

Comments on "Digital Sequence Information on Genetic Resources- Addendum"

ICC is pleased to share below its comments on the Executive Secretary's note on "Digital Sequence Information on Genetic Resources – Addendum" (CBD/WG2020/3/4/add.1). These comments are based on its members' practical experiences in generating and using DSI in the development of new products in different sectors. They are provided to support a fact and experience-based debate on DSI to help Parties find a path forward, and should not be understood as a change of ICC's previous positions on DSI¹.

Key messages

ICC welcomes the initiative to assess the potential impact of the different options, and thanks the Co-Leads of the Contact Group on DSI, the informal Co-Chairs' Advisory Group on DSI, and the Secretariat for their efforts to develop a methodology to assess the potential impact of the different options.

We support the objectives of the Convention on Biological Diversity, and fair and equitable benefit sharing that will support and encourage conservation and the sustainable use of biodiversity. We also agree that capacity building should be reinforced to help all countries create value and derive knowledge from genetic resources and DSI. It is our firm conviction that open access and exchange of "DSI" in the public domain must be preserved to achieve these goals.

We strongly urge for a broader assessment and review of the current approach to implementing ABS. This is hindering, rather than supporting, the creation and sharing of value and benefits from genetic resources² and should not be further expanded to cover DSI.

With regard to the current process, we would like to stress the crucial need to integrate the experience and perspectives of potential users from the private and public sector - this will be important in each step of the process.

We believe that many of the criteria proposed are relevant and agree that it is important for any potential system to facilitate research and innovation. Several of the other criteria identified are necessary for this purpose, such as the preservation of open access to public databases, legal clarity and certainty for implementation, technical feasibility, administrative simplicity, and ease of understanding and workability for users and providers.

While we understand the reasoning behind the proposed methodology, we would like to highlight some risks. A common understanding on some fundamental issues, such as the definition and scope of "DSI", is needed to provide the foundation on which to base decisions. Alignment on what "fair and

¹ "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 – May 2019); "Digital Sequence Information and Benefit Sharing" (2 May 2019);

[&]quot;Digital Sequence Information" (30 November 2016)

² "Towards a New Implementation Strategy for Access and Benefit Sharing" (5 October 2020)



equitable" means to Parties, and on the purpose and goal of benefit sharing, would also help provide a common framework for discussions. Given the importance of ensuring that any system delivers more value than it costs to set up, implement and maintain, a proper cost effectiveness assessment is crucial <u>before</u> narrowing down options.

We offer below more detailed comments on the methodology and criteria detailed in the "Co-leads' Report on the Work of the Informal Co-Chairs' Advisory Group on Digital Sequence Information on Genetic Resources" (*CBD/WG2020/3/inf/8*) and in this Addendum.

Specific comments

Section II.A - Framework for the assessment of policy options related to the access and benefit-sharing in respect of digital sequence information on genetic resources

The proposed methodology

While we understand the reasoning behind the proposed methodology, we would like to highlight the following concerns:

- There are still fundamental divergences among parties and stakeholders on many issues relating to DSI, as indicated in part B of this Co-Leads report, including: the question of the legal basis for addressing DSI and the scope of the CBD and its Nagoya Protocol; the definition and scope of "DSI"; modalities of benefit sharing that would fulfil the fair and equitable criteria in practical terms (monetary and/or non-monetary, voluntary and/or mandatory); and the definition of open access and associated questions around control to access. Without agreement on such basic issues, the foundation for decisions to select specific options remains weak, and is likely to evolve with time, with the risk that the basis for earlier decisions will no longer be valid. We believe that further clarification is necessary to support an effective analysis of the options proposed. The starting point is a common understanding of the scope and definition of DSI. An analysis of the options would be greatly enabled by alignment and agreement on the issues as outlined above.
- The proposed step-by-step approach is intended to narrow down options. However, at this conceptual stage, when the potential options are still abstract and lacking in the details that would allow a proper assessment, it would seem premature to already start discarding options and narrowing towards preferred solutions. More specifically, we would urge that no options be eliminated or selected before a proper cost-effectiveness assessment is undertaken this will no doubt require more detailed clarification of the different options.
- The multicriteria framework is described as "an effectiveness analysis tool that does not require quantification and monetization of all consequences like traditional cost benefit analysis". Whist this framework may have been chosen because of the inability to quantify the likely impact of different options, it will likely lead to decisions that are merely based on assumptions.
- Given that the success of any approach to the fair and equitable sharing of benefits will depend on the commitment and engagement of both providers and users, the process should be inclusive and closely involve users from the private and public sectors in each step of the process, including the scoring exercise and the weighting of the criteria and sub-criteria. It is essential to integrate



the experience and perspectives of potential private and public sector users who will be directly interfacing with the system and have experience with existing or similar systems.

