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Item 3 of the provisional agenda\*

#### DIGITAL SEQUENCE INFORMATION ON GENETIC RESOURCES

*Note by the Executive Secretary* 

- 1. The Conference of the Parties to the Convention on Biological Diversity at its thirteenth meeting and the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol on Access and Benefit-Sharing at its second meeting each adopted decisions on digital sequence information on genetic resources in which they recognized the need for a coordinated and non-duplicative approach on this matter under the Convention and the Nagoya Protocol (decisions XIII/16 and NP-2/14, respectively). They decided to consider, at the fourteenth meeting of the Conference of the Parties and the third meeting of the Parties to the Nagoya Protocol, any potential implications of the use of digital sequence information on genetic resources for the three objectives of the Convention, and for the objective of the Nagoya Protocol, respectively.
- 2. The Parties also agreed on a process to facilitate consideration of this matter. The process included:
- (a) An invitation to Parties, other Governments, indigenous peoples and local communities, and relevant organizations and stakeholders 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 (decision XIII/16, para. 2);
- (b) An invitation to Parties, other Governments, indigenous peoples and local communities, and relevant organizations and stakeholders to include information relevant to the Nagoya Protocol in the views and information submitted (decision NP-2/14, para. 2);
- (c) A request to the Executive Secretary 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 (decision XIII/16, para. 3(a); see also para. 5 below);
- (d) A request to the Executive Secretary to commission 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 digital sequence information on genetic resources in the context of the Convention and the Nagoya Protocol;
- (e) The establishment of an ad hoc technical expert group and a request to the Executive Secretary to convene a meeting of the group in accordance with the terms of reference contained in the annex to decision XIII/16.
- 3. The terms of reference for the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources provided that the group was to:

<sup>\*</sup> CBD/SBSTTA/22/1.

- (a) To consider the compilation, synthesis and the study referred to in paragraph 3(a) and (b) of decision XIII/16 in order to examine any 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 and implementation to achieve these objectives;
- (b) Consider the technical scope and legal and scientific implications of existing terminology related to digital sequence information on genetic resources;
- (c) Identify the different types of digital sequence information on genetic resources that are relevant to the Convention and the Nagoya Protocol;
- (d) Meet at least once face-to-face, subject to the availability of financial resources, prior to the fourteenth meeting of the Conference of the Parties and make use of online tools to facilitate its work, as appropriate;
- (e) Submit its outcomes for consideration by a meeting of the Subsidiary Body on Scientific, Technical and Technological Advice to be held prior to the fourteenth meeting of the Conference of the Parties.
- 4. In decision NP-2/14, paragraph 5, the Parties to the Nagoya Protocol decided that the Ad Hoc Technical Expert Group would also serve the Nagoya Protocol by considering the information relevant to the Protocol in the compilation, synthesis and study prepared in accordance with decision XIII/16, paragraph 3.
- 5. Furthermore, in decision NP-2/5 on cooperation with other international organizations, conventions and initiatives, the Parties to the Nagoya Protocol requested the Executive Secretary to continue to engage with relevant ongoing processes and policy debates to collect information on current discussions on the relationship between the use of digital sequence information on genetic resources and access and benefit-sharing arising out of the utilization of genetic resources, and to include relevant information gathered during these engagements in the compilation of views referred to in paragraph 2(c) above.
- 6. In decision XIII/16, the Conference of the Parties requested the Subsidiary Body on Scientific, Technical and Technological Advice to consider the outcomes of the Ad Hoc Technical Expert Group and to make a recommendation on the potential implications of the use of digital sequence information on genetic resources for the three objectives of the Convention for the consideration of the Conference of the Parties at its fourteenth meeting (para. 5). Similarly, in decision NP-2/14, the Parties to the Protocol requested the Subsidiary Body on Scientific, Technical and Technological Advice to consider the outcomes of the Ad Hoc Technical Expert Group and to make a recommendation on the potential implications of the use of digital sequence information on genetic resources for the objective of the Nagoya Protocol for the consideration of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol as its third meeting (para. 7).
- 7. By notification 2017-37 of 25 April 2017, the Executive Secretary set out the tentative timeline for the implementation of the activities foreseen in decisions XIII/16 and NP-2/14. The Executive Secretary also invited the submission of views and information pursuant to decision XIII/16, paragraph 2, and decision NP-2/14, paragraph 2.
- 8. More than 50 submissions were received in response, and the full text of all the submissions has been made available online.<sup>1</sup>
- 9. Given the volume of information received (more than 300 pages) and the richness of the submissions, preparing a synthesis that was as concise and easy to comprehend as possible was a significant challenge. The approach taken by the Secretariat was to prepare a main synthesis document organized into four sections. This was complemented by an addendum containing case studies and examples of the use of digital sequence information on genetic resources in relation to the objectives of

