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### OPEN-ENDED WORKING GROUP ON THE POST-2020 GLOBAL BIODIVERSITY FRAMEWORK

Third, meeting

Online, 23 August – 3 September 2021

Item 5 of the provisional agenda\*\*

### DIGITAL SEQUENCE INFORMATION ON GENETIC RESOURCES

*Note by the Executive Secretary*

#### I. BACKGROUND

1. The Conference of the Parties to the Convention on Biological Diversity at its fourteenth meeting considered any potential implications of the use of digital sequence information on genetic resources for the three objectives of the Convention and adopted decision [14/20](#). Furthermore, the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol at its third meeting also considered any potential implications for the objective of the Nagoya Protocol and adopted decision [NP-3/12](#) on digital sequence information on genetic resources (DSI).
2. In decision 14/20, the Conference of the Parties, among other things, noted that, as there was a divergence of views among Parties regarding benefit-sharing from the use of digital sequence information on genetic resources, Parties committed to working towards resolving this divergence through a science- and policy-based process, 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. The decision noted the importance of DSI for scientific research, both commercial and non-commercial, but also the disparity in capacity to access, use and benefit from the use of DSI.
3. The process, as set out in paragraphs 9 to 12 of the decision, encompassed an invitation to Parties and others to submit views and information for synthesis and analysis by the Executive Secretary, the commissioning of a number of studies by the Executive Secretary, and the convening of an Ad Hoc Technical Expert Group which was to report to the Open-ended Working Group on the Post-2020 Global Biodiversity Framework (the Working Group).
4. Additionally, the Executive Secretary was requested to cooperate with other intergovernmental organizations to inform them of the process and to take into account the work, approaches and outcomes that these organizations generate in the area in question.
5. According to decisions 14/20 and NP-3/12, the Working Group on the Post-2020 Global Biodiversity Framework is to consider the outcomes of the extended Ad Hoc Technical Expert Group and to make recommendations to the Conference of the Parties at its fifteenth meeting on how to address DSI

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\*\* CBD/WG2020/3/1.

in the context of the post-2020 global biodiversity framework, and to submit its outcomes to the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol at its fourth meeting.

6. In addition to the mandates established by decision [14/34](#), the Co-Chairs of the Working Group, Mr. Basile van Havre of Canada and Mr. Francis Ogwal of Uganda, with the support of the Secretariat, organized a series of informal activities on digital sequence information on genetic resources. The activities took the form of a series of information-sharing webinars on DSI,<sup>1</sup> followed by an informal online discussion forum.<sup>2</sup> The purpose of these activities was to share information, understanding and insight on the issue of DSI technically, and to initiate the exploration of potential policy options and criteria.

7. The present document has been issued to facilitate deliberations on DSI at the third meeting of the Working Group. Section II below provides an overview of the activities undertaken to implement the science- and policy-based process, including the convening of the Ad Hoc Technical Expert Group. Section III provides a summary of the informal activities on DSI carried out at the request of the Co-Chairs of the Working Group. Finally, section IV proposes elements of a draft recommendation.

## **II. OVERVIEW OF THE MEETING OF THE AD HOC TECHNICAL EXPERT GROUP ON DIGITAL SEQUENCE INFORMATION ON GENETIC RESOURCES**

### **A. Preparations for the meeting of the extended Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources**

8. As summarized above, in decision [14/20](#), the Conference of the Parties invited the submission of views on a number of areas, and it requested the Executive Secretary to compile and synthesize the views submitted and to commission a number of studies.

9. Pursuant to paragraphs 9, 10 and 11 of decision [14/20](#), the Executive Secretary issued notification 2019-012 (5 February 2019)<sup>3</sup> to invite the submission of views and information as follows:

(a) Parties, other Governments, indigenous peoples and local communities, relevant stakeholders and organizations were invited to submit views and information: (i) to clarify the concept, including relevant terminology and scope, of digital sequence information on genetic resources and if and how domestic measures on access and benefit-sharing consider digital sequence information on genetic resources; and (ii) on benefit-sharing arrangements from commercial and non-commercial use of digital sequence information on genetic resources;

(b) Parties, other Governments and indigenous peoples and local communities were invited to submit information on their capacity-building needs regarding the access, use, generation and analysis of digital sequence information on genetic resources, in particular for the three objectives of the Convention;

(c) The notification also included a tentative timeline for the implementation of activities related to DSI, leading up to the meeting of the Ad Hoc Technical Expert Group.

10. In response to the notification, the Secretariat received more than 30 submissions providing views and information from Parties to the Convention, non-Parties and organizations. The submissions are available online.<sup>4</sup>

11. Pursuant to decision [14/20](#), paragraph 11, studies were to address the following topics:

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<sup>1</sup> <https://www.cbd.int/article/dsi-webinar-series-2020>

<sup>2</sup> <https://www.cbd.int/dsi-gr/forum.shtml>

<sup>3</sup> <https://www.cbd.int/doc/notifications/2019/ntf-2019-012-abs-en.pdf>

<sup>4</sup> <https://www.cbd.int/dsi-gr/2019-2020/submissions/>

(a) The concept and scope of digital sequence information on genetic resources and how digital sequence information on genetic resources is currently used building on the existing fact-finding and scoping study;<sup>5</sup>

(b) Ongoing developments in the field of traceability of digital information, including how traceability is addressed by databases, and how these could inform discussions on DSI;

(c) Public and, to the extent possible, private databases of digital sequence information on genetic resources, including the terms and conditions on which access is granted or controlled, the biological scope and the size of the databases, numbers of accessions and their origin, governing policies, and the providers and users of DSI;

(d) How domestic measures address benefit-sharing arising from commercial and non-commercial use of DSI and address the use of DSI for research and development.

