

Solutions to Digital Sequence Information under the Convention on Biological Diversity Must Protect Research, Development, and Innovation

[Summary]

Currently, there is an ongoing debate within the Convention on Biological Diversity (CBD) on whether the use of digital sequence information on genetic resources (DSI) should be subject to benefit-sharing. While there is no agreed definition of DSI nor consensus on whether it is within the scope of the CBD, discussion on policy options for access and benefit-sharing of DSI is now underway.

Some of the proposals under the discussion could have serious negative impacts on accessing and using DSI that is currently available without restriction and free of charge to researchers around the world. This point has been clearly made within the current discussions and we reiterate this below. However, JBA is also concerned that, given how international databases operate, if monetary benefit-sharing were linked to the access and use of individual sequences, there is a risk that copied and/or fabricated "profitable DSI" and fake data could be generated which would profit only the source of the information or circumvent benefit-sharing. It is feared that spread of intentionally manipulated scientific data by dishonest individuals motivated by financial incentives would undermine the credibility and utility of the entire scientific infrastructure.

Biodiversity is one of the basis of scientific progress and innovation, and science and technology is essential for the conservation, restoration and sustainable use of biodiversity. Recognizing the interdependency of these factors, we need to seek solutions that will bring about a win-win situation rather than a trade-off between the two. JBA agrees that a robust financing strategy is needed for these purposes, however, we should not let any motivation coming from financial incentives into the important scientific infrastructure by placing overblown expectations on ABS system as a primary financing mechanism. A final solution to the DSI issue must protect research and development including free and open access to sequence data and the integrity of the international database system.

[Background]

Access to genetic resources (GR) and the fair and equitable sharing of benefits arising from their utilization (ABS) complement the conservation and sustainable use of biodiversity.

Recently, there is a concern that the ready availability of DSI will undermine ABS systems. It is argued that free and unrestricted availability of DSI obviates the need to access material GR. It is further argued that advances in biotechnology make it possible to conduct research and development using DSI alone without accessing GR. In order to block this "leakage from the system", there is currently a proposal under the CBD to expand the scope of ABS to include DSI. It is believed that such a proposal would strengthen the mobilization of resources (funds) to the developing countries to fund the conservation and sustainable use of biodiversity. This issue is expected to be one of the major points of contention at the 15th Conference of the Parties (COP15) to the Convention on Biological Diversity to be held in China in 2022, along with the next 10-year strategic plan, the Post-2020 Global Biodiversity Framework (GBF).

[Recent Discussions]

Negotiations on ABS related to DSI since COP14 (2018) have been hampered by COVID 19. The Open-ended Working Group 3 (OEWG-3) Part 1 process, held virtually in 2021, produced some documents for further discussions in Part 2 session to prepare draft recommendations for COP15^{1,2}. Many webinars and on-line discussions evaluated and led to several proposals for access and benefit-sharing mechanisms (policy options) for DSI. The co-chairs of OEWG-3 drafted a report that categorized options using multiple criteria (effectiveness, ease of implementation, ease of compliance and legal certainty, etc) to evaluate them². Importantly for JBA, "open access to public databases" and "not to inhibit research and innovation" are included, though, it is unclear how the weighting of these and other factors will be handled in the future.

[Our Previous Views]

Regarding DSI, JBA earlier expressed the following views in coordination with other related organizations^{3,4};

- DSI is not directly subject to ABS, because it is information and is not material GR as defined by the CBD. However, benefit-sharing with respect to those DSIs is not excluded from existing framework of the CBD and the Nagoya Protocol, as the treatment of DSIs obtained through the utilization of accessed GRs, including benefit-sharing, can be covered by mutually agreed terms (MAT) between the provider and user of genetic resources.
- DSIs are essential for modern life science and biotechnology research and development, and innovation in key areas of our global society (e.g., health, food/agriculture, environment) is supported by free and unrestricted access and use of DSI on the public database of the International Nucleotide Sequence Database Collaboration (INSDC). Any restrictions to free and open access for the sake of benefit-sharing would be detrimental not only to the conservation of biodiversity and the sustainable use of its components, but also to human well-being.

[New concerns regarding recent discussions]

JBA has the following concerns underpinning the benefit-sharing discussions on DSI.

(1) There is no common understanding or agreed definition of "DSI" or "open access". Our discussion herein limits DSI to genetic sequence data from genetic resources that are made available in international databases. Given to extent to which DSI has been described and wide range of technical fields affected, the current discussions on DSI are uninterpretable. As a result, it is impossible to estimate the cost and benefits of the options under discussion.

¹ CBD/WG2020/3/5, *annex V, section A* (Report of contact group 5 on digital sequence information on genetic resources), <https://www.cbd.int/conferences/post2020/wg2020-03/documents#>

² CBD/WG2020/3/INF/8 (Co-leads' report on the work of the Informal Co-Chairs' Advisory Group on digital sequence information on genetic resources), <https://www.cbd.int/conferences/geneva-2022/wg2020-03/documents#>

³ Views of Japan Bioindustry Association(JBA) on the issues of Digital Sequence Information on Genetic Resources (8 September 2017), <http://www.cbd.int/abs/DSI-views/JBA-DSI.pdf>

⁴ Promoting sustainable use and conservation of biodiversity through open exchange of Digital Sequence Information: Joint statement by public and private sector organisations, academic and scientific institutions, data repositories and collections representing a broad range of stakeholders (24 May 2019), <https://www.cbd.int/abs/DSI-views/2019/Joint-stakeholder-statement-DSI.pdf>

(2) Imposing a payment scheme for the accessing and using genetic sequence data in the INSDC creates a financial incentive for dishonest individuals to undermine the integrity of this international information exchange system. The extensive public DSI database managed by the INSDC provides free and unrestricted access to sequences that researchers upload. The process to upload sequence data assumes that the basic information is correctly described. The accession number (sequence identification number) assigned by the INSDC is required for submitting papers to international scientific journals. It is said that more than 90% of life science databases depend on the INSDC⁵. Developed to be a common good, the INSDC does not verify the authenticity of the data. Validation of the data and assessing its accuracy is left to the users (registrants). Therefore, there is no guarantee that the sequences to be registered and their functions are correct. Furthermore, duplicate data registration is possible. Given this situation, there is a clear risk that dishonest individuals could upload copied or fabricated sequence data hoping to circumvent benefit sharing obligations and/or profit from others accessing and using the information. Once such intentionally manipulated sequence data has spread, it will be impossible to eliminate them from public databases because strict peer review and/or other costly measures cannot be taken. Policy options that directly couple payments with access and use of DSI pose real risks to the integrity and utility of the international databases.

[Conclusion]

JBA supports the need to fund the Post 2020 Global Biodiversity Framework. However, we have serious reservations that imposing benefit sharing obligations on the access and use of DSI will achieve the conservation and sustainable use goals of the CBD. Instead, regulating DSI poses a real threat to scientific research, development, and innovation by thwarting the flow of information and potentially affecting the integrity of critically important international databases.



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⁵ CBD/DSI/AHTEG/2020/1/4 (Combined study on digital sequence information in public and private databases and traceability), <https://www.cbd.int/doc/c/1f8f/d793/57cb114ca40cb6468f479584/dsi-ahteg-2020-01-04-en.pdf>