindered and seeking ideas on how to mitigate delays in virus sharing. WHO also conducted a systematic review of all laws and policy documents that deal with influenza virus sharing and that were available in the Convention on Biological Diversity Access and Benefit-Sharing Clearing-House.¹⁹ For each WHO Member State and the European Union, entries tagged in the Clearing-House as “legislative, administrative, or policy measures” (instruments) were reviewed. Each instrument was then coded to identify if and how genetic resources were defined in the law or a policy instrument. This analysis covered express consideration of pathogens, influenza viruses (both seasonal and those with human pandemic potential) and genetic sequence data. Each instrument was also coded to determine whether it referred to instruments relevant to influenza virus sharing and public health, including the PIP Framework and the International Health Regulations (2005), as well as whether the instrument incorporated relevant provisions under the Nagoya Protocol, including recognition of specialized international access and benefit-sharing instruments (pursuant to Article 4(4) of the Nagoya Protocol) and special considerations (Article 8(b)). WHO also produced a [report](#) on influenza virus sharing that specifically addressed the request made in paragraph 1(a) of decision WHA72(12).²⁰ Additionally, as influenza virus-sharing issues continue to arise, and for seasonal influenza viruses in particular due to the complexities of national access and benefit-sharing laws, WHO is seeking inputs from its Member States on these issues and best practices for mitigating them; this is in alignment with decisions WHA73(14)²¹ and WHA72(12). WHO is working with its GISRS partners to identify short- and long-term solutions to provide greater clarity on influenza virus-sharing commitments and expectations as part of GISRS terms of reference.

¹⁷ See decision WHA72(12), paragraph 1(a).

¹⁸ See decision WHA72(12), paragraph 1(b).

¹⁹ The Access and Benefit-Sharing Clearing-House. Montreal: Convention on Biological Diversity; 2020 (<https://absch.cbd.int/>, accessed 27 October 2020).

²⁰ The report, in all 6 WHO official languages, is found at: [Implementation of Decision WHA72\(12\) \(who.int\)](#)

²¹ See paragraphs 2(d)(i)-(ii) of [decision WHA73\(14\)](#).

26. In decision [WHA72\(13\)](#), the Director-General was requested to broaden engagement with Member States, the Secretariat of the Convention on Biological Diversity,²² relevant international organizations and relevant stakeholders to provide information on current pathogen-sharing²³ practices and arrangements, the implementation of access and benefit-sharing measures, as well as the potential public health outcomes and other implications. WHO coordinated across its divisions, including the Secretariat of the Pandemic Influenza Preparedness (PIP) Framework, focal points for the International Health Regulations (2005), and the food safety and communicable disease teams, and contacted Member States, partners and other stakeholders, including the Secretariat of the Convention on Biological Diversity, United Nations agencies, funds and programmes such as the FAO, other international agencies such as the OIE, and civil society and public sector entities. These engagements were both formal – including two all-stakeholder briefings in late 2019 – and informal and continued throughout 2020. WHO 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 Convention on Biological Diversity and in consultation with various international organizations, including the FAO, OIE and experts, including members of the Pandemic Influenza Preparedness Framework Advisory Group. To ensure a broad reach in collecting data, the survey was made available on the WHO website to all stakeholders in English, French and Spanish. WHO contacted Member States, WHO collaborating centres, non-State actors in official relations with WHO, partner agencies, laboratories and laboratory networks, and private sector stakeholders to alert them to the opening of the survey. The Secretariat of the Convention on Biological Diversity issued a notification to all Parties to the Convention to encourage them to participate.²⁴ The World Health Assembly considered [the report](#) on the implementation of decision WHA72(13) in May 2021.²⁵

27. Although the results of implementing both decisions are wide-ranging, a summary of the most relevant aspects for the Open-Ended Working Group’s consideration of the issue of digital sequencing information includes:

(a) Decision WHA72(12): respondents to the survey on pandemic influenza sample sharing noted that implementation of access and benefit-sharing legislation, such as that on the Nagoya Protocol, has slowed the sharing of seasonal influenza samples between GISRS laboratories and some countries and WHO collaborating centres in the past two years. Most cases required lengthy bilateral negotiation of a material transfer agreement between a national influenza centre and a WHO collaborating centre. New legislation created uncertainty for national influenza centres and national focal points due to a lack of clarity about access and benefit-sharing or Nagoya Protocol requirements. The report noted that delays in the sharing of some influenza viruses due to new legislation and regulations took six to nine months to resolve or remained unresolved as of December 2019. The report also noted that there have been delays in the case of non-GISRS laboratories. For vaccine producers, recent legislation implementing the Nagoya Protocol has posed a challenge for the timely receipt and use of some seasonal influenza candidate vaccine viruses. In the influenza context, any delays in virus sharing due to national access and benefit-sharing and Nagoya Protocol requirements have implications for public health because they jeopardize the vaccine virus selection process, the timely development and use of candidate vaccine viruses and access to vaccines. Navigating a system in which each country has different access and benefit-sharing requirements that must be negotiated bilaterally

²² The WHO Secretariat has worked closely with the Secretariat of the Convention on Biological Diversity throughout the implementation of decision WHA72(13), including on developing the all-stakeholder survey, participation in joint stakeholder briefings, drafting the interim report and collaborative stakeholder outreach.

²³ For the purposes of this report, the term “pathogen sharing” refers specifically to physical sample sharing. Where the text discusses non-physical samples (i.e. genetic sequence data), this is noted explicitly.

²⁴ Notification – Survey on pathogen sharing, including for influenza, and access and benefit-sharing arrangements. Montreal: Secretariat of the Convention on Biological Diversity; 27 January 2020 (SCBD/NPU/DC/WY/BG/RKi/88360; <https://www.cbd.int/doc/notifications/2020/ntf-2020-012-abs-en.pdf>, accessed 30 November 2020).

²⁵ The report in all six official languages of WHO can be found at https://apps.who.int/gb/ebwha/pdf_files/EB148/B148_21-en.pdf.

is burdensome and inefficient and could cause inequities in benefit sharing and limit virus access for research and development of improved influenza vaccines;

(b) Decision WHA72(13): Nearly all responses indicated that genetic sequence data should be differentiated from physical sample sharing, noting that the benefit to public health is linked to the ability to share sequences almost instantaneously across the world at no cost. Respondents particularly highlighted differences due to the risks of handling physical samples; the broader potential for sharing genetic sequence data; and the huge logistic differences (relating to biosafety and biosecurity, cold-chain storage equipment, qualified personnel, correct certificates and adequate transportation). Nonetheless, it was also noted that sharing gene sequences can also be more complex than sharing physical samples because of the difference in scale and the ease and multiple ways of sharing, altering and re-sharing. With genetic sequence data, the implications for sharing or making data publicly available are more to do with ensuring appropriate credit for the work and data privacy issues. It was also noted that, thus far, it had not been possible to identify a feasible way of tracking genetic sequence data, as current audit systems did not allow monitoring of the uses made of sequence data downloaded from public databases. In addition, genetic sequence data cannot completely replace physical material, which is needed for assay validations, resistance and comparisons. Genetic sequence data and physical pathogen samples can serve quite different functions for public health: genetic sequence data form the bases of rapid response surveillance tools that can provide a high-resolution view of pathogen evolution, which is particularly important in outbreak situations, while physical pathogen samples may be essential for assessing the potential of any medical products for pathogen outbreaks.

Pathogen sharing in the context of the COVID-19 pandemic

28. Following the detection of SARS-CoV-2 virus, which causes COVID-19, genetic sequence data were made available by being uploaded to the GISAID Initiative database and a number of other databases, including GenBank and virological.org. Large-scale, rapid, geographically dispersed sharing of SARS-CoV-2 sequences has generally occurred during the pandemic. For example, laboratories from over 100 Member States have deposited SARS-CoV-2 sequences into GISAID.

29. As an urgent response to the public health needs arising from the COVID-19 outbreak, WHO established the WHO COVID-19 Reference Laboratory Network. Each laboratory in the network has agreed to: support capacity-building for laboratories, particularly those in low- and middle-income countries, for diagnosis of COVID-19; provide a global reference resource of well-characterized viral strains and sequences; track the evolution of the virus causing COVID-19 and identify changes that may be relevant to diagnostic tests, vaccine development and/or antiviral treatment; and develop and implement state-of-the-art methods and develop assays to perform the laboratory's tasks arising from its participation in the network. They also agree to limitations on the use of the virus and its sharing, to treating all virus materials and clinical samples as confidential and proprietary to the providing country, and to ensure that materials are not transferred or provided to any third party, unless clear standards are met.²⁶

F. World Intellectual Property Organization

30. There are six main contexts in which the topic of digital sequence information has been considered in the context of the [World Intellectual Property Organization \(WIPO\)](#).

