

*Ministry of Foreign Affairs  
Tokyo, Japan*

Dr. Elizabeth Maruma Mrema  
Executive Secretary  
Secretariat of the Convention on Biological Diversity  
413, Saint Jacques Street, suite 800  
Montreal QC H2Y 1N9  
Canada

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**Japan's submission of views on policy approaches, options or modalities for digital sequence information on genetic resources**

Dear Dr. Elizabeth Maruma Mrema

In response to Notification 2021-063, Japan would like to submit its views as follows:

**I. Principles**

- The term "genetic resources" as defined in Article 2 of CBD refers to tangible physical materials such as plants and animals, and therefore does not include DSI on genetic resources, which are intangible. As such, under our legal interpretation, DSI lies firmly outside of the scope of the CBD and NP.
- Free access to and use of DSI not only provides benefits such as vaccine development in the fight against infectious diseases such as COVID-19, but also contributes to the conservation of biodiversity. Public databases on DSI including INSDC, are freely accessible and usable by scientists around the world, thus contributing to research in countries with genetic resources. We highlight that the distribution of these non-monetary benefits is quite significant, and should not be underestimated. The significant public cost to maintain and manage the databases on DSI means that substantial benefit is already being shared. This is consistent with one of the objectives of the CBD, "the fair and equitable sharing of benefits arising from the utilization of genetic resources".
- If free access to and use of DSI in public databases were to be restricted by the introduction of new, uniform international rules on the acquisition of DSI and the sharing of benefits, it would have serious, negative implications globally on research and development linked to important areas such as vaccine development and food security. Therefore, it is important that: 1) no one-size-fits-all regulatory framework for DSI be established; 2) no restrictions be placed on access to and use of DSI, and 3) no traceability be made mandatory for the use of DSI.

**II. Policy Options (as outlined in document *Policy Options for ABS and DSI*)**

- Japan is concerned that informal discussions on policy options go far beyond the scope set by Decision 14/20, especially as they include ideas that deviate from the basic principles and framework of the CBD and NP. Japan believes that discussions at the CBD COP should be bound by the Convention, to raise the likelihood of reaching an agreement at COP15.

Having said all that, Japan would like to take this opportunity to express views on each option as outlined in the *Policy Options for ABS and DSI* document as follows.

- Option 1 (DSI in scope of CBD and NP)

This option would be inconsistent with the interpretation held by many parties that DSI is not equivalent to genetic resources under the CBD. This option would be incompatible with open access to DSI and facilitated research, as domestic access and benefit sharing legislation for genetic resources would automatically apply to DSI, leading to complexity for users who would face a patchwork of different national legislations in each country. The outcome would result in impeded research and lead to a loss of legal stability and predictability.

- Option 2.1 (Each country has a standard MAT/license)

Similar to above, this would subject researchers and companies to comply with a complex patchwork of various national legislations, under terms and conditions of a standard MAT developed and adopted by each respective country, based on the legal assumption that DSI is a genetic resource (which many Contracting Parties of the CBD do not share). This would have a similar effect of imposing unpredictable conditionalities on research and development, in addition to disadvantages from a loss of legal stability.

- Option 2.2 (Standard MAT at an international level)

This option would be difficult to operationalize under the CBD/NP in the absence of a legal provision that allows the Convention to develop common/ standardized contracts (unlike the ITPGRFA, which has such a provision, for example) and to interfere with the current international/national DSI databases, forcing them to change their rules of use. Considering these constraints, even if this option were to proceed, it would be extremely difficult to operationalize, and certainly cannot go beyond voluntary bounds.

- Option 3.1 (Payment for access to DSI: no PIC/MAT, multilateral mechanism)

Given the existing provisions of the CBD/NP and as long as many Contracting Parties legally interpret DSI to reside outside of the scope of these instruments, it would be difficult to introduce any mandatory payment scheme for access to DSI under the CBD/NP. This option greatly differs from the approach and basic principle of the Convention where benefits are to be shared to the provider when the use of genetic resources generate monetary benefits. Option to “decouple” access and benefit sharing, in our view, can only take place outside of the legal framework of CBD/ NP, and would require a different

approach involving separate instruments.