12. In notification 2019-012, referred to in paragraph 9 above, the Executive Secretary called for expressions of interest to undertake the studies and included a tentative timeline for the implementation of activities related to DSI. In addition, the Executive Secretary issued notification 2019-054 (19 June 2019)<sup>6</sup> inviting Parties and other Governments to complete a survey on domestic measures addressing benefit-sharing from DSI, as a contribution to the study commissioned on this topic. All four studies, commissioned thanks to the financial support provided by the European Union and Norway, were opened for peer review per notification 2019-094 (22 October 2019).<sup>7</sup> The studies were then finalized by the respective authors, taking into account comments received within the period of four weeks allocated for each study. The peer-review comments are available online.<sup>8</sup>

#### **B. Meeting of the extended Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources**

13. By notification 2019-053 (12 June 2019),<sup>9</sup> the Executive Secretary invited nominations to the Ad Hoc Technical Expert Group (AHTEG) on Digital Sequence Information on Genetic Resources. The composition of the AHTEG was announced in notification 2019-069 (28 October 2019).<sup>10</sup>

14. Due to circumstances arising from the COVID-19 pandemic, the AHTEG met virtually from 17 to 20 March 2020, with financial support from the European Union.

15. As set out in decision 14/20, paragraph 11, the AHTEG was to:

(a) Consider the compilation and synthesis of views and information and the peer-reviewed studies referred to in paragraphs 9 and 10 of the decision;

(b) Develop options for operational terms and their implications to provide conceptual clarity on DSI, considering in particular the study on the concept and scope of DSI and how DSI is currently used, building on the existing fact-finding and scoping study;

(c) Identify key areas for capacity-building.

16. The AHTEG worked on the basis of the following documents, which are available on the AHTEG meeting page:

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<sup>5</sup> The “existing fact-finding and scoping study” referred to here is the study prepared as part of the 2017-2018 inter-sessional process on DSI, namely “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).

<sup>6</sup> <https://www.cbd.int/doc/notifications/2019/ntf-2019-096-abs-en.pdf>

<sup>7</sup> <https://www.cbd.int/doc/notifications/2019/ntf-2019-094-abs-en.pdf>

<sup>8</sup> <https://www.cbd.int/dsi-gr/2019-2020/studies/>

<sup>9</sup> <https://www.cbd.int/doc/notifications/2019/ntf-2019-053-abs-en.pdf>

<sup>10</sup> <https://www.cbd.int/doc/notifications/2019/ntf-2019-096-abs-en.pdf>

- (a) The synthesis of views and information ([CBD/DSI/AHTEG/2020/1/2](#)), as well as a compilation of the views and information as received by the Secretariat ([CBD/DSI/AHTEG/2020/1/INF/1](#));
- (b) The study on concept and scope ([CBD/AHTEG/DSI/2020/1/3](#));
- (c) The combined studies on traceability and databases ([CBD/AHTEG/DSI/2020/1/4](#));
- (d) The study on domestic measures ([CBD/AHTEG/DSI/2020/1/5](#)).

17. The full report of the AHTEG has been issued as document [CBD/DSI/AHTEG/2020/1/7](#). The outcomes of the meeting of the AHTEG are contained in annex I of the report and have been reproduced in annex I below.

### III. INFORMAL ACTIVITIES AROUND DIGITAL SEQUENCE INFORMATION ON GENETIC RESOURCES

18. At the request of the Co-Chairs of the Working Group, the Secretariat organized a series of webinars on DSI to facilitate informal information exchange and to maintain momentum on the issue given the extended inter-sessional period as a result of the global COVID-19 pandemic. These webinars were organized with a view to (a) helping ensure that relevant information on DSI, including that arising from studies and dialogues, was available to all Parties as well as to indigenous people and local communities, and relevant organizations and stakeholders; (b) compiling this information and present it in a readily understandable form; and (c) fostering a common understanding of DSI and its importance and linkages to the Convention in terms of access and benefit-sharing, the Nagoya Protocol, and the Sustainable Development Goals.

19. The topics for the webinars were as follows:

- (a) Webinar 1: Understanding DSI: a technical overview of its production, distribution and use (December 2020);
- (b) Webinar 2: An overview of the process and recent outcomes related to digital sequence information on genetic resources under the Convention on Biological Diversity, with a focus on the outcomes of the AHTEG (December 2020);
- (c) Webinar 3: Policy options for access and benefit-sharing, and digital sequence information on genetic resources (February 2021);
- (d) Webinar 4: Criteria to consider policy options on digital sequence information on genetic resources (April 2021).

20. The webinars were well attended with good regional balance, including participants from academia, business and civil society as well as countries. Recordings of all the webinars as well as the PowerPoint slides, background papers and summary papers are available online.<sup>11</sup> Financing for the webinars was provided by the European Union, and translation of the slides for webinar 3 was made possible by financial support through the ABS Capacity Development Initiative.

21. A summary of webinars 3 and 4 can be found in annex II.

22. Also at the request of the Co-Chairs of the Working Group, the Secretariat organized an informal online discussion forum in order to exchange information and views on DSI policy options and criteria. The forum was held from 21 April to 3 May 2021, and the discussion posts and comments are available online,<sup>12</sup> with a summary of the points raised contained in annex III below. The three threads of discussion were:

- (a) Policy options categories and other options;

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<sup>11</sup> <https://www.cbd.int/article/dsi-webinar-series-2020>

<sup>12</sup> <https://www.cbd.int/dsi-gr/forum.shtml>

- (b) Criteria framework for assessing policy options;
- (c) Policy options feasibility and appropriateness.

23. The conversations considered overarching ideas around data access, conservation needs, processes to move forward and considerations for non-monetary benefits. The policy option discussions brought up the potential modalities of the various policy options, particularly a potential multilateral fund, arguments for or against each option, and the scope of the policy solution. The thread on criteria had a strong emphasis on the distribution of the funds collected. Finally, the thread on criteria applied to policy options highlighted the need to better understand the overarching flow of monetary benefits, the common understanding of economic aspects of the options, the legal scope, better understanding and developing solutions for capacity-building, and how to apply lessons learned from the past and from other international forums. It is to be noted that this informal discussion forum is a collection of personal opinions and observations.

24. Other dialogues have been organized by Parties and organizations. Notably, the ABS Capacity Development Initiative, with the sponsorship of Norway and South Africa, organized the first Global Dialogue on Digital Sequence Information on Genetic Resources, held in 2019, as well as several online events leading up to the second Global Dialogue on Digital Sequence Information on Genetic Resources. Several studies were commissioned by Parties and stakeholders on the topic of DSI and various aspects of policy solutions.

