



COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

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BENEFIT-SHARING FROM DIGITAL SEQUENCE INFORMATION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

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I. INTRODUCTION

1. The Commission on Genetic Resources for Food and Agriculture (Commission), at its last session, considered the role of digital sequence information (DSI) on genetic resources for food and agriculture (GRFA) and welcomed the establishment of a multilateral mechanism for benefit-sharing from the use of DSI on genetic resources by the Conference of the Parties (COP) to the Convention on Biological Diversity (CBD).¹

2. The Commission requested the Secretariat to continue monitoring developments regarding DSI in other fora, and participate where relevant, with a view to considering their implications, including potential opportunities and challenges for the Commission and its Members.

3. The present document provides information on relevant developments in other fora. The document focuses, in particular, on the CBD COP decision on DSI on genetic resources (Decision 16/2) through which the COP agreed on modalities for operationalizing the multilateral mechanism on DSI. The document also seeks the Commission's guidance regarding further work, if any, on DSI on GRFA.

II. THE ROLE OF DIGITAL SEQUENCE INFORMATION FOR FOOD AND AGRICULTURE

4. Current and potential applications of DSI show that the generation, storage, access to and use of DSI are fundamental for the characterization of all kinds of biodiversity for food and agriculture (BFA) and, therefore, also important to achieve sustainable agriculture. The examples of actual and potential applications of DSI relevant to the conservation and sustainable use of GRFA, as reviewed by the Commission's Working Groups,² clearly indicate the relevance of DSI and related technologies for all subsectors of GRFA.

5. More information on the role of DSI is provided in the study on *The role of digital sequence information for the conservation and sustainable use of genetic resources for food and agriculture: opportunities and challenges*.³ The study explores the availability and accessibility of DSI to the research community and the private sector in all parts of the world. It discusses applications of DSI that are relevant to GRFA, including DSI that is not derived from GRFA but nevertheless contributes to their identification, characterization, use, improvement and conservation, as well as obstacles to access and use of DSI and the need for capacity building to address global imbalances in its generation and use.

6. As requested by the Commission, the study was finalized and published following the Commission's last session. It was also brought to the attention of the CBD Ad Hoc Open-ended Working Group on Benefit-sharing from the Use of Digital Sequence Information on Genetic Resources⁴ and the Ad Hoc Working Group to Enhance the Functioning of the Multilateral System, established under the International Treaty on Plant Genetic Resources for Food and Agriculture (International Treaty).⁵

7. Submissions by Members on domestic access and benefit-sharing (ABS) measures applying to DSI and their actual or potential implications for the conservation and sustainable use of GRFA, including their exchange, access to them and the fair and equitable sharing of the benefits arising from their use, have been compiled in the document, *Submission by Members on digital sequence information*,⁶ for information of the Commission.

¹ CBD/COP/DEC/15/9.

² CGRFA-18/21/5, Table 2.

³ Smith, D., Ryan, M.J. & Buddie, A.G. 2023. *The role of digital sequence information in the conservation and sustainable use of genetic resources for food and agriculture: opportunities and challenges*. Background Study Paper, No. 73. Commission on Genetic Resources for Food and Agriculture. Rome, FAO.
<https://doi.org/10.4060/cc8502en>

⁴ <https://www.cbd.int/meetings/WGDSI-02> (under "Other").

⁵ IT/OWG-EFMLS-12/24/Report.

⁶ CGRFA-20/25/4/Inf.1.

III. DEVELOPMENTS IN OTHER FORA

8. Since the last session of the Commission, discussions on DSI continued in multiple fora, in particular under the CBD and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol), where agreement was reached on the modalities for operationalizing the multilateral mechanism for the fair and equitable sharing of benefits from the use of DSI on genetic resources (MMBS), including a global fund that will be known as the Cali Fund for the Fair and Equitable Sharing of Benefits from the Use of Digital Sequence Information on Genetic Resources (Cali Fund).