Annex II - Criteria, sub-criteria and scoring (text of the Addendum highlighted in grey)

We appreciate the efforts to take into account different priorities and perspectives in the selection of criteria, and believe that most of the criteria identified are relevant. We would like however to share the following specific comments:

- We regret the decision to remove the cost-effectiveness criterion and are concerned by the
 proposal to address this essential consideration only after a pre-selection of the options. Given the
 importance of ensuring that any system is efficient and brings in substantially more benefits than it
 costs, and based on the experience of current ABS systems, we believe that a cost-effectiveness
 analysis is an essential step before proceeding to select or eliminate options.
- The inevitable and necessary overlaps between specific criteria could be made more explicit. This is the case, for example, when achieving some of the stated policy goals will require them to be feasible, implementable and allow appropriate governance.

(a) Effective in achieving policy goals

• (1) Potential to deliver predictable monetary benefits

This policy option can deliver monetary benefits directly to the provider, or to a common fund. The predictability points to the ability of a country or indigenous peoples and local communities to anticipate the monetary benefit that they will receive at a point in time, according to the benefit-sharing modalities of the solution.

It would be helpful to clarify whether this criterion is intended to place more importance on the predictability of monetary benefits/revenue streams (even if limited) or on the amount of benefits potentially generated. If cost-effectiveness is considered at a later stage, as proposed in the report, the forecasted amount of monetary benefits will be an important criterion to be able to calculate the ratio of cost versus benefits.

• (2) Potential to deliver <u>and enhance</u> predictable non-monetary benefits <u>without</u> <u>undermining existing forms of non-monetary benefit sharing</u>

This policy option can deliver non-monetary benefits in a direct and systematic manner (imbedded in the option, not in an ad hoc manner).

It is important to clarify what is counted as non-monetary benefits, and how broadly beneficiaries are defined. We suggest that a broader, more holistic view is taken to ensure that a narrow perspective does not undermine other societal goals like food security, human health and development, and that any potential system aims also to enhance non-monetary benefits that contribute to these and other Sustainable Development Goals. It is also important that non-monetary benefit sharing which currently takes place through existing practices and mechanisms is not hindered or undermined and will be included in the overall estimate of expected non-monetary benefits. We therefore suggest the addition of the underlined text.



• (3) Access to public databases remains open

DSI in public databases remain openly accessible as is in the current system.

We consider this criterion to be essential to avoid hindering research and innovation, as well as the scientific collaboration and exchange which allows the spread of knowledge and skills among different countries and regions.

• (4) Facilitates research and innovation

The option would facilitate scientific research, innovation, and future technical and technological advances, both non-commercial and commercial.

This is a very important criterion as research and innovation are essential for the creation of solutions, processes and collaborations which result in significant non-monetary societal benefits supporting many Sustainable Development Goals, including those related to biodiversity conservation and sustainable use (see 5 below). Research and innovation are also the basis for the generation of monetary benefits.

• (5) Potential to contribute to the conservation and sustainable use of biodiversity

This option would yield benefits that would help the conservation of biodiversity and its sustainable use, either directly (through targeted capacity-building or financing of conservation) or indirectly (through investment in fields proven to positively impact conservation and sustainable use of biodiversity), from both monetary and non-monetary benefits.

We consider it to be extremely important that any solution supports, and is consistent with, the CBD's goals of biodiversity conservation and sustainable use. It is equally important that the solution provides transparency as to how it is contributing to these goals, so that users understand its end goals and can integrate this into their sustainability strategies. The contribution of research and innovation to supporting biodiversity conservation and sustainable use should be recognised - this criterion should therefore take into account the capacity of any solution to support and enhance, rather than hinder, research and innovation.

(b) Efficient and feasible to implement

• (6) Technically feasible

This relates to the technical feasibility of the option, and whether it can be done with existing infrastructure or whether it would require significant investments in new infrastructure and/or technology. Technical/infrastructure certainty also comes into consideration.

This is an important consideration that could have a significant impact on the costs and ease of implementation of the solution, and resulting consequences on research and innovation. It is doubtful, for instance, that tracking and tracing of individual sequences through the whole R&D process and value chain would be feasible technically, but also with regard to data protection considerations.

(8) Legally clear and certain to implement

This criterion relates to the legal burden that would be required to implement the option. Would the legal aspect be understandable by all, easily implemented, and provide certainty? Or would it require the establishment of a complicated legal framework and significant investments to be implementable?

Legal clarity and certainty, and the absence of retroactive consequences, are crucial for any solution to be workable in practice from the perspective of both provider and user. They are also essential to



ensure that research and innovation are not undermined.

• (9) Administratively simple

Administrative simplicity encompasses the procedures and processes needed for the implementation of the option. An administratively complex option would include high transaction costs and be a lengthy process.

Administrative simplicity is indeed extremely important, not only to ensure cost effectiveness and timeliness, but also to avoid discouraging research and innovation and to facilitate take up of the system.

• (11) Enables distinction between commercial and non-commercial use of DSI The option allows that distinctions be made between commercial and non-commercial uses of the data

to facilitate benefit-sharing on commercial applications of DSI.

This distinction is very difficult or even impossible in many cases to make in practice because the reality is an overlapping and necessary continuum between private and public sector research through collaborations and technology transfer along the value chain.

• (12) Cost of set-up and implementation and maintenance

The monetary costs (public and private) of set up, implementation <u>and maintenance</u> are clear (or can be estimated with ease). This information can be used at a later stage to perform a cost-effectiveness analysis.