25. An update and summary of DSI in other relevant international processes will be made available as information document CBD/WG2020/3/INF/1.

#### IV. ELEMENTS OF A RECOMMENDATION

26. In decision 14/20, paragraph 12, the Conference of the Parties requested the Working Group to consider the outcomes of the meeting of the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources and to make recommendations to the Conference of the Parties at its fifteenth meeting on how to address digital sequence information on genetic resources in the context of the post-2020 global biodiversity framework. In decision NP-3/12, paragraph 3, the Working Group was requested to submit the outcome of its deliberations for consideration by the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol at its fourth meeting. In view of these mandates, the Working Group may wish:

- (a) To recall relevant elements of decisions [XIII/16](#) and 14/20;
- (b) To welcome the outcomes of the meeting of the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources as contained in annex I to the present document;
- (c) To take note of the information summarized in annexes II and III to the present document, arising from the informal activities on DSI carried out at the request of the Co-Chairs of the Working Group, including:
  - (i) The listing of potential policy options;
  - (ii) The listing of potential criteria for assessing policy options;
  - (iii) The range of views made during the informal online consultation.

27. Some possible elements for a recommendation may include:

- (a) Recognition that any approach to address DSI should not prevent access to digital sequence information or significantly hinder scientific research and innovation;
- (b) Recognition that benefits arising from the use of digital sequence information on genetic resources should be shared fairly and equitably;
- (c) Consideration of the possible modalities for benefit-sharing;
- (d) Acknowledgement that capacity-building is relevant and necessary for addressing DSI.

28. In view of the time available before the resumed sessions of the Working Group and/or the fifteenth meeting of the Conference of the Parties, the Working Group may also wish to consider additional consultations and analyses with a view to furthering deliberations on DSI.

*Annex I*

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

1. The text below is a summary of the outcomes of the Ad Hoc Technical Expert Group (AHTEG) on Digital Sequence Information on Genetic Resources (hereinafter referred to as digital sequence information or “DSI”).
2. The experts recalled decision [14/20](#), which 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.

**I. SCOPE OF DIGITAL SEQUENCE INFORMATION ON GENETIC  
RESOURCES AND TERMINOLOGY**

3. In clarifying the scope of digital sequence information, the AHTEG considered the four groups proposed in Study 1 on concept and scope (Figure 7 and Table 4 of the Study) and concluded that the four proposed groups were rational and helpful as a starting point for discussions. It noted that clearly defined groups would assist negotiators in the Convention process and other forums when discussing topics related to digital sequence information.
4. The experts discussed the distinction between “data” and “information”, noting that the latter could imply more processing than the former, and noting also that there is no clear boundary between the two.
5. In relation to the biochemical flow of information within a cell, the experts noted the ability to infer nucleic acid sequences from protein sequences (although imperfectly, because different DNA sequences may code for the same protein) and the current inability to readily infer nucleic acid or protein sequences from metabolites and macromolecules.
6. Building on the rationale proposed in Study 1, the AHTEG considered that the degree of biological processing and the proximity to the underlying genetic resource provide a rationale to group information that may comprise digital sequence information. The proposed groups are cumulative (Group 2 includes all elements of Group 1, and Group 3 contains all elements of Groups 1 and 2).
7. A distinction was made between genetic and biochemical information as included in Groups 1 to 3 indicated in paragraph 6 above and associated information related to a genetic resource, such as traditional knowledge associated with genetic resources, and other information, variously described as contextual, associated, or subsidiary information (see table 1 below).
8. The AHTEG discussed the importance and relevance of associated traditional knowledge to the utilization of digital sequence information on genetic resources and recalled that there are obligations to share benefits from the utilization of traditional knowledge associated with genetic resources under the Nagoya Protocol and the Convention.
9. In clarifying the scope of digital sequence information, the AHTEG agreed that the first three groups proposed in Study 1 could be considered as digital sequence information, while associated information previously assigned (in the study) to Group 4, including traditional knowledge associated with genetic resources, is not digital sequence information (see table 1 below).

**Table 1. Clarifying the scope of digital sequence information on genetic resources**

	Information related to a genetic resource			Associated information
	Genetic and biochemical information			
Group reference	Group 1	Group 2	Group 3	
High-level description of each group	DNA and RNA	Group 1 + proteins + epigenetic modifications	Group 2 + metabolites and other macromolecules	
Examples of granular subject matter	<p>Nucleic acid sequence reads;</p> <p>Associated data to nucleic acid reads;</p> <p>Non-coding nucleic acid sequences;</p> <p>Genetic mapping (for example, genotyping, microsatellite analysis, SNPs, etc.);</p> <p>Structural annotation.</p>	<p>Amino acid sequences;</p> <p>Information on gene expression;</p> <p>Functional annotation;</p> <p>Epigenetic modifications (for example, methylation patterns and acetylation);</p> <p>Molecular structures of proteins;</p> <p>Molecular interaction networks.</p>	<p>Information on the biochemical composition of a genetic resource;</p> <p>Macromolecules (other than DNA, RNA and proteins);</p> <p>Cellular metabolites (molecular structures).</p>	<p>Traditional knowledge associated with genetic resources</p> <p>Information associated with digital sequence information Groups 1, 2 and 3 (for example, biotic and abiotic factors in the environment or associated with the organism)</p> <p>Other types of information associated with a genetic resource or its utilization.</p>

10. Further, during the discussion regarding the scope of digital sequence information, the experts noted the following:

(a) That using the groups proposed for describing digital sequence information and associated information can provide conceptual clarity;

(b) Achieving conceptual clarity regarding digital sequence information is important to ensure legal clarity in all circumstances, and some experts noted that the distinction among different groups might be more important for certain approaches (for example, bilateral approaches) than others (for example, multilateral approaches);

(c) The importance and value of passport data in traceability (such as the provider country,<sup>1</sup> where the biological sample was collected, coordinates of sample collection, sample collection date, accession number or other unique identifiers, collector, etc.) as exemplified by the minimum information about a genome sequence (MIGS) specification by the Genomics Standards Consortium;

(d) That technological innovations might add to the granular subject matter and that this could be taken into account to accommodate future technological developments.