9. The modalities for operationalizing the multilateral mechanism stipulate that all users of DSI on genetic resources under the multilateral mechanism should share benefits arising from its use in a fair and equitable manner. Users of DSI on genetic resources in sectors that directly or indirectly benefit from its use in their commercial activities should contribute a proportion of their profits or revenue to the Cali Fund, according to their size, as further specified in the modalities. The modalities also include provisions for the sharing of non-monetary benefits and guidance for entities operating databases that are dependent on DSI on genetic resources and that make such information publicly available.

10. As also set out in the modalities, resources from the Cali Fund are to be allocated in a fair, equitable, transparent, accountable and gender-responsive manner to support the realization of the objectives of the Convention in developing country Parties. Funding will also be available to Indigenous Peoples as well as local communities in both developing and developed countries. The multilateral mechanism, including the Cali Fund, will operate under the authority and guidance of and be accountable to the CBD COP. The modalities also include the establishment of a Steering Committee and of a Secretariat, and the designation of the Multi-Partner Trust Fund Office of the United Nations as the host of the Cali Fund. Some of the modalities may be supplemented or adjusted in light of intersessional work before the next meeting of the COP and in light of future reviews of the multilateral mechanism.

11. A summary of recent developments related to DSI in other fora, namely, the CBD and the Nagoya Protocol, the International Treaty, the World Health Organization (WHO), the Agreement under the United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas beyond National Jurisdiction (BBNJ Agreement), and the World Intellectual Property Organization Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge (WIPO GRATK Treaty) is contained in the *Annex* to this document.

IV. GUIDANCE SOUGHT

12. The Commission may wish to:

- (i) welcome Decision 16/2 of the CBD COP on *Digital sequence information on genetic resources*, including the modalities for operationalizing the MMBS, including the Cali Fund;
- (ii) take note of the submissions by Members on domestic ABS measures applying to DSI and their actual or potential implications for the conservation and sustainable use of GRFA, including their exchange, access to them and the fair and equitable sharing of the benefits arising from their use;
- (iii) recognize the vital role that Indigenous Peoples, farmers, fishers and local communities play in the conservation and sustainable use of GRFA and the need for building their capacity to support the effective implementation of DSI mechanisms, including the

exchange of, access to and the fair and equitable sharing of the benefits arising from the utilization of GRFA; and

- (iv) request the Secretariat to:
 - a. continue monitoring developments regarding DSI in other fora, with a view to considering their potential implications, including potential opportunities and challenges for the Commission, its Members, and other stakeholders, and to report back to the Commission; and
 - b. invite the Secretariats of the CBD and the International Treaty to co-convene a workshop, subject to the availability of resources, on the implications of Decision 16/2 for research and development in the food and agriculture sector, including the exchange of, access to and the fair and equitable sharing of the benefits arising from the utilization of DSI on GRFA.

ANNEX

SUMMARY OF RECENT DEVELOPMENTS RELATED TO DIGITAL SEQUENCE INFORMATION ON GENETIC RESOURCES IN OTHER FORA

(1) Convention on Biological Diversity/Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity

1. As reported to the previous session of the Commission, the 15th meeting of the Convention on Biological Diversity (CBD) Conference of the Parties (COP) ended with the adoption of the Kunming-Montreal Global Biodiversity Framework⁷ that refers in Goal C and Target 13 to digital sequence information (DSI) in the context of the fair and equitable sharing of benefits that arise from the utilization “of genetic resources and digital sequence information on genetic resources”. The COP also agreed that “the benefits from the use of digital sequence information on genetic resources should be shared fairly and equitably” and “decide[d] to establish, as part of the Kunming-Montreal Global Biodiversity Framework, a multilateral mechanism for benefit-sharing from the use of digital sequence information on genetic resources, including a global fund.”⁸ The COP established an ad hoc open-ended working group on benefit-sharing from the use of DSI on genetic resources to undertake further development of the MMBS and to make recommendations to the COP at its Sixteenth Meeting.