- Option 3.2 (Other payments and contributions)

Likewise, option to decouple access and benefit sharing can only take place outside of the legal framework of CBD /NP, and would require consideration of approaches involving separate instruments.

- Option 4 (enhanced technical and scientific cooperation)

This option is worthy of consideration, as further science and technology cooperation has been addressed as important by many countries including Japan.

- Option 5 (no benefit sharing from DSI)

This option would be consistent with the legal interpretation of CBD/ NP that DSI is not "genetic resources" as per Article 2 of the CBD.

### **III. New Multilateral Mechanisms**

- Should policy options and modalities on DSI are to be considered, we believe there needs to be further consideration and clarification on the term of DSI (as proposed by the AHTEG), as there will be implications on effects in practice of various policy options. In that context, we think that the following points should be the basis of any such future discussions:

- i. The requirements of benefit-sharing do not inhibit both free access to DSI posted in the public domain and innovation in the field of life sciences and biotechnology.
- ii. DSI in the public domain is public property, and no one has the authority to control them.
- iii. Both R&D and commercial use of genetic resources and DSI derived from them will not be hindered.
- iv. Recognizing that the use of DSI is directly linked to measures necessary for public health and to research and development of medicines and other products, research and development for public health purposes would not be discouraged.
- v. Recognizing the value and the importance of non-monetary benefits already shared, the benefits of open science would not be diminished.
- vi. Ensuring the certainty, predictability, and transparency of the mechanism. Various risks such as compliance would be eliminated in the future under the rules set by the mechanism.
- vii. The mechanism should be reasonable, understandable, and simple. In particular, users should be able to determine without confusion, whether a genetic resource and/or DSI in question resides in the public domain, requires an individual contract for use, or is subject to some multilateral mechanism.
- viii. There should be a balance between the protection and use of intellectual property

rights. For example, something similar to the limitation of the term of protection of intellectual property rights is worth considering.

- ix. There should be no benefit sharing retroactively on any DSI that is already in the public domain and acquired after entry into force of any such regulation.

#### **IV. Specific frameworks and institutions**

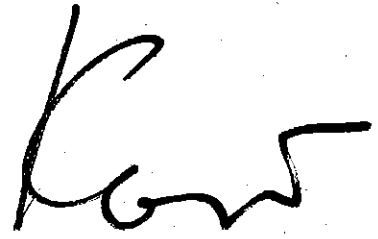
We believe that any specific frameworks and institutions for DSI should be treated in accordance with the provisions of CBD / NP, and should therefore follow the basic principles below in addition to those described above in this document.

- Feasibility and acceptability: The system should not require the user or donor countries to bear the financial burden of enforcing mandatory or restrictive national laws and regulations, such as taxation.
- Exemptions: The following nucleotide sequences and their use should be exempted from monetary benefit sharing.
  - i. Human-derived nucleotide sequences
  - ii. Nucleotide sequences derived from pathogens to humans, animals or plants (under consideration by WHO)
  - iii. Nucleotide sequences generated from genetic resources under the jurisdiction of other international organizations, such as ITPGRFA
  - iv. Nucleotide sequences in the public domain
  - v. Nucleotide sequences of genetic resources not subject to sovereign rights
  - vi. Nucleotide sequences that do not exist naturally
  - vii. Nucleotide sequences used for academic purposes
  - viii. Nucleotide sequences used for public health purposes.
- Benefit-sharing: Shared benefits should be used to conserve biodiversity and to support the sustainable use of its components, and should include all forms of non-monetary benefit sharing, rather than mere monetary benefit sharing.

#### **V. Cross-cutting and Comprehensive Considerations**

In our view, any mechanism that addresses the issue of DSI needs to be consistent with the provisions of the CBD/ NP, as well as those of other international legal instruments. We think that it might be useful to establish a mechanism for cross-sectoral coordination and consideration of overall consistency on the handling of DSI issues, and thus to promote a UN system-wide, comprehensive approach, while recognizing special needs of niche categories. This would help streamline efforts to comprehend the issues and implications of addressing DSI, which is currently being discussed separately under each treaty body.

*Ministry of Foreign Affairs  
Tokyo, Japan*



MORISHITA, Ko

Director

Global Environment Division  
International Cooperation Bureau  
Ministry of Foreign Affairs, Japan