Record

Toward resolution of issues for digital sequence information on genetic resources under the Convention on Biological Diversity and the Nagoya Protocol

This published record summarizes the results of deliberations of both the Genetic Resources Subcommittee – with the participation of the committees of Basic Biology, Integrated Biology, Agricultural Science, and Basic Medical Science – and the Nagoya Protocol Implications on Agricultural Science Review Subcommittee – with the participation of the committees of Agricultural Science and the Food Science.

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I. Background of DSI problem

1. DSI negotiation started in 2016

The Convention on Biological Diversity (CBD) is an international agreement with 42 articles in its main body. The CBD was opened for signature at “United Nations Conference on Environment and Development” (The Earth Summit) held in Rio de Janeiro in 1992, which entered into force in 1993. Currently, 196 countries and regions including the European Union (EU) are Parties to the Convention. The United States has signed but not yet ratified it. Japan signed the treaty in 1992 and accepted it in 1993.

In the CBD, the term “genetic resources” is used as "genetic material of actual or potential value" (Article 2). Information obtained from genetic material has not been considered as a part of genetic resources. Article 17 of CBD stipulates facilitated exchange of information, which “shall include exchange of results of technical, scientific, and socio-economic research.” In other words, genomic information and knowledge derived from it were originally regarded as matters to be exchanged smoothly. Even when protected by intellectual property rights, technology transfer was supposed to be based on mutually agreed terms (Article 16).

Originally, access to (acquisition of) genetic resources and the fair and equitable sharing of benefits arising from their utilization (Access and Benefit Sharing: ABS) was expected to function as a resource mobilizing measure to promote the conservation of biological diversity and the sustainable use of its components, which are the objectives of the Convention. Not a few countries, however, have insisted on insufficiency of ABS regulations, and that a legally binding international regime is necessary. At the 8th Conference of the Parties (COP) in 2006, it was decided to complete the elaboration and negotiation of the ABS by the 10th COP in 2010, but the discussions between developed and developing countries continued to be non-negotiable. Japan, which held the presidency of the COP in 2010, managed to adopt the Nagoya Protocol (NP) through the submission of a President's proposal on the last day. Thus, NP stipulated concrete measures for sharing of benefits arising from the utilization of genetic resources and their associated traditional knowledge (aTK) as a legally binding protocol.

In 2017, Japan accepted the NP and introduced domestic measures as the guidelines, "Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization" (the so-called ABS Guidelines) (https://absch.cbd.int/en/countries/JP). The Guidelines clearly stated that information on genetic resources is outside the scope of the NP. Currently, 137 countries and the EU have ratified the NP, but there are many developed countries such as Australia, New Zealand, Russia, Italy, and the United States that have not ratified the Protocol.

At the 13th COP in 2016, digital sequence information (DSI) on genetic resources was identified as “a cross-cutting issue that may concern the three objectives of the CBD” (CBD/COP/DEC/XIII/16). The DSI issue has been also discussed in other fora such as the Pandemic Influenza Preparedness (PIP) Framework, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), and the Convention on Marine

Biodiversity in Areas beyond National Jurisdiction (BBNJ). In addition, DSI is also discussed at the International Standards Committee on Biodiversity.

2. What DSI means and the present status of the discussion

From the beginning, the discussion has proceeded without a specific definition of DSI. The AHTEG report (CBD/DSI/AHTEG/2020/1/7) submitted in March 2020 detailed the use cases of sequence information, and defined the three DSI groups: 1. DNA and RNA, 2. proteins plus epigenetic elements, and 3. metabolites and macromolecules. Here, the aTK was not included in DSI. However, some developing countries still consider aTK to be included in DSI. The DSI controversy was also used by African countries as an exchange condition for a political bargaining to establish the Post-2020 Biodiversity Framework. Under these circumstances, a difficult situation has persisted in which scientific arguments for the distinction between aTK and DSI could not resolve the stalling debate.

Japan has maintained its view that DSI is outside the scope of the CBD. In addition, as in the acquisition process of genetic resources, benefit sharing should be based on mutually agreed terms between the provider and the recipient / user (Article 15 of the CBD). However, only Switzerland and Republic of Korea have adhered to the same principle, as the minority. Opinions began to coalesce into the direction of promoting benefit sharing through a multilateral mechanism, mainly by the European countries surmising the opinions of African region. In this process, several policy options, or solutions, were discussed informally by IAG (Informal Advisory Group). The options discussed were wide-ranging, but they were broadly classified as in Figure 1.