2. At its 16th meeting, held in October 2024, the CBD COP adopted the modalities for operationalizing the multilateral mechanism for the fair and equitable sharing of benefits from the use of DSI on genetic resources (MMBS), including the Cali Fund for the Fair and Equitable Sharing of Benefits from the Use of Digital Sequence Information on Genetic Resources (Cali Fund). The COP serving as the meeting of the Parties to the Nagoya Protocol is expected to adopt a decision taking note of the CBD COP decision on DSI at the second resumed session of its fifth meeting, which will be held at the end of February 2025.⁹

3. The CBD COP also decided to explore: (i) possible additional modalities of the MMBS; and (ii) possible new tools and models, such as databases, for making DSI on genetic resources publicly available and accessible in a transparent and accountable manner to all Parties.¹⁰ The Secretariat invited views on (i) by 21 March 2025¹¹ and on (ii) by 4 April 2025.¹²

Scope of the multilateral mechanism

4. While Decision 16/2 leaves the term DSI undefined, it clarifies that the MMBS covers DSI on genetic resources:

- (i) that is made publicly available, in compliance with national legislation, where applicable;
- (ii) that is not subject to mutually agreed terms established at the time of access to the genetic resources from which the DSI is derived, unless those terms allow for the making of the DSI on genetic resources freely available;
- (iii) for which the fair and equitable sharing of benefits from the use of DSI on genetic resources is not provided for under other international instruments on access and benefit-sharing (ABS), unless the MMBS is chosen for that purpose under those instruments.

5. This means, conversely, that the use of DSI that is not publicly available does not trigger benefit-sharing expectations under the MMBS. Likewise excluded from the MMBS is DSI for which benefits are shared under an agreement reached at the time of access between a provider and a user of the genetic resources from which the DSI was derived (unless the DSI may be made publicly available under that agreement). In addition, the MMBS does not cover DSI for which benefit-sharing is

⁷ CBD/COP/DEC/15/4.

⁸ CBD/COP/DEC/16/2.

⁹ CBD/NP/MOP/5/L.13.

¹⁰ CBD/COP/DEC/16/2, paragraphs 3 & 4.

¹¹ SCBD/OES/DC/TS/CGA/KB/91971. <https://www.cbd.int/notifications/2024-114>

¹² SCBD/OES/DC/TS/CGA/KB/91971. <https://www.cbd.int/notifications/2024-115>

provided under another international ABS instrument (unless the other ABS instrument provides otherwise).

Users that should share benefits

6. While all users of DSI on genetic resources under the MMBS should share benefits arising from its use in a fair and equitable manner,¹³ the MMBS expects only users of DSI on genetic resources “in sectors that directly or indirectly benefit from its use in their commercial activities (...) to contribute a proportion of their profits of revenue to the Cali Fund, according to their seize. An indicative list of such sectors is contained in enclosure I to Decision 16/2 and includes, among others, animal and plant breeding, nutraceuticals (food and health supplements) as well as biotechnology.¹⁴

7. Exempt from monetary benefit-sharing are:

- (i) entities operating public databases,¹⁵
- (ii) public research and academic institutions;¹³ and
- (iii) entities “that do not directly or indirectly use DSI” even though they belong to sectors that directly or indirectly benefit from the use of DSI in their commercial activities.¹⁶

8. It is noteworthy that the exclusion of public databases and public research and academic institutions seems to apply irrespective of whether their activities generate profits or revenue. With the exclusion from monetary benefit-sharing of entities that do not directly or indirectly use DSI, Decision 16/2 draws an important line between entities belonging to enclosure I sectors that use and those that do not use DSI. However, Decision 16/2 does not provide guidance as to which activities qualify as “indirect” use of DSI, e.g. whether the use in a conventional breeding programme of breeding material that has been subject to processes using DSI triggers benefit-sharing expectations.