11. In addressing terminology, experts discussed a variety of terms as potentially appropriate for each of the Groups. Table 2 below summarizes potential terminology for the proposed groups.

<sup>1</sup> In accordance with the Convention on Biological Diversity, provider country hereinafter is understood as the country of origin of the genetic resource or the Party that has acquired the genetic resource in accordance with the Convention.



**Table 2. Options for terminology to describe digital sequence information on genetic resources**

Group reference	Group 1	Group 2	Group 3	Associated information
<b>Category/term</b>	Nucleotide sequence data (NSD); Genomic sequence information; Genomics information; Nucleotide sequence information (NSI); Genetic Resource Sequence Data (GRSD); Digital sequence data (DSD); Data on the genomic DNA (or RNA) of a sample genetic resource	Genomic and proteomic sequence information; Nucleotide sequence information (NSI); Genetic information (GI); Sequence data; Nucleotide and amino acid sequence data (NASD); Nucleotide and amino acid sequence and structural information (NASSI); Nucleotide and amino acid sequence, structural and functional information (NASSFI); Functional digital information of NSD; Proteomic data; Data on the macromolecular composition of a sample genetic resource.	Genomic, proteomic and metabolomic information; Genetic and “omic” information; Metabolomic data; “Omic” information Genomic, proteomic and metabolomic information; Data on the biochemical and genetic composition of a sample genetic resource.	Associated information; Contextual Information; Subsidiary Information.
Other terms were additionally discussed, including the following: digital sequence information, natural information, digital genetic resource information, digital genetic resource data and information, genetic resource data and information, genetic information, all data on a sample (genetic resource) and <i>in silico</i> .				

## II. POTENTIAL IMPLICATIONS ARISING FROM THE DIFFERENT GROUPS

12. For each of the groups considered above, the AHTEG discussed implications: (a) concerning traceability of different types of information; (b) concerning the use of digital sequence information and technologies enabled by digital sequence information in life sciences research and innovation processes; (c) of the International Nucleotide Sequence Database Collaboration (INSDC) on the open exchange and use of digital sequence information; and (d) concerning measures governing access, benefit-sharing and compliance.

13. The experts noted the preliminary nature of the discussions and that the implications would depend on the nature of the benefit-sharing approach. They also noted that some of the potential implications were not discussed in depth as others and could benefit from further information or consideration.

### A. Potential implications of different groups concerning traceability and International Nucleotide Sequence Database Collaboration

14. In discussing the peer-reviewed Study 2 on databases and traceability, the following key observations were made, as follows.

15. The experts discussed implications of publicly accessible databases in relation to digital sequence information. They reiterated the value of open access, with some experts noting that “open” does not necessarily mean “free and unrestricted” access and noted that publicly accessible databases are functioning using differing terms and conditions of use.

16. Experts noted potential ways to improve traceability, such as:

- (a) Enhancing the inclusion of relevant passport data (for example, by requiring the provider country field entries when uploading relevant records to the databases);
- (b) Including information regarding the genetic resource in databases;
- (c) Linking journal publications with genetic resources stored in *ex situ* collections.

17. Some experts also considered:

- (a) Including disclosure of the provider country in patent applications;
- (b) Enhancing bioinformatic tools to support traceability, for example by direct comparison of sequences;
- (c) Explore the feasibility to link internationally recognized certificates of compliance (IRCCs) to genetic sequences uploaded in INSDC, including through interoperability.

18. With respect to the traceability of the different groupings, experts considered that Group 1 with the narrowest scope would in theory be the easiest to trace and verify, while Groups 2 and 3 would be progressively more difficult.

19. It was noted that traceability could be more or less relevant depending on the approach to benefit-sharing followed, and the related monitoring and compliance requirements. For example, in the case of a multilateral approach to benefit-sharing, traceability of digital sequence information to the provider countries and monitoring its use along the value chain may not be required.

20. Related to this, experts noted the potential complexity and cost of developing systems that could be used to trace and monitor the use of digital sequence information along the value chain.

21. With regard to the implications for INSDC, experts noted that it would be important to receive direct input from INSDC on this issue.<sup>1</sup> Experts noted that more consistent use of INSDC country tags and enhanced passport data could enhance traceability.

22. Experts noted that standard ST.26<sup>2</sup> under the World Intellectual Property Organization (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.

### **B. Potential implications of the different groups for technologies and/or sectors in the life sciences**

23. Experts, on the basis of Study 1, on concept and scope, considered the coverage of the technologies enabled by digital sequence information and the use of digital sequence information in the different sectors in the life sciences. In the discussions, experts indicated that table 3 of Study 1, providing an overview of the reliance of different sectors on digital sequence information, was particularly useful.

24. Experts noted that discussions on implications for life-science sectors was of a preliminary nature and that evaluating the implications of the different groups for the scope of digital sequence information would benefit from a deeper discussion, including:

- (a) Considering the implications of the groups for different technologies, as opposed to sectors;
- (b) Considering the benefit-sharing implications resulting from the different Groups;
- (c) Considering the implications of the use of digital sequence information by public and private scientists resulting from the different groups;
- (d) The shift in bioprospecting from testing of natural products to screening of chemical libraries.

25. In its limited deliberations on the implications for sectors in the life sciences, the AHTEG noted:

- (a) Challenges regarding traceability and enforceability which arise inherently from the inability to readily infer from metabolites their underlying DNA, RNA or proteins;
- (b) That data and information concerning metabolites, as proposed in Group 3, is important for research in the healthcare and pharmaceutical sector;
- (c) The extent of processing across the different groups is indicative of the correspondingly higher amount of effort required to realize value from a genetic resource and this may be a consideration for traceability and/or benefit-sharing, which may require a sector-based approach.

26. Experts highlighted the importance of having legal certainty regarding usage of digital sequence information for all sectors; therefore, any approach to benefit-sharing should provide legal certainty, incentivize the use of digital sequence information and decrease unnecessary burdens in monitoring, tracing, and tracking requirements.

### **C. Potential implications of the different groups or options concerning measures governing access, benefit-sharing and compliance**

27. In considering the study on domestic measures, experts acknowledged that some countries are currently regulating digital sequence information, others may be waiting for international consensus on this issue under the Convention and in other forums, and others have stated that they do not intend to regulate it at all.

