

## Business considerations for a multilateral mechanism for benefit sharing from Digital Sequence Information

As key stakeholders in the development of the Multilateral Mechanism for Benefit-sharing from the Use of Digital Sequence Information (MLM), businesses are willing to engage and contribute their experience and perspectives. As a representative of businesses of all sectors and sizes around the world, ICC submits the following points for negotiators to consider in their discussions on the design of the mechanism.

- To be effective, any benefit sharing system should be **simple, workable and affordable, provide legal certainty** – including with respect to how obligations under different legal frameworks will work together – and be **aligned with scientific and business realities**.
- The **criteria in Paragraph 9** of Decision 15/9 provide an essential framework to build an effective system and the design of the mechanism should remain aligned with these criteria. To support research and innovation, access to public digital sequence information (DSI) databases should remain open and free from ABS-related requirements, in line with criterion (f). While the avoidance of tracking and tracing DSI is not specifically mentioned in Paragraph 9, the impracticality of this is explicitly recognised in Paragraph 5. Tracking and tracing requirements are not feasible (criterion (a)), would hinder research and innovation (criterion (c)) and make monitoring of compliance impossible.
- It is **essential that the mechanism be exclusively multilateral** as set out in Decision 15/9. The co-existence of national obligations on DSI with the multilateral mechanism would not be compatible with the reality of how DSI is used in research and innovation and through value chains<sup>1</sup>.

So-called “hybrid approaches” should therefore be avoided for the following reasons:

- Users will avoid using DSI from countries where there is complexity and lack of legal clarity. Those countries could ultimately miss out on the value created and the sharing of benefits from the use of that DSI.

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<sup>1</sup> Current techniques include, for example, accessing, analysing and combining huge amounts of DSI in parallel, and applying artificial intelligence, resulting in high speed and highly complex paths towards results/products using a variety of data and often involving several different actors in the process.

- Any requirement to track and trace use of specific (and/or a subset of) DSI in processes/products throughout the value chain would effectively require all DSI to be traced. As indicated above, tracking and tracing requirements are not feasible and would make monitoring of compliance impossible.
  - For product development, predictability regarding costs and timeframe is needed early in the innovation process to determine commercial viability. Subjecting the use of DSI to bilateral obligations will lead to uncertainty, delay, high administrative costs and the risk of multiple payments.
  - The same DSI may be found in more than one country, as biodiversity – including plants and microorganisms – does not adhere to political borders and naturally spreads across countries, also through natural dispersion and migration<sup>2</sup>. Furthermore, the rate of identification of genetic diversity varies greatly amongst countries. Linking DSI to a specific provider country is therefore very complex.
- **The mechanism should be universal.** All CBD Parties, without exception, should therefore be part of the MLM which should replace all national ABS obligations on DSI, for the reasons set out above.
  - To encourage countries to implement the mechanism in practice, it will be **important to build in incentives**. For instance, the disbursement mechanism could ensure that all participating countries benefit from the fund in some way for conservation and sustainable use of biodiversity once they have effectively delegated national ABS management for DSI to the MLM.
  - **The geographical origin of DSI** is not appropriate as a criterion for disbursement of funds as this would penalise countries whose genetic resources and DSI have been assessed to a lesser extent.
  - The MLM should **recognise** and be **implemented in harmony with other existing specialised benefit-sharing mechanisms** to avoid duplication.
  - **Integrating DSI** and genetic resources into the multilateral framework would lead to a simpler, more workable and more encompassing system. The MLM must therefore be **designed to give countries the option to include their genetic resources**. It is critical for users that this option is integrated into the MLM's design for several reasons:
    - There is an urgent need to open a path towards simplifying and harmonising current ABS systems which are too complex, generate higher compliance and enforcement costs than shared benefits, and hinder research and innovation.

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<sup>2</sup> For example, many plants may be native to a region, but are then naturalised all over the world. Microbes are

continuously spreading through the air, water and the movement of humans, animals and plant species. It is also entirely possible that a novel zoonotic virus may be first isolated in the home country of a returned traveller before enzootic and endemic or epidemic transmission is detected in the source country.