9. Decision 16/2 states that all users of DSI on genetic resources should share non-monetary benefits in a fair and equitable manner, as appropriate.¹⁷ Non-monetary benefit-sharing is complementary to monetary benefit-sharing and should support self-identified capacity and technical development needs and priorities, including capacity-building for the generation of, access to and use and storage of DSI on genetic resources, as well as the self-identified needs of Indigenous Peoples as well as local communities, including women and youth within those communities.¹⁸

Benefit-sharing modalities

Monetary benefits

10. Decision 16/2 specifies monetary benefit-sharing expectations only for entities above a certain size. Entities that, on their balance sheet dates, exceed at least two out of three thresholds (namely, total assets: USD 20 million, sales: USD 50 million and profit: USD 5 million) averaged over the preceding three years should make an annual contribution to the Cali Fund of 1 per cent of their profits or 0.1 per cent of their revenues, as an indicative rate. Contributions to the Cali Fund are expected to be made either directly or through a national authority.¹⁹

11. Benefit-sharing modalities for other entities may be established by the next meeting of the COP in the light of studies on national and international standards for the identification of small, medium and large entities, including implications for revenue generation and economic competitiveness.²⁰ The Secretariat invited inputs to this work by 18 April 2025.²¹

¹³ CBD/COP/DEC/16/2, Annex, paragraph 2.

¹⁴ “Biotechnology,” according to article 2 of the CBD, means “any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.”

¹⁵ CBD/COP/DEC/16/2, Annex, paragraph 9.

¹⁶ CBD/COP/DEC/16/2, Annex, paragraph 5.

¹⁷ CBD/COP/DEC/16/2, Annex, paragraph 6.

¹⁸ CBD/COP/DEC/16/2, Annex, paragraph 7.

¹⁹ CBD/COP/DEC/16/2, Annex, paragraph 14.

²⁰ CBD/COP/DEC/16/2, Annex, paragraph 4.

²¹ SCBD/OES/DC/TS/CGA/KB/91971. <https://www.cbd.int/notifications/2024-116>

12. For each year that users of DSI make monetary contributions to the Cali Fund in line with the modalities of Decision 16/2, they will receive a certificate that excludes them from any expectation to share further monetary benefits from the use of such information within the scope of the MMBS for that year.

Non-monetary benefits

13. The sharing of non-monetary benefits is to be facilitated through an existing clearing-house under the CBD, which will primarily provide information on demand for capacity-building needs, knowledge exchange and the showcasing and reporting of ongoing non-monetary benefit-sharing activities.²²

Allocation of funding

14. Funding from the global fund should be allocated in a fair, equitable, transparent, accountable and gender-responsive manner.²³ It should support the realization of the objectives of the CBD in developing country Parties, in particular the least developed countries and small island developing states, and Parties with economies in transition, especially the conservation and sustainable use of biodiversity, contribute to scientific research on biodiversity, benefit Indigenous Peoples as well as local communities, including women and youth within those communities and support the building of capacity to generate, access, use, analyse and store DSI on genetic resources according to capacity needs. Funding will also be available for those purposes to Indigenous Peoples as well as local communities in developed countries, where appropriate.²⁴

15. Enclosure II to Decision 16/2 provides an indicative list of criteria for funding allocation. On the basis of these criteria, an allocation methodology for disbursing funding from the Cali Fund is going to be developed by an ad hoc expert group.²⁵

16. Funding will be disbursed through direct allocations to national entities designated by Parties, which may allocate resources, in a transparent manner, on the basis of projects developed through a country-driven or community-driven process and should be accountable for ensuring that the funds are used for the self-identified purposes for which they are distributed.²⁶

17. Where appropriate, and subject to national legislation, at least half of the funding of the Cali Fund should support the self-identified needs of Indigenous Peoples as well as local communities, including women and youth within these communities.²⁷