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<sup>1</sup> The expert nominated by INSDC was not able to attend the meeting.

<sup>2</sup> WIPO Standard ST.26, "Recommended Standard for the Presentation of Nucleotide and Amino Acid Sequence Listing Using XML (Extensible Markup Language)", of which version 1.3 was approved on 5 July 2019. WIPO ST.26 will take effect on 1 January 2022.

28. The experts noted that the multiplicity of different ABS national frameworks addressing digital sequence information on genetic resources poses challenges for users, including those involved in basic non-commercial research, academic research and small and medium-sized enterprises.

29. It was noted that digital sequence information on genetic resources may result, directly or indirectly, from utilization of genetic resources.

30. In this regard, the importance of a concerted and cost-effective international approach to digital sequence information on genetic resources was highlighted, and experts noted possible approaches, including measures at the time of access (noting, for example, flat-fee access or creative commons licensing approaches, database access agreements), open access with benefit-sharing triggered by utilization or commercialization, and a possible multilateral approach.

31. The experts noted that the discussion on potential implications for the different groups concerning measures governing access, benefit-sharing and compliance was of a preliminary nature, and it was noted that this issue would benefit from further discussion. In general, experts noted that the implications of the different groups concerning measures governing access, benefit-sharing and compliance would depend on the different approach to benefit-sharing that might be taken. For example, it was noted that access measures would be unnecessary in a bounded openness model, and other multilateral approaches in which utilization or commercialization would trigger benefit-sharing.

### III. IDENTIFICATION OF KEY AREAS FOR CAPACITY-BUILDING

32. The experts highlighted that capacity-building was critical for digital sequence information on genetic resources, including the capacity of countries to develop their endogenous research and to identify, understand, monitor and manage their own biodiversity.

33. It was suggested that capacity-building to utilize genetic resources and digital sequence information should be integrated in broader capacity-building initiatives/strategies, adapted and tailored to the needs of each country and research institutions, and take into account the needs and specificities associated with carrying out research in different types of environments (for example, marine versus terrestrial).

34. The need to secure appropriate funding and support for development and maintenance of scientific infrastructure was emphasized.

35. Experts discussed capacity-building as a form of non-monetary benefit-sharing. It was noted that capacity-building initiatives intended as a form of benefit-sharing should take into account the socioeconomic contexts of provider countries and be designed to contribute to enhancing the endogenous research capacities of these countries.

36. In discussing key stakeholders for capacity-building related to digital sequence information, experts agreed:

(a) On the need to build the capacity of national focal points and regulators/legislators as well as indigenous peoples and local communities to understand issues related to digital sequence information;

(b) On the importance of ensuring engagement and collaboration among different governmental agencies at the domestic level;

(c) On the need for universities, *ex situ* collections, research institutions, the private sector, and institutions working on bioinformatics to play a role in capacity-building related to digital sequence information.

37. Experts identified the following key areas for potential capacity-building:

(a) General understanding of issues related to digital sequence information, including the relevance of the economics of information to better understand links between access and benefit-sharing and digital sequence information;

- (b) Understanding of the steps involved in the research and development of different products along value chains based on genetic resources/digital sequence information;
- (c) Analysis and processing of big data related to digital sequence information;
- (d) Reinforcement of the effectiveness of access to and use of international databases by the research community in all countries, including developing countries;
- (e) Taxonomy, molecular biology applications for DNA/RNA extraction from genetic resources, PCR and/or sequencing, digital sequence information processing and uploading to databases, bioinformatics, database management.

38. Experts discussed the potential for model contractual clauses, frameworks, and models for addressing digital sequence information in mutually agreed terms to avoid divergent approaches creating obstacles and complexities.

39. Finally, experts also raised different modalities for capacity-building activities, such as:

- (a) On-site and/or virtual courses/workshops in all the official languages of the United Nations;
- (b) Case studies, exchange of information and experiences, and sharing of lessons learned in the official languages of the United Nations;
- (c) Joint scientific research, technology transfer, scientific visits, partnerships and collaborations including through regional networks;
- (d) Support for development of scientific infrastructure, including through regional approaches (for example, CGIAR centres);
- (e) Intercultural dialogue through face-to-face meetings for indigenous peoples and local communities following culturally appropriate tools and methodologies in indigenous languages which could include dialogue between scientists and traditional knowledge holders;
- (f) Integration in academic curricula;
- (g) Integration in regional and international development agendas.

## *Annex II*

### **SUMMARY OF POINTS FROM THE WEBINARS ON POLICY OPTIONS AND CRITERIA FOR DIGITAL SEQUENCE INFORMATION ON GENETIC RESOURCES**

#### **A. Typology of policy options/archetypes**

Drawing upon a range of sources,<sup>3</sup> this note attempts to organize and categorize potential policy options for addressing access and benefit-sharing (ABS) of digital sequence information (DSI) related to genetic resources. The intention is to present the various options in a relatively simple and practical manner. The list of options is not exhaustive. Additional studies or ideas may exist that have not been taken into consideration while new options could still emerge.

The figure below, presents the options in according to various characteristics. The options are being presented in a neutral manner, without judgement on their viability, cost-efficiency, enforceability, or capacity requirements. It should be noted that the options are not mutually exclusive, and in some cases, two or more options or components of options could be combined. While traditional knowledge associated with genetic resources can be an important aspect of DSI, we are not aware of studies that have been published on this topic. Thus, this topic is not covered here.

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<sup>3</sup> The list of studies and publications taken into consideration in this summary can be found on the website of the Convention at <https://www.cbd.int/article/dsi-webinar-series-2020#webinar3>.