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

the Convention and the Nagoya Protocol. It was also complemented by another addendum addressing developments and coordination with other international processes pursuant to decision NP-2/5, paragraph 4. The documents were made available for the meeting of the Ad Hoc Technical Expert Group.

- 10. As requested in decision XIII/16, and with funding from the Governments of Canada and Switzerland and the European Union, the Executive Secretary commissioned 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 digital sequence information on genetic resources in the context of the Convention and the Nagoya Protocol. A draft of the study was made available online for peer review from 8 November to 1 December 2017. The peer review comments received were made available online.<sup>2</sup> The study was revised in the light of the comments received and made available for the meeting of the Ad Hoc Technical Expert Group.
- 11. The synthesis and the study have also been made available as information documents for the twenty-second meeting of the Subsidiary Body on Scientific, Technical and Technological Advice.<sup>3</sup>
- 12. By notification 2017-049 of 12 June 2017, Parties, other Governments, indigenous peoples and local communities, relevant organizations and stakeholders were invited to nominate experts to the Ad Hoc Technical Expert Group. The experts were selected in accordance with the consolidated modus operandi of the Subsidiary Body on Scientific, Technical and Technological Advice (see decision VIII/10, annex III), taking into account their expertise and experience and the need to ensure equitable geographical distribution and gender balance. Following consultation with the Bureau of the Subsidiary Body on Scientific, Technical and Technological Advice, the composition of the Ad Hoc Technical Expert Group was announced in notification 2017-109 of 20 October 2017.
- 13. With the financial support of the Government of Canada and the European Union, the meeting of the Ad Hoc Technical Expert Group was held from 13 to 16 February 2018 at the offices of the Secretariat in Montreal.
- 14. The outcomes of the meeting of the Ad Hoc Technical Expert Group are contained in the annex to its report and are also reproduced in the annex to the present document. The full report of the Ad Hoc Technical Expert Group has been made available as an information document.<sup>4</sup>

#### SUGGESTED RECOMMENDATIONS

- 15. The Subsidiary Body on Scientific, Technical and Technological Advice may wish to take note of:
- (a) The compilation and synthesis of the views and information related to digital sequence information on genetic resources, submitted pursuant to decision XIII/16;<sup>5</sup>
- (b) The fact-finding and scoping study to clarify terminology and concepts and to assess the extent and the terms and conditions of the use of digital sequence information on genetic resources in the context of the Convention and the Nagoya Protocol, prepared pursuant to decision XIII/16;<sup>6</sup>
- (c) The report of the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources.<sup>7</sup>
- 16. The Subsidiary Body may also wish to consider the outcomes of the Ad Hoc Technical Expert Group and prepare recommendations on:

<sup>&</sup>lt;sup>2</sup> https://www.cbd.int/abs/dsi-gr/ahteg.shtml#peerreview.

 $<sup>^3\</sup> CBD/SBSTTA/22/INF/2,\ CBD/SBSTTA/22/INF/2/Add.1\ and\ CBD/SBSTTA/22/INF/2/Add.2;\ and\ CBD/SBSTTA/22/INF/3\ .$ 

<sup>&</sup>lt;sup>4</sup> CBD/SBSTTA/22/INF/4.