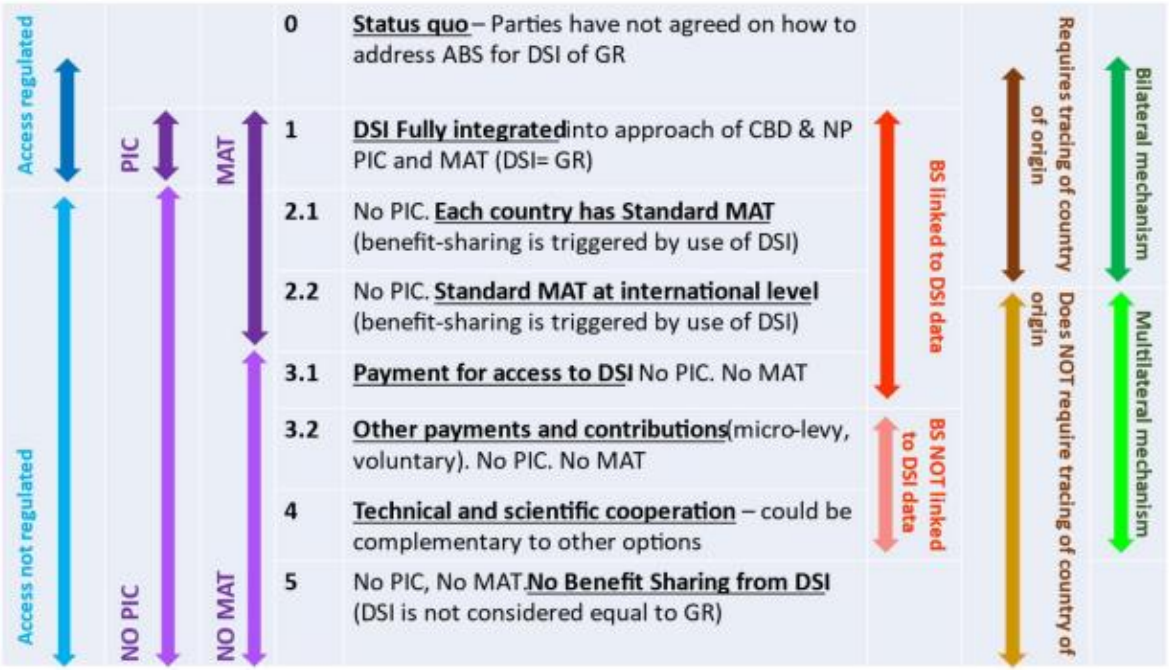

Figure 1. DSI policy options proposed in the AHTEG report submitted in March 2020

(CBD/WG2020/3/4).

Options 1 and 2.1 extended the system of Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) to DSI, as detailed in the NP. These options are infeasible in the current situation where information is freely distributed across databases. Option 5, requiring no benefit sharing from DSI, was also not discussed much. The options that received much attention and consideration were Option 3, which charges a fee for the DSI utilization, and Option 4, providing non-monetary benefits such as technology transfer. Option 3 was further subdivided according to how fees were collected, into 3.1 charging a login fee for DSI-related databases and cloud services, and 3.2 aiming at sharing benefit from donations or through the establishment of fund. A proposal to collect a "DSI tax" of 1% of commodity sales involved in DSI was submitted as Option 6 by African countries in early 2022.

3. Decisions at the 15th Meeting of the Conference of the Parties

At the 15th COP in 2022, the decision supporting the Kunming-Montreal Biodiversity Framework agreed to establish an open-ended working group (OEWG) on DSI to continue discussions and to encourage deposition of more DSI in public databases. The decision also dismissed tracking and tracing of DSI as impractical, and recognized that benefit sharing through a multilateral approach has the potential to meet the criteria. Furthermore, it was agreed that the benefit-sharing solution should meet all of the following conditions (CBD/COP/DEC15/9).

(a) Be efficient, feasible and practical;

(b) Generate more benefits, including both monetary and non-monetary, than costs;

(c) Be effective;

(d) Provide certainty and legal clarity for providers and users of digital sequence information on genetic resources;

(e) Not hinder research and innovation;

(f) Be consistent with open access to data;

(g) Not be incompatible with international legal obligations;

(h) Be mutually supportive of other access and benefit-sharing instruments;

(i) Take into account the rights of indigenous peoples and local communities,

These conditions include keywords, such as open access and traditional knowledge, which developed and developing countries have been demanding. A major progress from the previous mutual understanding was the commitment to the multilateral benefit sharing mechanism for DSI, and the elimination of high-cost methods such as data tracking and tracing. In other words, DSI was reconfirmed as an issue to be considered in the NP. As

listed above, however, the data will remain open access and will not inhibit research and innovation. In the future a more rigorous discussion follows, including the definition of terms.

