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AD HOC TECHNICAL EXPERT GROUP ON DIGITAL SEQUENCE INFORMATION ON GENETIC RESOURCES Montreal, Canada, 17-20 March 2020

SALIENT POINTS THAT MAY FACILITATE DELIBERATIONS BY THE AD HOC TECHNICAL EXPERT GROUP ON DIGITAL SEQUENCE INFORMATION ON GENETIC RESOURCES

Note by the Executive Secretary

I. INTRODUCTION

- 1. In <u>decision 14/20</u>, paragraph 11, the Conference of the Parties decided to establish an extended Ad Hoc Technical Expert Group (AHTEG) on digital sequence information on genetic resources¹ (DSI) to:
- a) Consider the compilation and synthesis of views and information and the peer-reviewed studies undertaken pursuant to decision 14/20;
- b) Develop options for operational terms and their implications to provide conceptual clarity on DSI, considering in particular the commissioned study concerning scope and terminology;
 - c) Identify key areas for capacity-building; and
- d) Submit its outcomes for consideration by a meeting of the open-ended working group established under decision 14/34 to be held prior to the fifteenth meeting of the Conference of the Parties.
- 2. Further, in paragraph 6, the Conference of the Parties noted that "as there is a divergence of views among Parties regarding benefit-sharing from the use of digital sequence information on genetic resources, Parties commit to working towards resolving this divergence through the process established in the present decision, with the aim of strengthening the fulfilment of the third objective of the Convention and Article 15, paragraph 7, without prejudice to the circumstances to which this article applies."
- 3. In the same decision, the Conference of the Parties requested the Executive Secretary to facilitate the work of the AHTEG by, among other things, collecting and synthesizing relevant information; commissioning the studies and coordinating peer-review; as well as convening a meeting of the AHTEG.
- 4. In response to the invitation by the Conference of the Parties for views and information as specified in paragraphs 9 and 10 of decision 14/20, a total of 37 submissions were received by the Secretariat. Among the submissions, 17 were from Parties to the Convention, 1 from a non-Party, and 19

¹ Convened in accordance with the modus operandi of the Subsidiary Body on Scientific, Technical and Technological Advice, except that there will be five experts nominated by each of the five regions.

from organizations.² The Executive Secretary has prepared a synthesis of the views and information as contained in document CBD/DSI/AHTEG/2020/1/2.³

- 5. The Executive Secretary, as requested, also commissioned several studies and made them available online for peer review. The studies are:
- (a) Study on the concept and scope of digital sequence information on genetic resources and how digital sequence information is currently used (CBD/AHTEG/DSI/2020/1/3); ("Study on concepts and scope");
- (b) Combined study on ongoing developments in the field of traceability of digital information and on databases of digital sequence information on genetic resources (CBD/AHTEG/DSI/2020/1/4) ("Study on traceability and databases"); and
- (c) 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/AHTEG/DSI/2020/1/5) ("Study on domestic measures").
- 6. A face-to-face meeting of the AHTEG is being convened. The current document has been prepared to facilitate the deliberations of the AHTEG during its meeting, particularly items 4 and 5 of the annotations of the provisional agenda (CBD/DSI/AHTEG/2020/1/1/Add.1) addressing the elements of decision 14/20, paragraph 11, which concern options for operational terms and their implications, and capacity-building, respectively. The information in the present document is drawn principally from the submissions received and the studies commissioned.⁵
- 7. Members of the AHTEG are encouraged to review the documents noted above and as listed in the annotated agenda (CBD/DSI/AHTEG/2020/1/1/Add.1) for further information.⁶
- 8. Section II of the document sets out some issues relevant to developing options for operational terms and their implications which are the focus of agenda item 4, while section III sets out some issues relevant to key areas for capacity-building which is the focus of agenda item 5.