We agree with the importance of estimating both public and private costs to enable a cost-effectiveness analysis. The methodology for estimating costs has to be clearly defined to ensure that all pertinent costs are included. We suggest that the costs of maintenance of the system should also be taken into account and have proposed additional text accordingly.

(c) Enables good governance

• (13) Easy to understand by providers and users

Each option involves a certain level of complexity that may make it easier or harder for all stakeholders concerned, both providers and users of DSI, to understand. Easy to understand options can help foster greater buy-in and a smoother implementation on the ground.

Ease of understanding must be accompanied also by ease of implementation, administrative simplicity and transparency as to how it contributes to biodiversity conservation if the solution is to foster greater buy-in and smoother implementation.

• (14) Easily enforceable by providers

High enforceability means that, legally and technically, the option can be enforced by providers.

• (15) Ease of compliance for users

Ease of compliance for the option means that it is easy for the user to comply with the policy in place.

We support the importance of ease of implementation for both providers and users to ensure effective take up of any solution. Ease of implementation should also take into account the workability and affordability of any solution, as well as the desired increase in legal certainty.



Section II.B - Areas of potential convergence and apparent divergence on digital sequence information on genetic resources, and potential further work

B. 18. Building on the discussions in the group, the co-leads have identified the following key points of consideration, of elements, that they believe could lead to 'higher-level criteria' or 'principles' for a solution on DSI (see CBD/WG2020/3/INF/8, section II, subsection C):
..............]

See comments on the criteria set out in draft recommendation below. We agree that capacity building should be reinforced to help all countries create value and derive knowledge from genetic resources and DSI.

In this context the co-leads consider that further work or discussions in the following areas could be useful:

(a) Characterization of the <u>kind of monetary and non-monetary benefits that are currently being created and shared through utilisation of DSI and/ or could be further created and shared through a solution on DSI;</u>

Before characterizing what benefits could be shared through a new system, it would be useful to understand the types of benefits that are already being created and shared. It will also be important to clarify what "sharing" means and the scope of the intended beneficiaries. We therefore propose the additional underlined text above.

(d) Consideration of special cases, such as health emergencies, and their implications for the solution.

We agree that it remains essential to include consideration on how to address special cases where rapid access to DSI for use in R&D is crucial (e.g. to respond to human, plant or animal health emergencies, or food spoilage) to ensure that any solution envisaged does not prevent the development of timely solutions necessary in such cases. The exclusion of pathogens harmful to human, plant or animal health should be considered to address these situations as well as ongoing threats .

Section III - Elements of a recommendation

5. Recognizes the following key points of potential convergence that may lead to "higher-level criteria" or "principles" for a solution on digital sequence information on genetic resources:

(a)—Any bBenefits from the use of genetic resources should be shared in a fair and equitable way, and solutions should be found explored on how to share benefit arising from the sustainable use of DSI can most effectively contribute to biodiversity conservation and other Sustainable Development Goals to the benefit of all Parties;

The use of "any" does not reflect the reality that not all genetic resources are subject to benefit sharing obligations e.g. many countries do not require benefit sharing on genetic resources under their sovereignty. We therefore suggest that "any" in this sentence should be deleted.

Given the lack of convergence on this issue, and so as not to lose sight of the wider goals and context, we suggest that this bullet focuses on how DSI can contribute to the broader aims of conservation and



sustainable use of biodiversity, and of the other SDGs.

- (b) Access to digital sequence information in public databases remains open;
- (c) Indigenous peoples and local communities are also stewards of biodiversity and their role and rights where relevant should be taken into account in addressing digital sequence information on genetic resources;
- (d) Capacity-building is an integral part of the solution on digital sequence information on genetic resources.
- 6. Endorses the recommendation of the co-leads for a step-by-step approach, to help gradually narrow in on the elements needed to move the discussion forward and requests the Informal Co-Chairs' Advisory Group to continue its work, in particular to advance the following areas of work while ensuring ongoing consultation with Parties and stakeholders:

Please see our comments above on the step-by-step approach.

(a) The exploration of potential modalities that would help to further elucidate a common understanding on what fair and equitable benefit sharing would entail in practical terms in this context;

We agree on the importance of obtaining a common understanding of what constitutes "fair and equitable benefit sharing". It would however seem more logical to begin with a structured discussion on what different parties consider to be the purpose and goal of benefit sharing and what it means for such benefit sharing to be "fair and equitable," in order to have a common framework for discussing modalities, rather than discussing modalities without a clear idea of what these would be trying to achieve.

- (b) The possible modalities that would help consider indigenous peoples and local communities in a solution on digital sequence information on genetic resources;
- (c) The advancement of the multi-criteria analysis of policy options (annex I) according to criteria (annex II), and with a view to advance the assessment to the next steps, such as the weighing the criteria, and the assessment of available information;

Please see our comments above on the methodology and the need to include users in a balanced and fact-based discussion.

(d) The potential timetable for the implementation of any solution on digital sequence information on genetic resources in the context of the post-2020 global biodiversity framework, and any implications of that timetable.

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