II. Results of deliberations

We believe that DSI is not a part of genetic resources as it has been. We acknowledge that DSI related to genetic resources has made tremendous contribution to science and socio-economic development of the current society, and continue to adhere to the principle of open access to DSI as public commons of the international community in a direction consistent with the objectives of CBD. To this end, we shall engage in serious discussions on all possible options and cooperate in the search for rational and socially acceptable solutions in science and technology.

1. Necessity of accurate understandings of function and benefits brought by International Nucleotide Sequence Database Collaboration (INSDC)

The International Nucleotide Sequence Database Collaboration (INSDC) began in 1982 as a partnership between EMBL-Bank in Europe and GenBank in the United States, and was joined by DDBJ of Japan in 1987. It is a common understanding in life sciences that nucleotide sequence information (including amino acid sequences of proteins) published in major scientific journals are registered at one of the three INSDC nodes. The three nodes exchange updates daily, share the same data, and have a principle of free and unrestricted access without any licenses.

Each INSDC node is a public repository supported through national funding, and the total number of users is 10-15 million. Open access of DSI is essential in life science research, and the INSDC is an important mechanism to ensure this (Scholz *et al.* 2022 Nat Commun 13, 1086).

China is set to join the INSDC very soon; the INSDC triad expects other groups to join in the future and is preparing a membership arrangement of the INSDC. In addition, INSDC has decided to mandate, from March 2023, the information of the geolocation and date/time of sample collection; this INSDC standard was welcomed in the DSI decision of the 15th COP (CBD/COP/DEC15/9).

The country-qualifier listing used by the INSDC includes names such as Taiwan and the Pacific Ocean. There is also an option not to submit the information for endangered or rare species whose habitat should not be disclosed. For genetic resources, the scientific description of spatiotemporal information should be respected.

2. Necessity of exact definition of public database and open access

Databases like the INSDC should continue to be free of charge without any licenses, as the

foundation of research and as global commons. They are open access in the true meaning of the word. The United States, which shares the INSDC data, has not ratified the CBD nor NP. Any access barrier will incur a tremendous burden on all R&D/industries involved in the medical and life sciences. The 15th COP advocated open access of data, but its definition should be clarified so that not only free access but also free derivation and integration is ensured. For example, the GISAID database, which collects SARS-CoV-2 genome sequences, calls itself "open access" but its data comes with a strict license that requires a login and prevents sharing data with others (https:// gisaid.org/about-us/mission/). Some countries also interpret open access as not necessarily free access. The Parties need to agree on the meaning of “open access”.

The same is true for the term "public”. Public databases should not charge for access, have the obligation and responsibility to provide data fairly and equitably to the world, and to operate stably based on permanent financial resources. A clear distinction should be made between such public databases and databases that commercialize collected information.

3. Multiple difficulties encountered by charging DSI

Benefit sharing from the “use” of DSI?

Uniform pricing including unlimited access is hardly a benefit-sharing arrangement in line with the third objective of the CBD. In addition, setting the exact trigger point of benefit sharing is hardly configurable. The "DSI tax" proposed by African countries as Option 6, for example, is not grounded on the utilization of genetic resources and aTK. If benefit sharing is associated with geographic region, preventive measures for false information would be necessary.

Difficulty in developing infrastructure

As stipulated in the CBD Article 8(j), we respect traditional knowledge associated with genetic resources (aTK). However, an appropriate management of aTK requires appropriate infrastructure. Some countries have prepared national repositories to identify users of its genetic resources, including aTK, and proceed with their own contract scheme. There remains deep concern that such a scheme may slow down research and innovation.

4. Introduction of multilateral mechanism would require the review of the Nagoya Protocol

Necessity of more diverse options

One multilateral option is a voluntary endowment such as the "Lion’s Share Fund". It is unclear, however, whether the industry at large would accept this. Another option is a micro-levy for a cloud computing resource. The computing environment varies tremendously, however, between countries. Further discussion on more options for benefit sharing should be studied.

Reassessment of multilateral mechanism

It should be noted that the decisions of the COP, *per se*, may not legally bind Contracting Parties. We are of the opinion that mandatory benefit sharing from DSI would lead to a revision of the CBD itself, or to negotiation of a new legal instrument that stipulates benefit sharing based on DSI, as NP does for genetic resources.