II. CONSIDERATIONS IN DEVELOPING OPTIONS FOR OPERATIONAL TERMS AND THEIR IMPLICATIONS (AGENDA ITEM 4)

9. Decision 14/20, in its preamble, notes that the term "digital sequence information" may not be the most appropriate term and that it is used as a placeholder until an alternative term is agreed. The AHTEG is expected to develop options for operational terms and their implications to provide conceptual clarity on

² All submissions are available at: https://www.cbd.int/dsi-gr/2019-2020/submissions/ and contained in the compilation document CBD/DSI/AHTEG/2020/1/INF/1.

³ https://www.cbd.int/meetings/DSI-AHTEG-2020-01.

⁴ All draft studies and peer review comments are available at: https://www.cbd.int/dsi-gr/2019-2020/studies/.

⁵ In undertaking its deliberations, members of the AHTEG are encouraged to consider previous work undertaken on digital sequence information on genetic resources during the 2017-2018 biennium, including:

⁽a) The 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/DSI/AHTEG/2018/1/2).

⁽b) Fact-Finding and Scoping Study on digital sequence information on genetic resources in the context of the Convention and the Nagoya Protocol (CBD/DSI/AHTEG/2018/1/3).

⁽c) The report of the meeting of the AHTEG on digital sequence information on genetic resources (CBD/DSI/AHTEG/2018/1/4).

⁶ https://www.cbd.int/meetings/DSI-AHTEG-2020-01.

digital sequence information on genetic resources, considering in particular the Study on concepts and scope. Accordingly, the considerations in this section are derived principally from the Study on concepts and scope.

10. Noting that certain submissions cautioned that clarifying the scope of subject matter concerning DSI is more important than clarifying terminology to replace DSI, and also that the Study on concepts and scope uses the potential scope of DSI subject matter to inform discussions on terminology, the AHTEG may wish to commence discussions by focusing on issues of scope and the implications they raise, and then considering operational terms.

A. Scope

- 11. There are varying views regarding the type of digital sequence information associated with a genetic resource that are relevant to the Convention and the Nagoya Protocol. For example, the report of the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources (pursuant to its meeting held in Montreal, Canada, in February 2018) identified various types of information that may be relevant to the utilization of genetic resources and hence may potentially constitute DSI. Diverse views are also reflected in the current submissions. Whereas some submissions consider that DSI subject matter should be narrow in scope and limited to naturally occurring DNA or RNA nucleotides sequences, other submissions consider that a broader scope of subject matter should be adopted, for example, extending to sequence of amino acids, molecular information (such as methylation patterns) and associated metadata.
- 12. The Study on concepts and scope considers different types of data and information that may be understood to constitute DSI, including genomic, transcriptomic, metabolomic, epigenomic information as well as metadata and other types of information associated with a genetic resource or its derivatives (referred to as "subsidiary information" for convenience). The AHTEG may wish to review these elements.
- 13. The flow of data and information associated with the utilization of a genetic resource particularly the manner in which such data/information is generated (including extent of biological processing involving transcription, translation and biosynthesis) and its degree of proximity to the underlying genetic resource is used as the basis for certain new logical groups/options proposed in the Study on concepts and scope, to assist in evaluating the concept and scope of DSI.

14. These are as follows:

- a) Group 1 Narrow: concerning DNA and RNA: this group has a narrow scope or proximity to the genetic resource and is limited to nucleotide sequence data associated with transcription.
- b) Group 2 Intermediate: concerning (DNA and RNA) + proteins: this group has an intermediate scope, extending to protein sequences, thus comprising information associated with transcription and translation.
- c) Group 3 Intermediate: concerning (DNA, RNA and proteins) + metabolites: this group has a wider intermediate scope and extends to metabolites and biochemical pathways, thus comprising information associated with transcription, translation and biosynthesis.
- d) Group 4 Broad: concerning (DNA, RNA, protein, metabolites) + traditional knowledge, ecological interactions, etc.: this group has the broadest scope and includes associated data and information with the weakest proximity to the underlying genetic resource. This option includes a broadrange of subsidiary information as may be associated with a genetic resource (i.e. in addition to information associated with transcription, translation and biosynthesis) such as behavioural data,

 $^{^{7} \ \} The \ \ AHTEG \ \ report \ \ is \ \ available \ \ at \ \ \underline{https://www.cbd.int/doc/c/4f53/a660/20273cadac313787b058a7b6/dsi-ahteg-2018-01-04-en.pdf}$

information on ecological relationships, sample metadata, taxonomy, biotic/abiotic environmental factors, and traditional knowledge amongst other things.