Access regulated	PIC	MAT	0	<b>Status quo</b> – Parties have not agreed on how to address ABS for DSI of GR	BS linked to DSI data	Requires tracing of country of origin	Bilateral mechanism
			1	<b>DSI Fully integrated</b> into approach of CBD & NP PIC and MAT (DSI= GR)			
Access not regulated	NO PIC	NO MAT	2.1	No PIC. <b>Each country has Standard MAT</b> (benefit-sharing is triggered by use of DSI)	BS NOT linked to DSI data	Does NOT require tracing of country of origin	Multilateral mechanism
			2.2	No PIC. <b>Standard MAT at international level</b> (benefit-sharing is triggered by use of DSI)			
			3.1	<b>Payment for access to DSI</b> No PIC. No MAT			
			3.2	<b>Other payments and contributions</b> (micro-levy, voluntary). No PIC. No MAT			
			4	<b>Technical and scientific cooperation</b> – could be complementary to other options			
			5	No PIC, No MAT. <b>No Benefit Sharing from DSI</b> (DSI is not considered equal to GR)			

Figure 1. High-level classification of policy options according to specific characteristics

*Note:* These characteristics were selected according to their prevalence in the literature and subjective logic. However, other characteristics can be used to classify policy options according to their importance to various stakeholder groups. The short labels for the characteristics are used for convenience and are further explained below.

### Explanation of characteristics used in Figure 1

*Access regulated:* Access to the DSI is not open but is regulated in some way. Note that “access not regulated” does not mean that there are no conditions associated with access; it is not necessarily free of charge.

*PIC:* Prior and informed consent is required to access DSI.

*MAT:* Mutually agreed terms, or standard licence, are negotiated to share benefits from the use of DSI. A MAT can include the necessity for PIC but is not always the case (see option 2).

*BS linked to DSI data:* The sharing of benefits from the use of DSI is linked to the specific product or service stemming from that particular DSI, as opposed to a general contribution by users of DSI.

*Requires tracing to the country of origin:* It is necessary for the policy option proposed to be able to identify the country of origin of the genetic resource from which the DSI came from.

*Bilateral mechanism:* The policy option requires an agreement between the provider and user countries to set the terms of benefit-sharing and the sharing of those benefits back from the user country to the provider country of DSI, as opposed to the benefits from the use of DSI being channelled through a multilateral fund or mechanism.

*Description of the options by group*

**Option 0: Status Quo**

In this option, Parties have not agreed on how to address ABS for DSI. Some Parties may decide to include measures on access to DSI and/or benefit-sharing from DSI use as part of their domestic ABS system, and some will consider open access to DSI in databases to be a sufficient form of non-monetary benefit-sharing.

**Option 1: DSI fully integrated into the Convention on Biological Diversity and the Nagoya Protocol**

In this case, ABS is subject to each country's legislation. It is the traditional bilateral approach to ABS. Access is regulated in a similar way than the genetic resources under the Convention on Biological Diversity and the Nagoya Protocol, meaning that depending on the national legislation in place in a particular country, access to DSI could be subject to PIC and MAT (i.e., essentially, GR = DSI). The utilization of DSI is to be regulated by MAT, as are benefit-sharing obligations, and MATs are negotiated for each DSI access. According to the study on ABS measures made available for the consideration of the AHTEG on DSI, some countries are already including DSI within the scope of their national ABS measures, and more are planning to do so in the near future.

In this option, researchers have to comply with national ABS requirements when accessing DSI through a database, trace each DSI back to the country of origin and negotiate with different ABS requirement for each country, as they potentially each have a different MAT.

**Option 2: Standard MAT**

This more general grouping of options recognizes the obligation to share benefits from the use of, but in a way that is not linked to the access to DSI itself (there is no PIC). The obligation to share benefits can be triggered by determined milestones along the value chain. Access is therefore not restricted, but the obligation to share benefits is determined by some type of standard MAT/license/standard multilateral transfer agreement/terms and conditions. The fact that the MAT is standardized implies that there is no need for individual negotiation of contract for each DSI utilization, but one or a limited number of standard contracts. This category of policy options requires downstream monitoring of DSI use for enforcement and monitoring. The difference between the two sub-options is the way that MATs are dealt with, either at the national or the international level.

**Option 2.1: Each country has a standard MAT/licence**

In this scenario, each Party establishes a system with one or a limited number of standard MAT/licences with which users need to comply at the pre-determined point where the obligation to share benefits is triggered. This system goes through each country's domestic legislation. Triggers can occur at commercialization, for example, and the benefits would be shared bilaterally. This is similar to the approach taken by the latest ABS measures in Brazil, where the benefit-sharing obligations are communicated at the point of registration of a pattern and start after successful commercialization of a product developed or produced using DSI. Researchers must comply with the national system and trace the DSI back to the country of origin of the genetic resource. If a researcher uses multiple DSI from different countries, he/she is required to potentially comply with a limited number of MAT/licences, depending on which standard MAT/licence the country has decided upon for their DSI.

*Note:* A variant of this approach is the adoption of a standardized system for all countries that would simplify compliance. Each country would have the same system in place for DSI, which would still go through each country's ABS system.

**Option 2.2: Standard MAT/licence at the international level**

This option addresses benefit-sharing at the international level, as opposed to going through each country's national system as presented under option 2.1. One or more standard licences are agreed upon and the terms and conditions depend on the licence attached to the DSI. The benefits from the use of DSI are handled by

an international system that redirects them to the country of origin of the genetic resource. This means the researcher/user does not have to approach each country individually.

This option offers the possibility to integrate the licences in the DSI database itself, and the terms and conditions are communicated to the user at access (for example, obligations for commercial and non-commercial uses of a particular DSI). Another possibility is the integration of the terms and conditions or licences in the intellectual property system (for example, when seeking intellectual property protection, on the basis of a disclosure requirement on the use of DSI). This option is explored in the “bounded openness over natural information”, where benefits consist of pre-negotiated fixed royalties on the successful commercialization of a product.

A collaboration with journals, patent offices, databases, or any other point along the value chain of DSI will help enforce the reporting back to the DSI provider. In this case, the user is responsible for complying with the licence terms and conditions, and a downstream utilization tracking/monitoring mechanism will ensure the enforcement of these ABS measures.

### **Option 3: No PIC, No MAT**

This general grouping of options requires a payment or contribution to go into a multilateral fund. It avoids the need for tracing the origin of the genetic resource from which the DSI was extracted, or the need to monitor the downstream utilization of the product or service derived from DSI. This option includes various possible forms of payments and contributions, the first sub-option being linked to the DSI itself, and the second sub-option being separate from the information itself.