Governance of the multilateral mechanism

18. The MMBS, including the Cali Fund, will operate under the authority and guidance of and be accountable to the CBD COP, which will be supported by a steering committee²⁸ and a secretariat²⁹ that serves the committee and supports the functioning of the MMBS. The Cali Fund will be administered by the United Nations through the Multi-Partner Trust Fund Office.³⁰ The MMBS and its fund will operate according to the principles of inclusivity, equity and transparency.³¹ It also must respect the rights of Indigenous Peoples as well as local communities, including women and youth within these communities.³²

Relationship of the MMBS with national ABS measures covering DSI

²² CBD/COP/DEC/16/2, Annex, paragraph 8.

²³ CBD/COP/DEC/16/2, Annex, paragraph 17.

²⁴ CBD/COP/DEC/16/2, Annex, paragraph 18.

²⁵ CBD/COP/DEC/16/2, Annex, paragraph 19 & Enclosure III.

²⁶ CBD/COP/DEC/16/2, Annex, paragraph 20.

²⁷ CBD/COP/DEC/16/2, Annex, paragraph 21.

²⁸ CBD/COP/DEC/16/2, Annex, Enclosure IV.

²⁹ CBD/COP/DEC/16/2, Annex, Enclosure V.

³⁰ CBD/COP/DEC/16/2, Annex, paragraph 23.

³¹ CBD/COP/DEC/16/2, Annex, paragraph 24.

³² CBD/COP/DEC/16/2, Annex, paragraph 25.

19. Decision 16/2 addresses the risk of “duplication of expectations”, including duplicated payments, by excluding from its scope DSI on genetic resources that is subject to mutually agreed terms at the time of access to the genetic resources from which the DSI is derived.³³ Thus, where under national ABS measures access to DSI is subject to mutually agreed terms, the MMBS will not apply. In addition, Decision 16/2 invites Parties that put in place national measures on ABS from DSI on genetic resources to align these measures with the MMBS, “such that there is no duplication of expectations to share the benefits arising from the use of digital sequence information on genetic resources under the multilateral mechanism.”³⁴

Relationship with other international instruments

20. Decision 16/2 accommodates in two different ways the possibility that other international instruments, such as the International Treaty on Plant Genetic Resources for Food and Agriculture (International Treaty) may address the sharing of benefits from the use of DSI derived from specific genetic resources. With a view to avoid any duplications, Decision 16/2 excludes from the coverage of the MMBS DSI on genetic resources for which fair and equitable sharing of benefits is provided under other international instruments.³⁵ On the other hand, it opens up the possibility for other intergovernmental fora to use the MMBS as a benefit-sharing mechanism in which case “the funding should also support their objectives.”³⁶

Data governance

21. While entities operating databases that make DSI on genetic resources publicly available are exempt from monetary benefit-sharing, Decision 16/2 formulates several expectations they should meet regarding data governance. They should: (i) provide information to users of the database on the benefit-sharing requirements under the MMBS; (ii) inform providers of DSI of the need to comply with national and international ABS obligations; (iii) require the provision of information on the country of origin of the genetic resources from which DSI was derived, where known, including associated metadata and traditional knowledge; (iv) be consistent with open access to data, taking into consideration the FAIR-TRUST-CARE principles;³⁷ and (v) require providers of DSI on genetic resources to indicate that the information is not subject to any restrictions that prohibit its sharing.³⁸

Implementation of Decision 16/2

22. While COP decisions indicate a political commitment, they are generally not legally binding. Decision 16/2 therefore only “invites” Contracting Parties to the CBD as well as Non-Parties to take administrative, policy or legislative measures, consistent with national legislation, to incentivize users in their jurisdiction to contribute to the Cali Fund in line with the above modalities.³⁹ Parties funding, sponsoring or hosting sequence databases should ensure that entities operating such databases take measures to ensure the effective implementation of Decision 16/2 and relevant future decisions of the CBD COP.⁴⁰ Other Governments funding, sponsoring or hosting sequence databases are encouraged to do the same.⁴¹

Review of the MMBS, including Cali Fund

23. The effectiveness of the MMBS, including the Cali Fund, will be reviewed by the COP at its eighteenth meeting and at every second subsequent meeting against the principles established at the

³³ CBD/COP/DEC/16/2, Annex, paragraph 1(b).