15. The AHTEG is invited to review the proposed groups above and consider whether they can serve as basis for discussions on the concept and scope of DSI, bearing in mind that different scopes may be relevant for different purposes. In its evaluation, the AHTEG may wish to review the rationale for the proposed groups and/or the subject matter content proposed for each group.

B. Potential implications of the different options

- 16. Irrespective of the terminology ultimately used to refer to DSI, the different options for the scope of subject matter comprising DSI raise implications which are relevant to the AHTEG's discussions. The AHTEG is invited to evaluate the implications arising from the different groups proposed, with particular regard to the following issues:
- (a) Concerning traceability of different types of information: The AHTEG is invited to consider the implications of the different groups for the traceability of information to a particular genetic resource and also in identifying the source of the information, including whether it has been generated through the utilization of a genetic resource or independently. For example, based on the observations in the Study on databases and traceability, it appears that if traceability of DSI is important, a narrow-scope of DSI subject matter may be desirable given the increasing technical difficulties in identifying or inferring origin from information beyond nucleotide sequence data and perhaps proteins. If traceability is not important, it appears that an intermediate or broad-scope of subject matter may be able to be accommodated. In considering traceability, the AHTEG may also wish to also consider the implications that the different groups may have for benefit-sharing associated with DSI;
- (b) Concerning the use of DSI and technologies enabled by DSI in life sciences research and innovation processes: The AHTEG is invited to consider the implications of the different groups for technologies and/or sectors in the life sciences that could be relevant depending on scope of DSI subject matter. For example, based on the observations in the Study on concepts and scope, it appears that a narrow-scope of DSI subject matter may result in technologies driven or enabled specifically by genomic and transcriptomic information to potentially be subject to measures concerning DSI, whereas intermediate-scope of DSI subject matter may result in comparable measures applying to a broader range of life-sciences technologies, such as those driven or enabled by proteomic, metabolomic and/or epigenomic information associated with a genetic resource. It is difficult to predict the full range of technologies that could be relevant to DSI if DSI subject matter were to extend to subsidiary information associated with a genetic resource. Irrespective of the scope of DSI subject matter, based on the observations in the Study on concepts and scope it appears that all sectors of life sciences research and innovation processes would likely be comparably relevant to DSI discussions (i.e. whether commercial or not in nature and whether related, for example, to pharmaceuticals, food and agriculture or synthetic biology);
- (c) Concerning the International Nucleotide Sequence Database Collaboration (INSDC) in the open exchange and use of DSI: The AHTEG is invited to consider the implications that the different groups may have on the INSDC as the database infrastructure which underpins the open exchange of nucleotide sequence data and other information, and which facilitates traceability across the research and development spectrum including in patent applications and databases. For example, based on the observations in the Study on databases and traceability, it appears that irrespective of the scope of DSI subject matter under consideration, efforts would be needed to ensure that any measures addressing DSI and practices in the INSDC would need to be operationally aligned;
- (d) Concerning measures governing access, benefit-sharing and compliance: The AHTEG is invited to consider the implications of implementing access, benefit-sharing and compliance measures to the different groups of DSI subject-matter. For example, considering the observations in the Study on databases and traceability, the open access exchange of DSI may present significant challenges in the

context of regulating DSI through existing domestic ABS measures. Indeed, several submissions noted that existing measures focusing on access to genetic resources, when applied in the context of DSI, may give rise to potential limitations, including concerning traceability, enforceability, and transaction costs. Some submissions identified existing regulatory approaches which focus on benefit-sharing, rather than on access, in order to overcome such limitations. Both approaches are explained in the Study on domestic measures. Irrespective of the scope of DSI subject matter under consideration, any measures addressing DSI would need to consider appropriate approaches to govern access, benefit-sharing and compliance.