#### **Option 3.1: Payment for access to DSI**

Here, the principle of a payment for access to the sequence itself is central and can be set up in several ways. One way is to require a membership fee to access DSI in the databases. This fee can be determined following pre-negotiated criteria, such as but not limited to research application, sector of research, revenue, or a flat rate annual fee.

Another way is to require a very small payment for access to individual DSI in the database. An account is created, and each sequence download results in a pre-determined fee being charged to the account.

Finally, a different arrangement is to provide free access to the sequence data itself, including some minimal data around it, such as species name, but require a fee be paid on the associated data resulting from the analysis and processing of the data, such as protein function or gene association, as this associated data is estimated to be valuable for research and development. The BioSample database currently links sequence data with other data associated with the sequence itself, or the genetic resource from which it comes. In this policy sub-option, the BioSample database would charge for access.

#### **Option 3.2: Other payments and contributions**

Several ways in which payments and contributions can be established to be paid into a multilateral fund for benefit-sharing from the use of DSI have been proposed in the literature. One proposal includes payment for a DSI-related service, such as storage, processing, expertise, and analysis of the sequences, offered in return for a payment.

Another proposal imposes a levy on products or services associated with DSI. One example is the imposition of a micro-levy on laboratory equipment linked with the production of DSI, while another is on the cloud-computing space rented for the purpose of sequence storage and/or processing.

Yet, another proposal is around biodiversity bonds, as experiences from other fields, such as payments for the use of wildlife images, or climate change green bonds could be used to inform options for DSI. Another option involves a marketing programme whereby a label or badge is used on products to boost their sale and convey an idea around biodiversity conservation, while the companies selling these products would commit to redirecting a negotiated percentage of benefits to a multilateral fund. Finally, voluntary



contributions could fuel a multilateral fund and come from the private sector, database users, countries, private donors, etc.

#### **Option 4: Enhanced technical and scientific cooperation**

Under this option, technical and scientific cooperation becomes a systematic and mandated part of DSI policy. Enhanced capacity support for developing countries will democratize the access and use of DSI, making it more equitable so that each country has the capacity and opportunity to access and use DSI to its full potential. This could take the form of research collaborations, training, knowledge platforms, technology transfer, technology co-development, and more. This option is almost always presented in combination with other policies.

#### **Option 5: No Benefit Sharing from DSI**

This option does not consider that benefit-sharing from the use of DSI from genetic resources is necessary and, thus, no mechanisms are proposed to be implemented.

### **B. Typology of criteria to consider for policy options**

#### *Background*

Several common key criteria came up in publications on DSI:

1. Fair and equitable sharing of benefits from the use of DSI from genetic resources;
2. Open data;
3. Contribution to conservation and sustainable use of biodiversity;
4. Linking across biodiversity regimes and international forums;
5. Financial feasibility of monetary benefit-sharing;
6. Simplicity of solution.

Taking the “phases” of policy development into consideration, the first three criteria can be defined as addressing the “why” for the policy options, in terms of goals and measurement of success. The last three can be attributed to the “how” and conveys the way in which a policy option can address these objectives.

The first two key criteria were systematically addressed in DSI papers and require particular attention as potential overarching criteria:

- *Fair and equitable sharing of benefits* resulting from the use of DSI from genetic resources can be defined around two points: the benefits from the use of DSI coming from genetic resources should be shared, and this sharing should be fair and equitable.
- *Open data* aims at data access not as an impediment to scientific research or innovation. All papers converge on the fact that DSI should remain discoverable and accessible, but differ on cost and conditions of use attached to the data.

These two goals reflect the pillars of access and benefit-sharing, and a policy solution should aim at finding a balance between these two notions, and, if Parties agree, to not work against either of those.

#### *Proposed criteria framework*

Based on the foregoing, and inspired by other frameworks from the literature, a bespoke framework has been developed with a view to reflecting the issues raised in DSI policy papers and reports (see table below). The four groupings/categories reflect the four “steps” of a policy option analysis, implementation and context. This classification is not exhaustive or exclusive, and each stakeholder should reflect on the classification of criteria that makes the most sense to them.

1 - The first category is the why, the end-goal, objectives. This encompasses objectives already common to all literature on DSI, but also those that will be determined through consultation, discussions, and eventually negotiations.

2 - The second is more on the how, the feasibility, the implementability of policy options. Anchoring the goals and principles of a policy in practicality and realistic expectations is essential for success.

3 - The good governance is also a how but overarching both goals and tools. These are guiding criteria for ethical and transparent governance and management: being transparent, emphasizing communication and inclusion.

4 - The last grouping is about context. The different elements of a policy options should be comprehensive and complementary. In addition, the solution should aim at coherence with the effort of other bodies and initiatives on ABS for DSI.

**Table. Proposed criteria framework**

Category	Criteria	Means for assessment
<b>Effective in achieving Goals</b> (Note: goals may be agreed, or to be agreed)	1. Delivers fair and equitable benefits from DSI (associated with GR)	Quality and quantity of benefit-sharing (monetary and non-monetary) Timeliness of benefit-sharing Specificity/targeting of benefit-sharing (to providing community; to providing country; shared broadly, formula for sharing)
	2. Facilitates access to DSI and does not disrupt R&D	Open access (with or without conditions; burden of conditions) Promotes R&D partnerships in support of technology transfer and capacity-building
	3. Contributes to the conservation and sustainable use of biodiversity	Directly or indirectly (through incentives)
	4. Contributes to sustainable development	Note: achieves 4 as a consequence of achieving 1, 2 and 3 (no separate evaluation needed)
<b>Efficient and feasible to implement</b>	5. Cost-efficient in achieving goals	Transaction and administration costs minimized relative to benefits shared Institutional/infrastructural/governance costs minimized relative to benefits shared
	6. Feasible and practical to implement	Technical requirements minimal or feasible to meet (eg. need for tracking, capacity-building tools, Degree to which existing infrastructure and processes can be built upon
	7. Easy to enforce	Inbuilt incentives for compliance (self-enforcing) If enforcement needed, enforcement costs minimal
<b>Enabling of good governance</b>	8. Legally sound	Legal certainty/predictability Dispute resolution mechanism
	9. Just	Positive and negative consequences for indigenous peoples and local communities, stakeholders Reducing information asymmetry among countries and users
	10. Transparent	Simplicity, transparency, ease of understanding
<b>Comprehensive and Coherent</b>	11. Coherent	Degree of coherence with existing systems of ABS Degree of coherence across international agreements covering different sectors (environment, food & agriculture, health, oceans etc)
	12. Comprehensive and/or compatible	Degree to which option covers all needs/scope, or compatibility of option with others so that overall system covers all needs/scope Future proof (adaptability of system; likelihood to remain effective and efficient in face of future technological developments