Simplifying the overall system will help reduce costs and delays, and will enable more agile innovation while supporting the objectives of the CBD.

- DSI is derived from genetic resources - both are therefore inseparable in research projects. Having a multilateral system for DSI on top of national ABS laws for genetic resources will result in multiple/parallel ABS processes/obligations for the same research project.
- Delegating management of genetic resources under their sovereignty to the MLM provides an additional option for countries to leverage the value of their biodiversity to support socio-economic development. Some countries may prefer not to establish, or to continue administering, ABS regimes themselves because of resource or capacity constraints, and/or the administrative burden required for national implementation. Including genetic resources in the MLM could allow such countries to overcome these constraints while conserving their ability to receive benefits.
- The rapid evolution of technology in genetic research and biotechnology presents challenges in forecasting the future requirements and uses of genetic resources. A comprehensive, effective and workable benefit-sharing system encompassing physical genetic resources and DSI could possess the flexibility and adaptability necessary to integrate emerging technologies, making it future-proof.

It is therefore important that **incentives for countries to include GRs are built into the system** from the beginning to operationalise this option. For instance, financial and other incentives to include GRs could be integrated into the funding mechanism.

- The question of **benefit sharing trigger points** can be broken down into two components:
  - Which activity should trigger benefit sharing obligations?
  - At which point(s) in the R&D, innovation, and value chains should benefits be collected?

It will be essential to address the details of how the MLM will function and be implemented to be able to properly evaluate its workability and impact on countries and stakeholders. The following **considerations** are submitted for negotiators to take into account when they reflect on the above questions:

- Users are extremely diverse. For example, there can be significant differences in size and capacity of businesses, their dependence on the use of DSI and genetic resources (which can be a large or small part of their business), their research and development models, operating context, the proportion of turnover resulting directly from the use of genetic resources and/or DSI and profit margins, among others.
- Any payment collection mechanism has to be simple for the payer, the collecting

entity and the authorities ensuring compliance to avoid unnecessary costs and administrative burdens that would undermine the cost-benefit ratio of the system.

- There should be no tracking and tracing required for the use of DSI in the development of commercial products as this is recognised as not being feasible.
- The amount of funds that can potentially be raised is an important consideration but it should not impede adoption of a MLM, since benefit sharing from DSI should be seen as only one of many sources of funding and will not be sufficient in itself to finance the implementation of the Kunming-Montreal Global Biodiversity Framework.

Based on these considerations, the **activity which triggers benefit sharing obligations** should not be access, to avoid creating barriers to access. The trigger should also not be based on individual transactions or linked to the use of specific sequences as this would lead to tracking and/or tracing.

With regard to the **point at which benefits are collected**, ICC suggests that the following considerations be kept in mind:

- The payer base should be broad to allow the load to be distributed across many players, thereby lightening the load for individual(s)(entities). This will increase the potential for the mechanism to raise funds and encourage compliance as payments are likely to be more affordable and seen to be a broad collective responsibility.
- The basis for calculating payments should be as simple as possible for ease of compliance and monitoring.
- There should be no payment stacking for individual entities. For example, the same entity should not have to pay at different stages in the innovation process or value chain for the same use or for the use of multiple pieces of DSI in the development of the same product. Further, the same entity should not have to pay for DSI if already paying under mutually agreed terms related to the genetic resource used to develop that DSI. Similarly, the same entity should also not have overlapping benefit sharing obligations under different specialised benefit-sharing mechanisms.
- There should be predictability early in the innovation process as to when payments will be necessary and the level of such payments.
- **Benefits should be used to support conservation and sustainable use**, including by supporting the role of indigenous peoples and local communities as stewards of biodiversity and by building capacity in biodiversity-based research and innovation as a form of sustainable use. It is important for all stakeholders to have

transparency on how the funds will be used. To ensure that the benefits from the fund are used also to enrich the data pool, the MLM could encourage the inclusion of DSI generated with funding by the mechanism into open-access databases.

ICC remains at the disposal of Parties and other stakeholders to clarify any of the above points.

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