C. Terminology

- 17. In considering alternative terminology that is better suited to convey the concept and scope associated with DSI, the AHTEG may wish to commence by considering the limitations identified in the various submissions, and also in the Study on concepts and scope, associated with the constituent terms 'digital', 'sequence' and 'information'.
- 18. The AHTEG may wish to recommend options for terminology that would be best suited for each of the different groups proposed in paragraph 14, whether drawn from existing terms proposed in the submissions, the Study on concepts and scope⁸ or the Study on domestic measures, or from new terms considered appropriate by the AHTEG

III. CONSIDERATIONS REGARDING KEY AREAS FOR CAPACITY-BUILDING (AGENDA ITEM 5)

- 19. Decision 14/20 recognizes the need for capacity-building and technology transfer, as appropriate, to assist in the access, use, generation and analysis of DSI on genetic resources for the conservation and sustainable use of biodiversity and benefit-sharing. Under paragraph 11 of the same decision, the AHTEG is expected to identify key areas for capacity-building concerning DSI.
- 20. Submissions acknowledged the importance and need for capacity-building related to DSI and it is generally accepted that a lack of capacity in many countries hinders greater generation and use of DSI, particularly in developing countries. Capacity-building efforts associated with DSI need to reflect national needs and priorities, as well as meeting the needs of communities that have contributed to conservation and generation of associated knowledge, in order to ensure they are not left behind as technology continues to advance.
- 21. The following capacity-building related aspects were identified in the submissions:
- (a) Joint research targeting researchers from developing countries which involves, inter alia, the generation and analysis of DSI, bioinformatics, datamining and use of databases/repositories;
- (b) Training targeting regulatory institutions and enforcement bodies (e.g. in science, technology, trade, industry, agriculture and health) which are responsible for developing or implementing ABS policies;
- (c) Legal terms/frameworks addressing access and use of DSI, for example, as may concern intellectual property ownership and licensing in order to address issues such as commercial use and monetary benefit-sharing.
- 22. It is important to note that during the evaluation of the strategic framework on capacity-building and development for the effective implementation of the Nagoya Protocol, DSI also emerged as a new area for capacity-building. Currently the Nagoya Protocol's capacity-building strategic framework identifies

⁸ Section 4.3 of the Study on concepts and scope considers potential terms for each of the groups proposed for DSI subject matter.

⁹ CBD/NP/CB-IAC/2019/1/3

five key areas for capacity-building. Of relevance to DSI are the following key areas: capacity to develop, implement and enforce ABS measures; and capacity to develop endogenous research capabilities.

- 23. Furthermore, in decision 14/24, the Conference of the Parties requested the Executive Secretary to develop a draft long-term strategic framework for capacity-building beyond 2020 aligned with the draft post-2020 global biodiversity framework and the 2030 Agenda for Sustainable Development for consideration by the Subsidiary Body on Implementation at its third meeting and for subsequent consideration by the Conference of the Parties at its fifteenth meeting. The purpose of the long-term strategic framework on capacity-building is to provide Parties and relevant stakeholders including civil society, academia and the business community with high-level strategic guidance and direction for capacity-building in support of the post-2020 global biodiversity framework.
- 24. The AHTEG is invited to further discuss key areas for capacity-building related to DSI. The AHTEG may want to organize the discussion considering the following elements:
 - (a) Technical capacities needed for the generation, use and analysis of DSI;
 - (b) Infrastructure and technologies needed for the generation, use and analysis of DSI;
- (d) Possible capacity-building modalities such as joint scientific research and development ventures, bioinformatics training, technology transfer, and academic exchanges and fellowships among others; and
- (e) The key stakeholders that would be involved in receiving and providing capacity-building related to DSI.
- 25. The AHTEG may wish to identify key issues for capacity-building which concern DSI for consideration by the Open-Ended Working Group on the Post-2020 Global Biodiversity Framework.