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

Note by the Executive Secretary

Addendum

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

INTRODUCTION

1. At their second meeting, the Parties to the Nagoya Protocol adopted [decision NP-2/5](#) on cooperation with other international organizations, conventions and initiatives. In paragraph 4 of the decision, the Executive Secretary was requested “to continue to engage with relevant ongoing processes and policy debates, including in the World Health Organization, the World Intellectual Property Organization, the Commission on Genetic Resources for Food and Agriculture of the Food and Agriculture Organization of the United Nations, the International Treaty on Plant Genetic Resources for Food and Agriculture, the CGIAR Centers and others, as appropriate, to collect information on current discussions on the relationship between the use of digital sequence information on genetic resources, and to include relevant information gathered during these engagements in the compilation of views referred to in decision XIII/16, paragraph 3(a) of the Conference of the Parties”.

2. In [decision XIII/16](#) on digital sequence information on genetic resources, Parties, other Governments, indigenous peoples and local communities, and relevant organizations and stakeholders were invited to submit views and relevant information to the Executive Secretary on the potential implications of the use of digital sequence information on genetic resources for the three objectives of the Convention on Biological Diversity (para. 2), and the Executive Secretary was requested to prepare a compilation and synthesis of the views and information submitted, including the information gathered from engagement with relevant ongoing processes and policy debates (para. 3 (a)).

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3. Against this background, section I of the present document summarizes relevant ongoing international processes and policy debates of relevance to digital sequence information on genetic resources and its relationship with access and benefit-sharing. In addition, Section II contains a synthesis of the views and information received through the submissions which relate specifically to digital sequence information in other international processes. The information contained in section II is complementary to the synthesis of information and views ([CBD/DSI/AHTEG/2018/1/2](#)). The submissions received have also been made available online.¹

I. RELEVANT ONGOING INTERNATIONAL PROCESSES AND POLICY DEBATES

4. The Executive Secretary of the Convention on Biological Diversity has continued to engage with relevant ongoing processes and policy debates, including with regard to digital sequence information on genetic resources, and to cooperate with other international organizations on this matter. The following provides an overview of developments in other international processes of relevance to digital sequence information on genetic resources and its relationship to access and benefit-sharing.

A. Commission on Genetic Resources for Food and Agriculture

5. The sixteenth regular session of the [Commission on Genetic Resources for Food and Agriculture](#) was held at the headquarters of the Food and Agriculture Organization of the United Nations in Rome from 30 January to 3 February 2017. In his statement to the Commission, the Executive Secretary outlined key outcomes from the [United Nations Biodiversity Conference](#) of relevance to the work of the Commission, including the decisions on digital sequence information on genetic resources.

6. In its deliberations, the Commission established a new work stream on digital sequence information on genetic resources for food and agriculture (GRFA) and requested its Secretary to prepare an exploratory fact-finding scoping study on this issue. This study is meant to provide information on, among other things, terminology used in this area, actors involved, the types and extent of uses, as well as the relevance of digital sequence information on GRFA for food security and nutrition. The study will facilitate consideration by the Commission, at its next session, of the implications of the use of “digital sequence information on GRFA” for the conservation and sustainable use of GRFA, including exchange, access and the fair and equitable sharing of the benefits arising from their use. The Commission agreed to submit the study to the Executive Secretary of the Convention on Biological Diversity.²

7. The Commission also requested its Secretary to invite members to submit information on the use of digital sequence information on GRFA and potential implications for the conservation and sustainable use of GRFA, including exchange, access and benefit-sharing, and to submit this information to the Executive Secretary of the Convention on Biological Diversity as a contribution to the process established in decision XIII/16.³ The Secretariat of the Convention received a number of submissions transmitted by the Commission Secretariat in this regard. These have been made available online and the views and information provided have been incorporated in the synthesis.⁴

B. CGIAR Centers

8. The [CGIAR](#) Portfolio 2017-2022 sets out the research areas and priorities for the CGIAR Research Centers to be undertaken in collaboration with partners. The Portfolio includes a number of research programmes grouped into two clusters – one cluster on agri-food systems, the other cluster consisting of cross-cutting global integrating programmes. In addition to the programmes, the CGIAR Portfolio 2017-2022 also includes three research support platforms that underpin the research of the

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

² See paras. 86-87 of the report on the sixteenth regular session of the Commission ([CGRFA-16/17/Report/Rev.1](#)).