*Annex III*

**SUMMARY POINTS ON THE ONLINE DISCUSSION FORUM ON DIGITAL SEQUENCE  
INFORMATION ON GENETIC RESOURCES**

*Note:* This contains a summary of points raised in the informal online discussion (21 April -3 May 2021) organized to exchange information and views on DSI policy options and criteria. The discussion posts and comments are available on the website of the Convention on Biological Diversity.<sup>1</sup> This information is provided without prejudice to the official position of Parties and observers on these matters.

**Most frequent/pertinent remarks**

**General**

- On data:
  - o Access should not be limited to preserve innovation, eliminates jurisdiction shopping, minimize cost to obtain natural information
  - o Has to be FAIR (Findable, Accessible, Interoperable, Reusable)
  - o Data comparison could be considered a view and not a use of the data (and be exempt from any data use obligations)
  - o Open access will only succeed if all can use and benefit from the data
- The definition of DSI has practical implications for policy
- Conversation needs to be less theoretical and more practical
- Benefit-Sharing and Access should be decoupled in the discussion on DSI
- There is an urgency to agree on a way forward for DSI
  - o to be able to integrate post-2020
  - o not to delay any potential benefits for conservation
  - o for other international forums to leverage our outcomes in their own discussions
  - o legally binding policies might delay implementation too much
- Lessons learned from Nagoya negotiations and implementation have to be considered here
- Database is an operational tool for the information, so a broader framework on information should be decided first
- Taxonomy is an international public good
- Results from publicly funded basic research are non-monetary benefits enough and should not have to contribute to monetary benefit
- A compromise must be made between the owners of the technology and the owners of the germplasm for benefit-sharing and technology transfer
- The modalities of benefit-sharing will influence consideration of different options
- Regulatory oversight of benefit-sharing could be at country/jurisdiction level or will rely on civil providers to pursue fraudulent cases (which implies naming and geographical location of activity)
- There is a need to focus on what is being done with DSI and its impact on society and biodiversity, more than the DSI tools

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<sup>1</sup> <https://www.cbd.int/dsi-gr/forum.shtml>

## **Policy options**

- A system of rewards for the production of DSI, innovation could be facilitated and incentivized
- Avoid/minimize transaction cost, bureaucracy, compliance burden
- Ensure legal certainty and predictable cost for users to encourage investment
- Additional policy options:
  - o Should broader mobilization initiatives be considered here?
    - Option 3.2. Biodiversity bonds or labels can go beyond DSI
  - o Multilateral and universal policy options (harmonized or interdisciplinary)
    - As a way to link across biodiversity regimes and international forums
  - o National Governments make benefit-sharing payments based on levels of relevant commercial activity of companies on their soil. These benefits can be used to address priorities in the post-2020 global biodiversity framework. Companies can seek to recoup part of this in their jurisdiction.
- Policy options should include the context in which to view them (Convention on Biological Diversity or Nagoya Protocol)
- Non-monetary benefits should be part of any policy solution
- The platform proposed by Elisa Morgera in her study by the United Kingdom of Great Britain and Northern Ireland should be considered as it combines knowledge exchange, capacity-building, technology transfer, cooperation, and co-production of DSI solutions.
- Non-monetary benefits could be integrated in the research funding stream of wealthier countries
- Open data and fair and equitable sharing of benefits exclude option 0, 1 and 5
- Option 2.2 is similar to the current default benefit-sharing option in Article 6.7 of the Plant Treaty's Standard Multilateral Transfer Agreement

## **Criteria**

- Open access (and innovation facilitation) and fair and equitable benefits are not antithetical and should be overarching principles of DSI policy solution
- Distribution of funds:
  - o Contribution to conservation should be an overarching goal – biodiversity is the first beneficiary
  - o Funds should be used for capacity-building
- Second tier criteria
  - o Minimize regulatory arbitrage
  - o Minimize regulatory complexity
  - o Minimize transaction costs
  - o Minimize implementation costs
- Additional criteria: reversibility (to be flexible to technological development), viability, enforceability.

## **Issues to be explored further**

- Overarching flow of monetary benefits: collection (compliance monitoring), distribution (governance) and use (data management). Which criteria apply to which component?
- Databases:

- Can all data sources be consistent? Public and private database present different hurdles/potential issues.
  - Can we add a registration to databases while keeping the data open (e.g. Global Biodiversity Information Facility) to allow for tracking?
  - Databases are a third party. We need to discuss core data. Are they willing to attach terms and conditions?
  - More economic aspects of proposed policies need to be considered/studied
    - Clear/accessible definition of natural information and economic rent
    - The theory of the economics of information are relevant for natural information, but need to integrate the generation of information and its reproduction
    - Modelling of monetary benefits and costs of implementation (set up and maintenance) of each or a subset of policy options
    - Value of the information associated with GR and DSI should be considered/evaluated
    - The phase of obtention of DSI from GR is more analogue while DSI access and reuse is more digital and will behave like information
  - The past 30 years' worth of literature on GR should bring answers on feasibility, challenges, values or markets of DSI
  - Legal questions:
    - Many propositions in the online forum can be treated as amendments to the Convention, Protocol negotiations and decisions of the Conference of the Parties. However, negotiations of the MLS under the International Treaty on Plant Genetic Resources for Food and Agriculture by a group of legal experts concluded that a multilateral solution is better implemented as a resolution of the governing body, and not as amendments.
    - Will the model form part of a legally binding treaty?
  - There is a need to explore why some multilateral funds are not as successful as expected.
-