<sup>&</sup>lt;sup>5</sup> CBD/SBSTTA/22/INF/2.

<sup>&</sup>lt;sup>6</sup> CBD/SBSTTA/22/INF/3.

<sup>&</sup>lt;sup>7</sup> CBD/SBSTTA/22/INF/4.

- (a) The potential implications of the use of digital sequence information on genetic resources, for the three objectives of the Convention for the consideration of the Conference of the Parties at its fourteenth meeting;
- (b) The potential implications of the use of digital sequence information on genetic resources, for the objective of the Nagoya Protocol for the consideration of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol at its third meeting.

#### Annex

# OUTCOMES OF THE MEETING OF THE AD HOC TECHNICAL EXPERT GROUP ON DIGITAL SEQUENCE INFORMATION ON GENETIC RESOURCES

### Terminology and different types of digital sequence information on genetic resources

- 1. Participants discussed the various types of information on genetic resources that may be relevant to the three objectives of the Convention and the objective of the Nagoya Protocol. There was consensus that the term "digital sequence information" (DSI) is not the appropriate term to refer to these types of information. However, the group continued to use "DSI" as a place holder, without prejudice to future consideration of alternative terms.
- 2. The experts identified various types of information that may be relevant to the utilization of genetic resources, recognizing that the statements made further in the document might not apply equally to each of them. This included, among other things, the following:
  - (a) The nucleic acid sequence reads and the associated data;
- (b) Information on the sequence assembly, its annotation and genetic mapping. This information may describe whole genomes, individual genes or fragments thereof, barcodes, organelle genomes or single nucleotide polymorphisms;
  - (c) Information on gene expression;
  - (d) Data on macromolecules and cellular metabolites;
  - (e) Information on ecological relationships, and abiotic factors of the environment;
  - (f) Function, such as behavioural data;
  - (g) Structure, including morphological data and phenotype;
  - (h) Information related to taxonomy;
  - (i) Modalities of use.
- 3. Some experts expressed the view that the information could be grouped into two categories. One category would be information providing an indication of the genetic and/or biochemical composition of the genetic resources which would include (a) to (d) from the list above. The second category relates to observational data that provides contextual information, which would include (e) to (i) from the above list, and which may or may not result from utilization of genetic resources. It was expressed that contextual information may have been collected when sourcing a particular genetic material or independently, and it provides context on the sample's provenance, among other things. It was also noted that such information may facilitate the interpretation of information obtained regarding the genetic and/or biochemical composition of a genetic resource and thus may allow for meaningful and useful understanding of the properties of the genetic resource.
- 4. Some participants were of the view that some or all of these types of information, taken together, can be referred to as "natural information" or "genetic resource information". Some experts noted that "genetic sequence data" is widely used and is a clear term in the scientific community. It was also noted that additional types of information may arise from the application of new technologies.
- 5. There was an understanding that information that provides an indication of the genetic and/or biochemical composition of the genetic resource at some point originated from a physical source.
- 6. The group also considered the technical scope and legal and scientific implications of existing terminology related to digital sequence information on genetic resources.
- 7. The experts discussed the relationship between "DSI" and definitions in the Convention and the Nagoya Protocol. Different views were expressed, including the following:

- (a) Some experts were of the view that the definition of "genetic resources" includes "DSI";
- (b) Others stated that the definition of "genetic resources" refers to tangible or physical material while "DSI" is intangible and so is not covered by the definition;
- (c) Some experts considered that the phrase "or other origin" contained in the definition of "genetic material" refers, for example, to other taxonomic categories not listed in the definition. Others were of the view that the phrase could include "DSI";
- (d) Some experts were of the view that, even if "DSI" is not within the definition of "genetic resources", it is within the scope of the Nagoya Protocol insofar as it results from the utilization of the genetic resource or subsequent applications and commercialization and therefore should be covered by benefit-sharing;
- (e) Others expressed that the only "DSI" that may be considered a result of utilization of the genetic resources is nucleic acid sequence reads and the associated data;
- (f) Some experts noted that the legal implication of understanding "DSI" as equivalent to a genetic resource would be obligations for prior informed consent, mutually agreement terms and benefit-sharing. The legal implication of understanding "DSI" as the product of utilization of a genetic resource would be obligations for benefit-sharing.
- 8. It was noted that there were questions regarding traditional knowledge associated with genetic resources as it relates to dematerialized information. Recalling that traditional knowledge associated with genetic resources is the subject of specific provisions under the Nagoya Protocol, some experts considered that it should therefore be discussed separately.
- 9. Experts discussed the term "digital sequence information on genetic resources", including proposals for alternate terminology that may be more appropriate.
- 10. It was noted that the word "digital" helps with understanding the *raison d'être* of the discussions. That being said, there was general agreement that "digital" only refers to the method by which the information is stored and transmitted and that new alternative forms of storage or transmission could raise similar questions.
- 11. A number of issues were raised by the experts in considering the terms "sequence", "information" and "functional unit of heredity":
- (a) Some experts recalled the reference to "functional unit of heredity" in the definition of "genetic material" and expressed concern that the concept of a "sequence" may not include "units of heredity";
- (b) Some noted that genomic sequence is the description of a nucleic acid molecule, which is not the same as a "functional unit of heredity";
- (c) Some noted that genomic sequence is the description of a nucleic acid molecule, which could be re-materialized as a "functional unit of heredity";
- (d) Some experts noted that the Convention does not contain a definition of "functional unit of heredity" and that, therefore, further discussions might be useful;
- (e) Some experts also noted that "sequence" refers mainly to the linearity of a DNA, RNA or protein molecule but not to other kinds of molecules resulting from the metabolism of a genetic resource or to the natural post-transcriptional or post-translational modifications/regulations (i.e. methylations, folding, etc.);

<sup>&</sup>lt;sup>8</sup> Convention on Biological Diversity, Article 2: "Genetic resources" means genetic material of actual or potential value.

<sup>&</sup>lt;sup>9</sup> Convention on Biological Diversity, Article 2: "Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.

- (f) There was some discussion on the use of the word "data" as an alternative to "information".
- 12. The experts agreed that more discussion on the terminology associated with this issue is required to find the balance between terminology that is adaptive and dynamic enough to accommodate scientific, technological, market and other change, and at the same time is clear and solid enough to provide legal certainty.

# Potential implications of the use of digital sequence information on genetic resources for conservation of biological diversity and sustainable use of its components

- 13. The experts agreed on the importance of "DSI" for the conservation and sustainable use of biodiversity while emphasizing that the three objectives of the Convention are interlinked and mutually supportive.
- 14. They recognized, as illustrated in the documents prepared for the meeting, <sup>10</sup> that "DSI" is used for a number of different purposes to support conservation and sustainable use including taxonomy, breeding, monitoring and control purposes, as well as public health and food security.
- 15. The experts noted that open access to "DSI" plays a critical role in facilitating the conservation and sustainable use of biodiversity by supporting the implementation of several articles of the Convention, in particular Articles 17 and 18, as well as Articles 8, 20, 22, 23 and the annex to the Nagoya Protocol, and contributing to the achievement of Aichi Biodiversity Target 19 and other targets.
- 16. The experts noted that the technical ability to use, generate and analyse "DSI" is limited in many countries, and that, therefore, there is a need for more capacity-building and technology transfer to use "DSI" to contribute to conservation and sustainable use, while recognizing that there has been progress in the analytical capacities of some countries.
- 17. Some experts noted with concern that, in the absence of rules on the sharing of benefits arising from the use of "DSI", countries could restrict access to their genetic resources, with negative consequences for the conservation of biodiversity and the sustainable use of its components.
- 18. In the light of the general recognition of the positive value of "DSI" for conservation and sustainable use as well as the rapidly evolving nature of the underlying technology, experts agreed that a deeper review of the relationship between biodiversity conservation, sustainable use and "DSI" may not be required at this stage although further work on some areas may be useful.
- 19. Regular horizon scanning of future technological developments that are of relevance to the objectives of the Convention and the Nagoya Protocol may be necessary.