³ [Ibid.](#), para. 88.

⁴ For further information on the submissions received via the Secretary of the Commission, see the annex to the synthesis of views and information ([CBD/DSI/AHTEG/2018/1/2](#)).

whole system. One of these platforms is on “Big Data for Agriculture”.⁵ Another platform is the “Genebank Platform”, which consists of three modules: conservation, use and policy. The policy module coordinates representation of the CGIAR in intergovernmental forums dealing with genetic resources policy issues.⁶

9. As outlined in its submission pursuant to decision XIII/16, paragraph 2, CGIAR Centers 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.

10. The Secretariat of the Convention was also invited to present information on the process on digital sequence information on genetic resources under the Convention and the Nagoya Protocol to meetings of the CGIAR intellectual property focal points and genebank managers.

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

11. Prior to and back-to-back with the [seventh session of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture](#), a special event on genomics information was held in Kigali on 28 October 2017. A multidisciplinary team of experts informed the International Treaty community about current and emerging technologies, practices related to the generation, exchange and use of genomic information in digitized forms, which are relevant for the key objectives and structural dimensions of the International Treaty and its Multilateral System of Access and Benefit-Sharing in particular. The team of experts presented the methodology and findings of a scoping study commissioned by the Secretariat of the International Treaty. The scoping study considered the main features of the ABS approach that the International Treaty follows, i.e. pooling and standardization to facilitate access, decoupled benefit-sharing from individual providers, and diversity and interdependence of benefits. In keeping with such features, the study explored questions related to: (a) technology and data management (e.g., the characteristics of the technological change; whether genomics information can be traced to material); (b) ownership, intellectual property practices and monitoring of digital sequence information; and (c) benefit-sharing (e.g., how actors currently assign value to digital sequence information – how accessible digital sequence information is to individuals, institutions and countries).

12. The study is available online, together with the presentations delivered at the special event.⁷ The Secretariats of the International Treaty, the Commission on Genetic Resources for Food and Agriculture (see above) and the Convention on Biological Diversity exchanged information on the preparation of their respective studies. The experts undertaking the research for these different studies also engaged in some discussions.

13. Furthermore, the Secretariat of the International Treaty invited the Secretariat of the Convention on Biological Diversity to participate in the special event on genomics information where a representative of the Secretariat of the Convention provided an update on the process on digital sequence information on genetic resources under the Convention and the Nagoya Protocol.

14. In recognition of the relevance of the topic to multiple work tracks, the Governing Body of the International Treaty at its seventh session provided guidance on how to advance the further consideration of digital sequence information in the biennium 2018-2019. With regard to the Multilateral System of Access and Benefit-Sharing, the reconvened Open-Ended Working Group on the enhancement of the Multilateral System will continue considering issues regarding genetic information associated with the

⁵ For information on the CGIAR Portfolio 2017-2022, see <http://www.cgiar.org/about-us/our-programs/>.

⁶ See “Reports from Institutions that have Concluded Agreements with the Governing Body under Article 15 of the International Treaty” (document IT/GB-7/17/24), available online at: <http://www.fao.org/3/a-mu437e.pdf> (August 2017), especially pp. 7-8.

⁷ See http://www.fao.org/fileadmin/user_upload/faoweb/plant-treaty/GB7/gb7_90.pdf and <http://www.fao.org/plant-treaty/seventh-governing-body/special-event/en/>. The study has also been made available as an information document ([CBD/DSI/AHTEG/2018/1/INF/1](#)). See also the submission from the International Treaty.

material accessed from the Multilateral System, including in the context of revisions to the Standard Material Transfer Agreement.⁸

15. In relation to the Global Information System under Article 17 of the International Treaty (GLIS), the Governing Body mandated the GLIS Scientific Advisory Committee to consider the scientific and technical issues of relevance to genetic sequence information, insofar as such information is generated from the use of plant germplasm and related to the implementation of the vision and programme of work for GLIS.⁹