³⁴ CBD/COP/DEC/16/2, Annex, paragraph 26.

³⁵ CBD/COP/DEC/16/2, Annex, paragraph 1(c).

³⁶ CBD/COP/DEC/16/2, Annex, paragraph 18.

³⁷ Decision 16/2, Annex, paragraph 10 (d) refers to: “the principles of findability, accessibility, interoperability and reusability (FAIR), of collective benefits, authority to control, responsibility and ethics (CARE) and of transparency, responsibility, user-focus, sustainability and technology (TRUST), as well as the recommendations set out in section III of the United Nations Educational, Scientific and Cultural Organization *Recommendation on Open Science*.”

³⁸ CBD/COP/DEC/16/2, Annex, paragraph 10.

³⁹ CBD/COP/DEC/16/2, Annex, paragraph 13.

⁴⁰ CBD/COP/DEC/16/2, Annex, paragraph 11.

⁴¹ CBD/COP/DEC/16/2, Annex, paragraph 12.

fifteenth meeting,⁴² taking into account the factors set out in enclosure VI and a methodology to be adopted by the COP at its seventeenth meeting. The review will also be informed by the relevant indicators of the monitoring framework of the Kunming-Montreal Global Biodiversity Framework.

(2) International Treaty on Plant Genetic Resources for Food and Agriculture

24. As reported to the last session of the Commission, the Governing Body of the International Treaty at its Ninth Session, decided to resume the process for enhancing the functioning of the Multilateral System (MLS). It re-established for this purpose the Ad Hoc Open-ended Working Group to Enhance the Functioning of the Multilateral System of Access and Benefit-sharing (OWG EFMLS) and decided that it should address all three blocks of a package of measures previously developed: the revised Standard Material Transfer Agreement (SMTA); the expansion of the list of crops covered by the MLS (Annex I); and, through a Resolution of the Governing Body, implementation measures. The Governing Body also requested the Co-Chairs of the OWG EFMLS to accord early attention to the issue of DSI/genetic sequence data (GSD), payment rates and other relevant aspects.⁴³

25. At its Tenth Session, held in November 2023, the Governing Body took note of the CBD COP decision to establish the MMBS and urged the OWG EFMLS to take this decision and related developments into account when addressing the issue of DSI/GSD in the context of the process to enhance the functioning of the MLS.⁴⁴ The Governing Body further encouraged Parties to the CBD, in further developing a solution for benefit-sharing from the use of DSI on genetic resources, to consider how it might be mutually supportive of, and adaptable to, the International Treaty.⁴⁵ It also invited the OWG EFMLS to examine possible ways to address DSI/GSD in the package of measures, taking into account developments in the CBD, including progress in the development of the MMBS, as well as initiatives in other relevant fora.

26. Following the Tenth Session of the Governing Body, the OWG-EFMLS held its eleventh meeting in April 2024. It agreed to consider the possibility of developing a specialized approach for DSI/GSD on plant genetic resources for food and agriculture (PGRFA) under the International Treaty, while monitoring the relevant processes under the CBD, to ensure mutual supportiveness. The OWG EFMLS also expressed the view that any solution should not restrict facilitated access to PGRFA or open access to DSI/GSD on PGRFA and should seek to exclude double payments by users.⁴⁶ The Working Group further recommended including provision for a section on DSI/GSD in the draft Governing Body Resolution on implementation measures.