# Potential implications of the use of digital sequence information on genetic resources for the fair and equitable sharing of benefits arising out of the utilization of genetic resources

- 20. In considering potential implications of the use of digital sequence information on genetic resources for the fair and equitable sharing of benefits, experts noted the following, with the understanding that the Conference of the Parties and the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol have not decided whether utilization of "DSI" falls within the scope of the Convention or the Nagoya Protocol:
- (a) "DSI" could bring transformational change to the use of genetic resources, which may influence the type of benefits and the way benefits are shared. There may be useful lessons in this respect

<sup>&</sup>lt;sup>10</sup> "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), "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), Addendum 1: "Case studies and examples of the use of digital sequence information in relation to the objectives of the Convention and the Nagoya Protocol" (CBD/DSI/AHTEG/2018/1/2/Add.1) and Addendum 2: "Digital sequence information on genetic resources in relevant ongoing international processes and policy debates" (CBD/DSI/AHTEG/2018/1/2/Add.2).

from how digitization of information in other sectors has impacted benefit-sharing, including possible lessons from the music, software, publishing and other industries;

- (b) On one hand, access to and utilization of "DSI" can lead to the generation of benefits, and promote the sharing of non-monetary benefits through technology transfer, partnerships and collaboration, information exchange and capacity development in support of several articles of the Convention, in particular Articles 12 and 18 as well as Articles 8, 20, 22, 23 and the annex to the Nagoya Protocol;
- (c) On the other hand, "DSI", in the light of advances in sequencing technologies in particular, may, in some cases, challenge the implementation of arrangements for access to genetic resources and benefit-sharing (ABS) by obviating the need for users to seek access to the original tangible genetic resource, thus potentially enabling users to bypass procedures for access and benefit-sharing:
  - (i) In the context of the Pandemic Influenza Preparedness (PIP) Framework, for example, laboratories and manufacturers are relying increasingly on genetic sequence data to the exclusion of physical materials. This has the potential to undermine the PIP Framework. There are currently discussions on this matter within the World Health Organization;
- (d) Accessing and using "DSI" for some scientific activities is cheaper relative to sequencing, and is enabled by databases;
- (e) "DSI" is commonly used for analysis; however, it is also used for re-materializing genetic material and both are relevant for benefit-sharing;
  - (f) There may be a need for economic valuation of the information per se;
  - (g) For comparative purposes, larger data sets are more valuable;
- (h) Specific benefit-sharing conditions related to "DSI" resulting from utilization of a genetic resource could be included in mutually agreed terms;
- (i) In the light of the challenges related to the bilateral benefit-sharing approach as it relates to "DSI", consideration of multilateral approaches may be warranted in some circumstances:
  - (i) Such circumstances might include: sequences with no known provenance; conserved genes; sequences of widely distributed genetic resources and information voluntarily contributed by Parties;
  - (ii) A multiplicity of national approaches to ABS relating to "DSI" may create cumbersome processes, and could lead to access restrictions, or to "jurisdiction shopping". One effect of such restrictions may be to limit benefit-sharing and its contribution to conservation and sustainable use;
  - (iii) Fair distribution of benefits among providers may be difficult if genetic material from various sources is combined;
  - (iv) However, a multilateral benefit-sharing mechanism under the Nagoya Protocol cannot extend beyond the scope of the Protocol;
  - (v) The global multilateral benefit-sharing mechanism referred to under Article 10 of the Nagoya Protocol is still under discussion;
  - (vi) Other discussions on "DSI" are also ongoing in other forums;
  - (vii) A multilateral approach for "DSI" could provide an alternative to requirements for prior informed consent and mutually agreed terms and therefore help to reduce transaction costs and facilitate equitable sharing of benefits;
  - (j) Monetary benefits are important for conservation in situ and ex situ and sustainable use;
- (k) The boundary between research for commercial and non-commercial uses can be particularly blurred in the context of "DSI";