31. Member States have referred to the topic in the WIPO [Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore \(IGC\)](#). The use of digital sequence information was discussed in the context of patent disclosure requirements for genetic resources and traditional knowledge. 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](#)" of IGC.

²⁶ The terms of reference for WHO reference laboratories providing confirmatory testing for COVID-19 are available at <https://www.who.int/publications/m/item/terms-of-reference-for-who-reference-laboratories-providing-confirmatory-testing-for-covid-19> (accessed 27 October 2020).

32. While the COVID-19 pandemic disrupted the meetings of the IGC in 2020 and 2021, Members wanted to see that the work on the issues continues and, as part of that effort, a [WIPO Seminar on Intellectual Property and Genetic Resources](#) was organized in January 2021. While the Seminar was not formally part of the IGC process as such, it contributed in a valuable way to the work of WIPO on these issues. The Seminar contained a theme on “Intellectual Property and Genetic Resources: New and Emerging Technologies.” Under this theme, speakers with suitable technical and legal expertise and diverse perspectives were invited to explain some of the relevant new and emerging technologies and reflect on how the impact of these new and emerging technologies may relate to the negotiations under way in IGC. DSI and related technologies were included among these new and emerging technologies. The seminar addressed important issues negotiated in IGC and gave insightful historical accounts of how the issues have evolved on the international stage over many decades; shared information about the experiences in and proposal from countries, views of industry and indigenous peoples; informed about new data mining in machine learning techniques that can increasingly unlock information coming from the patent system; and learned a huge amount about new technologies, such as DSI that are disrupting current business models and legal frameworks.

33. In 2020, WIPO also participated in the Convention on Biological Diversity Ad Hoc Expert Group on Digital Sequence Information on Genetic Resources, which was held from 17 to 20 March 2020. In the “Outcomes of the AHTEG”, as contained in annex I of the report of the AHTEG, the experts noted that standard ST.26 under WIPO on machine readability of nucleotide sequence listings may facilitate data consistency between patent information systems and INSDC, and therefore facilitate comparison of patent information and accessions in INSDC” (CBD/DSI/AHTEG/2020/1/7, para. 22).

34. In the publication [Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge](#), which was requested by the WIPO IGC, the issue of digital sequence information appears in the discussion on what relationship or link between the subject matter of a patent disclosure and the claimed invention will trigger the application of a patent disclosure requirement for a genetic resource. The WIPO *Key Questions* represent an updated version of the WIPO [Technical Study on Disclosure Requirements in Patent Systems Related to Genetic Resources and Traditional Knowledge](#), which the Conference of the Parties to the Convention on Biological Diversity had requested WIPO to prepare in 2002 and which was made available to the Conference of the Parties in 2004.

35. The WIPO Online Database of Biodiversity-related Access and Benefit-sharing Agreements (Online Database) contains, among other things, actual access and benefit-sharing agreements which either directly set out rights and obligations concerning data from genome sequencing projects or indirectly address rights to such data. Recently, additional contracts have been added to the database which contain clauses specific to intellectual property rights management for research data. The online database and the WIPO [Draft Intellectual Property Guidelines for Access to Genetic Resources and Equitable Sharing of the Benefits arising from their Utilization](#), which have been based on it, have been referenced on the [ABS Clearing House](#).²⁷

36. Issues related to digital sequence information have been addressed in-depth in the training and capacity-building activities on intellectual property and genetic resources of WIPO. For example, WIPO offers a Distance Learning Course on Intellectual Property and Genetic Resources in the Life Sciences, which addresses, inter alia, intellectual property aspects of data-driven innovation in the life sciences, including aspects related to DSI. Several other WIPO training activities have also addressed issues related to digital sequence information, intellectual property and genetic resources.

²⁷ See <https://absch.cbd.int/database/A19A20/ABSCH-A19A20-SCBD-238061>.