16. The Governing Body invited Contracting Parties, other governments, relevant stakeholders and individuals with relevant expertise to provide information to the Governing Body on, inter alia: (a) terminology; (b) actors involved with digital sequence information derived from plant genetic resources for food and agriculture; (c) the types and extent of uses of digital sequence information; (d) the relevance of digital sequence information to food security and nutrition. The information will be compiled for the next session of the Governing Body to inform discussions on the potential implications of digital sequence information for the objectives of the International Treaty, including exchange, access and the fair and equitable sharing of the benefits arising from their use, and in view of the possible inclusion of digital sequence information in the Multi-Year Programme of Work of the International Treaty. The Governing Body also requested the Secretary to continue following processes in relevant fora and coordinate with the Secretariat of the Convention on Biological Diversity to ensure coherence and avoid duplication of efforts.¹⁰

D. United Nations General Assembly – international legally binding instrument under the United Nations Convention on the Law of the Sea on the conservation and sustainable use of marine biodiversity of areas beyond national jurisdiction

17. 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 (UNCLOS). 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 UNCLOS.

18. The Preparatory Committee completed its work on 21 July 2017 with the adoption of its report, including recommendations to the General Assembly on the elements of a draft text under UNCLOS ([A/AC.287/2017/PC.4/2](#)). As reflected in the various Chair's overviews and non-papers prepared in the context of the Preparatory Committee, different views have been expressed on whether access to and benefit-sharing from genetic resources *in silico* would be included in the scope of an international instrument under UNCLOS.¹¹

19. At its seventy-second session, 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 framework as soon as possible. Negotiations would address topics identified in the package agreed to in 2011, which includes marine genetic resources, including

⁸ Resolution 2/2017, available at <http://www.fao.org/3/a-mv104e.pdf>

⁹ Resolution 5/2017, available at <http://www.fao.org/3/a-mv103e.pdf>

¹⁰ Resolution 13/2017, available at <http://www.fao.org/3/a-mv176e.pdf>

¹¹ Submission from the Office of Legal Affairs, Division for Ocean Affairs and the Law of the Sea.

questions on the sharing of benefits.¹² The conference would convene for four sessions of 10 working days each, with the first taking place in September 2018, the second and third in 2019, and the fourth in the first half of 2020.

E. World Health Organization

20. In 2011, the [World Health Assembly](#) adopted the [Pandemic Influenza Preparedness Framework](#) for the sharing of influenza viruses and access to vaccines and other benefits (PIP Framework). The PIP Framework refers to “genetic sequences”, which is defined to mean “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 virus.”

21. Section 5.2 of the PIP Framework addresses genetic sequence data and paragraph 1 provides that “[g]enetic sequence data, and analyses arising from that data, relating to H5N1 and other influenza viruses with human pandemic potential should be shared in a rapid, timely and systematic manner with the originating laboratory and among WHO [global influenza surveillance and response system] laboratories.”

22. Furthermore, in both Annex 4 and Annex 5 to the PIP Framework, the WHO global influenza surveillance and response system laboratories are required to “submit genetic sequences data to GISAID and Genbank or similar databases in a timely manner consistent with the Standard Material Transfer Agreement” (para. 9).

23. The PIP Framework establishes an Advisory Group to monitor implementation of the Framework and provide evidence-based reporting, assessment and recommendations on its functioning. In section 5.2.4 of the PIP Framework, the WHO Director-General is requested “to consult the Advisory Group on the best process for further discussion and resolution of issues relating to the handling of genetic sequence data from H5N1 and other influenza viruses with pandemic potential as part of the [PIP] Framework.”

24. The PIP Framework Advisory Group began working on issues related to the handling of genetic sequence data in 2013. Since then, it has conducted technical work, in consultation with PIP stakeholders, in order to understand how genetic sequence data is developed, shared and used with a view to proposing to the Director-General options for handling genetic sequence data under the Framework that are consistent with and reflect the Framework’s objectives.¹³

25. Section 7.4 of the PIP Framework addresses the monitoring and review of the Framework and, among other things, it provides that the Framework and its annexes will be reviewed by 2016 with a view to proposing revisions reflecting developments, as appropriate, to the World Health Assembly in 2017 (section 7.4.2). A Review Group was established to carry out this work and it submitted its final report to the WHO Director-General in October 2016 for consideration by the 140th Executive Board of WHO and the Seventieth World Health Assembly (held in May 2017).