- (l) The special considerations in Article 8 of the Protocol;
- (m) The fact that a number of challenges related to the implementation of the Nagoya Protocol have not yet been addressed continues to be a subject of concern for a number of stakeholders who are therefore apprehensive of discussions that could create further barriers to access and scientific research, in particular fundamental biodiversity research.
- 21. With regard to non-monetary benefits, the following points were made:
- (a) There are large social and public benefits from use of and access to "DSI" underscoring the importance of publicly accessible databases;
- (b) While the sharing of information and data is also a benefit in and of itself, it is not, alone, sufficient to meet the expectations for benefit-sharing. Furthermore, the benefits from data sharing do not necessarily accrue to the providers proportionately or predominantly;
- (c) Continued effort for technology transfer and capacity-building is essential, in order to enable developing countries to access and use "DSI";
- (d) Although there is already international cooperation, there is a need to learn from existing practices and build on them to further develop capacity;
- (e) It would be helpful to develop further studies to quantify non-monetary benefit-sharing. It may be easier to examine this by sector.
- 22. It was suggested that a challenge to monetary benefit-sharing is the fact that there may be no cutoff point and that benefit-sharing obligations may continue in perpetuity.
- 23. It was noted that monitoring, access to and use of "DSI" may be very complex.
- 24. With regard to monitoring, it was noted that some countries and international frameworks have taken the approach to establish as the triggering event for benefit-sharing, and to focus monitoring on, the commercialization of products arising from the utilization of "DSI", rather than controlling research and technological development from "DSI".
- 25. Some experts noted that intellectual property rights and other property rights should be safeguarded.
- 26. With respect to the issue of databases, some experts expressed the following views:
- (a) There can be different interpretations of what constitutes a publicly accessible database; these may range from databases that allow completely open access (e.g. GenBank) to those that impose certain requirements (e.g. the Global Initiative on Sharing All Influenza Data (GISAID), which requires registration by users and data access agreements);
- (b) Access to publicly available databases is important and could require user agreements that address benefit-sharing;
- (c) Data in publicly accessible databases may still be subject to intellectual property rights or be utilized for intellectual property-protectable subject matter or be subject to ABS obligations;
- (d) The value of including information on environmental context in the metadata associated with "DSI" is increasingly recognized by the scientific community as it contributes to conservation efforts and good research practices. This information may also contribute to access and benefit-sharing;
- (e) Although some databases (e.g. the DNA Databank of Japan) provided information on user statistics and metadata of "DSI", there continues to be a need for more information on where "DSI" comes from (e.g. country of origin of the genetic resource whose sequences are in databases), by whom it is submitted and the countries from which users are accessing "DSI";
- (f) There is a need for more information on the extent of use of "DSI" (e.g. public/private databases, commercial/non-commercial) to inform future discussions.

- 27. The experts agreed that restricting the use of publicly accessible data would not be desirable. However, some pointed out that there are proprietary data, the content of which is not publicly known.
- 28. Some experts shared information on steps being taken by different sectors with a view to respecting the principles of the Nagoya Protocol. Good practices have been developed and are available (e.g. International Barcode of Life Project, TRUST, GGBN).
- 29. With regard to traceability, experts noted the following:
- (a) There are concerns that requirements for traceability may create unnecessary barriers to data access and use;
- (b) A framework for traceability would be helpful for tracking information through the value chain and this could be facilitated through the use of unique identifiers;
- (c) The ability to trace is improving with new technological developments (e.g. blockchain) and there is a need to keep an eye on developments to determine whether traceability remains a challenge;
  - (d) Traceability should be mandatory in order to be effective;
  - (e) The nature of "DSI" does not lend itself to traceability.
- 30. Some experts suggested that the concept of "bounded openness over natural information" may merit consideration; however, the concept was not discussed by the AHTEG.

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