27. At its twelfth meeting, held in September 2024, the OWG EFMLS undertook a first reading of a Co-Chairs' proposal containing the draft Resolution, the revised SMTA and the draft text for the amendment of Annex I. According to the draft Resolution benefit-sharing payments under the revised SMTA should "also reflect any contributions to the development and commercialization of products that are plant genetic resources for food and agriculture from the use of digital sequence information/genetic sequence data."⁴⁷

28. The OWG EFMLS reviewed the section on DSI/GSD in the draft Resolution and provided a number of suggestions for discussion at its next session. It reiterated that any proposals that address DSI/GSD within the International Treaty should aim at being mutually supportive with a mechanism developed under the CBD, including to avoid duplicative payments. The Working Group reiterated its strong support for the subscription mechanism and considered that the subscription mechanism may also meet the expectations for monetary benefit-sharing from the use of DSI/GSD.⁴⁸

29. The Working Group is expected to hold two more meetings in 2025, with the outcomes to be submitted to the Eleventh Session of the Governing Body in November 2025.

⁴² CBD/COP/DEC/16/2, Annex, paragraph 29.

⁴³ IT/GB/9/22/Report, Resolution 3/2022.

⁴⁴ IT/GB-10/23/Report, Resolution 3/2023.

⁴⁵ IT/GB-10/23/Report, Resolution 16/2023.

⁴⁶ IT/OWG-EFMLS-11/24/Report, paragraph 22.

⁴⁷ IT/OWG-EFMLS-12/24/Report, Appendix 3, paragraph 43.

⁴⁸ IT/OWG-EFMLS-12/24/Report, paragraph 8.

(3) World Health Organization

30. The sharing of DSI also plays a role in the ongoing negotiations of a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (WHO Pandemic Agreement), that the second special session of the World Health Assembly (WHA) initiated in December 2021 in response to the COVID-19 pandemic.⁴⁹ As reported previously,⁵⁰ the WHA established an intergovernmental negotiating body (INB) to draft and negotiate the WHO Pandemic Agreement. While negotiations focus on human health, it is generally recognized that the health of humans, domestic and wild animals, plants and the wider environment is closely interlinked and interdependent.

31. The INB held nine meetings between February 2022 and May 2024. In June 2024, the WHA extended the mandate of the INB to finish its work as soon as possible, and submit its outcome for consideration by the Seventy-eighth WHA in 2025, or earlier by a special session of the WHA if possible, in 2024.⁵¹ Subsequently, the INB met in July, September, November and December 2024 and progressed in its negotiations, including on access to pathogens with pandemic potential and the fair and equitable sharing of benefits.

32. The draft text, as presented to the Seventy-seventh WHA,⁵² provides that the parties to the WHO Pandemic Agreement establish a “multilateral system for safe, transparent, and accountable access and benefit sharing for pathogens with pandemic potential, the ‘WHO Pathogen Access and Benefit-Sharing System’ (PABS System)”. The provisions governing the PABS System, including definitions of pathogens with pandemic potential and PABS Materials and Sequence Information, modalities, legal nature, terms and conditions, and operational dimensions, are to be developed and agreed in a separate instrument. The draft text further lists issues the instrument should address and indicates that the PABS System should be recognized as a specialized international ABS instrument, within the meaning of Article 4(4) of the Nagoya Protocol.⁵³

(4) Agreement under the United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas beyond National Jurisdiction

33. After nearly 20 years of discussions and negotiations culminating in the further resumed Fifth Session of the Intergovernmental Conference on an international legally binding instrument under the United Nations Convention on the Law of the Sea (UNCLOS) on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction (ABNJ), the *Agreement under the United Nations Convention on the Law of the Sea on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction*⁵⁴ (BBNJ Agreement) was adopted on 19 June 2023.