26. Among other things, the review of the PIP Framework addressed the issue of genetic sequence data and made a number of recommendations in this regard in its final report.¹⁴

27. Following the report, the Seventieth World Assembly adopted [decision WHA70\(10\)](#). The decision included a request to the Director-General, regarding the Review Group’s recommendations concerning

¹² The topics in the package agreed to in 2011 are “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”. See the submission from the United Nations Division of Ocean Affairs and the Law of the Sea.

¹³ For further details on the work undertaken, see http://www.who.int/influenza/pip/advisory_group/gsd/en/.

¹⁴ See “Report of the 2016 PIP Framework Review Group”, Annex 1 to document EB140/16 (29 December 2016), online: http://apps.who.int/gb/ebwha/pdf_files/EB140/B140_16-en.pdf?ua=1.

genetic sequence data, to conduct a thorough and deliberative analysis of the issues raised, including the implications of pursuing or not pursuing possible approaches (paragraph 8(b)).¹⁵ The World Health Assembly also requested the Director-General to continue consultations with the Secretariat of the Convention on Biological Diversity (para. 8(f)).

28. To implement the request in paragraph 8(b), the Director-General has initiated an analysis to address, among other things, the implications of including or not including genetic sequence data in the definition of PIP biological materials under section 4.1 of the PIP Framework. The Secretariat of the Convention participated in an initial consultation session in November 2017 as part of this process. The Director-General is to report to the Seventy-first World Health Assembly (to be held in May 2018) on progress in implementing decision WHA70(10).¹⁶

F. World Intellectual Property Organization

29. There are four main contexts in which the topic of digital sequence information has been considered in the context of the [World Intellectual Property Organization \(WIPO\)](#) and its Program 4.

30. Member States have discussed 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.

31. In the publication [Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge](#), which was requested by 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.

32. 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. 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](#).¹⁷

33. 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. Several WIPO training activities have addressed issues related to digital sequence information, intellectual property and genetic resources.

II. SYNTHESIS OF VIEWS AND INFORMATION

34. A number of submissions pointed to relevant ongoing discussions in other forums and suggested that coordination and exchange of information is needed:

¹⁵ It should also be noted that the report of the PIP Framework Review Group and decision WHA70(10) also addressed other issues of relevance to the Nagoya Protocol which are beyond the scope of the present document.

¹⁶ For more information on digital sequence information in relation to public health and pathogens, see also the peer review comments submitted by WHO available via: <https://www.cbd.int/abs/dsi-gr/ahteg.shtml#peerreview>.

¹⁷ See <https://absch.cbd.int/database/A19A20/ABSCH-A19A20-SCBD-238061>.

(a) Consideration of digital sequence information on genetic resources under the Convention on Biological Diversity and the Nagoya Protocol need to take into account similar discussions happening elsewhere, such as the International Treaty on Plant Genetic Resources for Food and Agriculture and the Pandemic Influenza Preparedness Framework under the World Health Organization, in accordance with decision NP-2/5. Such discussions are especially relevant in the context of Article 8(b) and (c) of the Nagoya Protocol.¹⁸

(b) Processes on digital sequence information being undertaken by different bodies should be coordinated in order to ensure coherence and consistency. The Secretariat of the Convention should be invited to take a leading role in organizing regular exchange and coordinated planning among the secretariats of the relevant agreements to facilitate mutual supportiveness of the work streams in these different bodies.¹⁹

(c) The World Health Organization may be an appropriate source of knowledge on proportionate frameworks to ensure benefit-sharing from research based on digital sequence information which does not hinder epidemic preparedness, response efforts or international collaborations.²⁰

(d) Whenever possible, the term “digital sequence information on genetic resources” should be harmonized with the terminology used in other international treaties.²¹

¹⁸ European Union and its Member States.

¹⁹ Switzerland.

²⁰ Royal Society of Biology.

²¹ Brazil.