34. Part II of the Agreement addresses the sharing of benefits arising from activities with respect to marine genetic resources and DSI on marine genetic resources of ABNJ. The Agreement provides for modalities for non-monetary benefit-sharing. It also sets out interim modalities for monetary benefit-sharing, which apply until the COP has taken a decision on the matter. Payment will be made through a special fund established under the Agreement.

35. The Agreement also address traditional knowledge associated with marine genetic resources in areas beyond national jurisdiction that is held by Indigenous Peoples as well as local communities. Parties shall take legislative, administrative or policy measures with the aim of ensuring that such

⁴⁹ SSA2(5).

⁵⁰ CGRFA-19/23/5.

⁵¹ WHA77(20),

⁵² WHA77/10

⁵³ Nagoya Protocol, Article 4(4) reads: “This Protocol is the instrument for the implementation of the access and benefit-sharing provisions of the Convention. Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.”

⁵⁴ <https://www.un.org/bbnj/>

knowledge is accessed only with the free, prior and informed consent or approval and involvement of these Indigenous Peoples as well as local communities.

36. The Agreement is currently open for signature until 20 September 2025. It will enter into force 120 days after the date of deposit of the sixtieth instrument of ratification, approval, acceptance or accession. As at 1 February 2025, 15 countries had ratified the Agreement.

(5) World Intellectual Property Organization Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge

37. The World Intellectual Property Organization Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge (WIPO GRATK Treaty) was adopted in May 2024. The WIPO Treaty establishes a mandatory patent disclosure requirement that requires patent applicants to disclose the country of origin of the genetic resources and/or the Indigenous Peoples or local community providing the associated traditional knowledge, if a claimed invention is based on genetic resources and/or associated traditional knowledge. If such information is unknown or where the provision on disclosing the country of origin does not apply, the source of the genetic resources or associated traditional knowledge shall be disclosed. In cases where there is more than one country of origin, the applicant shall disclose the country of origin from which the genetic resources were actually obtained. One source of genetic resources explicitly mentioned in the WIPO GRATK Treaty is the Multilateral System of the International Treaty.⁵⁵ If no information about the source is known, Contracting Parties to the WIPO GRATK Treaty shall require the applicant to make a declaration to that effect, affirming that the content of the declaration is true and correct to the best knowledge of the applicant.

38. Each Contracting Party to the WIPO GRATK Treaty shall put in place appropriate, effective and proportionate legal, administrative and/or policy measures to address a failure to provide the information required. However, no Contracting Party shall revoke, invalidate, or render unenforceable the conferred patent rights solely on the basis of an applicant's failure to disclose the required information.

39. The WIPO GRATK Treaty's substantive scope covers patents, including patents on plants, animals and microorganisms. Other forms of intellectual property protection, such as plant variety protection, are not covered by the WIPO Treaty.

40. In line with the CBD, the WIPO GRATK Treaty defines "genetic resources" as genetic material of actual or potential value. "Genetic material" is defined as material of plant, animal, microbial or other origin containing functional units of heredity. However, unlike the Nagoya Protocol, the WIPO GRATK Treaty does not cover inventions based on a "derivative" that does not contain functional units of heredity and, therefore, does not seem to require the disclosure of the country of origin for inventions that are based on DSI only and have been created without utilizing genetic resources. This could change in the future as the WIPO GRATK Treaty foresees a review of its scope and contents four years after its entry into force, which may address "issues, such as the possible extension of the disclosure requirement (...) to other areas of intellectual property and to derivatives and addressing other issues arising from new and emerging technologies that are relevant for the application of this Treaty (...)." ⁵⁶

41. The WIPO GRATK Treaty will enter into force three months after 15 eligible Parties have deposited their instruments of ratification or accession. The work of WIPO, through its Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, continues with the objective of finalizing an agreement relating to intellectual property, which will ensure the balanced and effective protection of traditional knowledge and traditional cultural expressions.

⁵⁵ WIPO GRATK Treaty, Article 2.

⁵⁶ WIPO GRATK Treaty, Article 8.