

DIGITAL SEQUENCE INFORMATION AND BENEFIT SHARING

ICC SUBMISSION TO THE CBD

Key messages:

1. ICC proposes using the term “Genetic Resource Sequence Data” (GRSD) instead of “Digital Sequence Information” (DSI) to enable a more fact- and science-based discussion.
2. Open access to and use of DSI for advancing research and development creates huge benefits, both from commercial and non-commercial use, which help achieve the objectives of the United Nations Convention on Biological Diversity (CBD) and the Nagoya Protocol.

This submission is provided in response to Convention on Biological Diversity (CBD) decision 14/20, paragraph 9, which invites parties and stakeholders to provide views and information on:

- relevant terminology and scope related to “Digital Sequence Information” (DSI) and
- benefit sharing from commercial and non-commercial use of DSI.

Relevant terminology and scope related to “Digital Sequence Information”

When the term “DSI” arose in CBD discussions, it was understood to refer to electronically stored and exchanged DNA sequence information. The content of the term has since expanded, and discussions on this subject matter are now confounded by multiple interpretations of it.

The term “DSI” has been qualified by many as being unclear and imprecise. The report of the *Ad Hoc Technical Expert Group* on DSI states that there is agreement that the term “DSI” is not apt and should be used as a mere placeholder. ICC agrees with the view that the term “DSI” is imprecise and not appropriate for the ongoing discussions.

ICC would like to propose instead the term “**Genetic Resource Sequence Data**” or “GRSD”, as a clearer, more scientifically-precise alternative which would be more appropriate for use in the discussions. ICC is proposing this term solely to facilitate a more fact- and science-based discussion on this subject matter.

Genetic Resource Sequence Data refers to the description of the order of nucleotides (DNA or RNA), as found in nature, in the genome or encoded by the genome of a given genetic resource. The “genome” includes nuclear and extra-nuclear DNA, and coding (gene) and non-coding DNA sequences. It does not include other molecules resulting from natural metabolic processes associated with or requiring the genetic resource.

1. “Genetic Resource” provides for the necessary link with the DNA or RNA sequence that provides an exact description of the DNA or RNA in a specific genetic resource, thereby ensuring the direct link with the genetic and/or biochemical composition of the genetic resource. It makes a clear reference to the fact that the genetic sequence correlates exactly with the DNA or RNA in a specific genetic resource. In the context of the discussions under the CBD and/or the Nagoya Protocol, GRSD does not and cannot include a DNA or RNA sequence that is not identical to that found in a genetic resource. In addition, it is important to note that GRSD must originate from a physical source, consistent with the definition of ‘genetic resource’ in the CBD.
2. “Sequence” results from the process of determining the order of nucleotides (nucleic acids) in a DNA genome or RNA molecule of a genetic resource of a specific species.
3. “Data” refers to the actual genetic sequence data of a specific genetic resource. Data is to be distinguished from information since “information” involves a level of additional processing or analysis. Thus, GRSD cannot, and does not, include information connected with or resulting from the analysis or further application of GRSD, e.g. sequence assembly, sequence annotation, genetic maps, metabolic maps, three-dimensional structure information or

physiological properties related to it. Including information resulting from human interaction on GRSD would result in yielding man-made genetic sequences, which would no longer be considered GRSD.

Regarding “Digital Sequence Information”, our understanding is that the word “digital” refers to the format in which nucleic acid sequences may be stored and shared (e.g. in a sequence database) and used for subsequent analyses or uses. ICC does not consider this necessary to retain as this does not describe the genetic sequence itself.

ICC is proposing the term “Genetic Resource Sequence Data” to enable a more fact- and science-based discussion. This does not impact ICC’s position, as communicated in its previous submissions on DSI and in the joint statement by numerous stakeholder organisations on the need to maintain open exchange of DSI.¹

“Digital Sequence Information” & existing systems of benefit sharing

As pointed out in the section above, ICC has proposed the term “Genetic Resource Sequence Data” or “GRSD” for use in the ongoing discussions on this subject matter. “GRSD” is hence used in this section on the existing systems of benefit sharing.

Under the existing CBD and Nagoya Protocol framework, benefit-sharing provisions relating to GRSD can already be included by provider countries in mutually agreed terms related to the utilisation of a specific genetic resource. However, the subject of obligations under a MAT should not include open-ended or ambiguous concepts such as “DSI”.

ICC wishes to emphasise that amending the scope of the CBD and the Nagoya Protocol to allow for the imposition of additional Access and Benefit Sharing (ABS) obligations on access to and/or the use of GRSD² - other than through the existing mechanism of mutually agreed terms - will have a significant negative impact on the future of biological research and the benefits resulting from it for society. Open access to and use of GRSD for advancing research and development creates huge benefits, from both commercial and non-commercial use, which help achieve the objectives of the CBD and the Nagoya Protocol. ICC would like to explicitly emphasise the following key elements to be carefully considered:

1. GRSD is a critical tool in the conservation and sustainable use of genetic resources, and its use is currently leading to many societal benefits, including the availability of innovative products improving food security and human health. Impeding the flow and use of data or information would work against research projects in several different areas, many of which contribute to the objectives of the CBD and the Nagoya Protocol. The CBD specifically encourages the exchange of information to support conservation, protection and sustainable use of biodiversity.³ The system of open exchange of GRSD is essential to

¹ Promoting sustainable use and conservation of biodiversity through open exchange of Digital Sequence Information, 8 November 2018

² The concerns expressed regarding the negative impact of imposing additional ABS obligations applies *a fortiori* to every more open-ended term, including “DSI”

³ Article 17, Convention on Biological Diversity

unlock the value of physical genetic resources, by enabling the sustainable use and hence supporting the valorisation and thus conservation of biodiversity.

One of the original aims of the Nagoya Protocol was to incentivise countries and biodiversity custodians to preserve physical ecosystems and species by providing a mechanism which would allow them benefit from such conservation. This is clearly stated in the preamble of the Nagoya Protocol by “*Recognizing that public awareness of the economic value of ecosystems and biodiversity and the fair and equitable sharing of this economic value with the custodians of biodiversity are key incentives for the conservation of biological diversity and the sustainable use of its components*”. If the focus of benefit sharing shifts to data, any incentives provided by the ABS mechanism to preserve physical ecosystems and species will be greatly reduced.

It is therefore of paramount importance that GRSD which is now in the public domain continues to remain freely accessible to achieve the broader aims of the CBD.

2. Making the sharing of GRSD more legally uncertain, time-consuming, administratively burdensome and costly by regulating its use conflicts with the aim of the Nagoya Protocol to improve legal certainty and will have a chilling effect on the use of GRSD in biological research, and consequently lead to less benefits. All countries rely on and benefit from unencumbered access to and exchange of GRSD to deal with key societal issues, such as human, animal and plant health, food security and the environment. There is currently a well-established and functioning international framework supporting the open exchange of GRSD, consistent with established principles of ethical and responsible scientific research that are foundational for the advancement of science. Open exchange is especially important for GRSD, the unencumbered use of which allows the swift compilation, comparison and re-analysis of information from a variety of sources, across multiple databases and gene sequences.
3. Considerable “non-monetary” benefits can be derived by all countries from the open exchange of publicly available GRSD. The extensive public GRSD database managed by the International Nucleotide Sequence Database Collaboration (INSDC), maintained at the expense of the three host governments, is freely accessible to researchers in all countries; and was accessed by 172 countries from all regions between 2014 and 2016.⁴ Open exchange of GRSD is also necessary for international research collaborations, which not only allow the pooling of expertise and resources to resolve problems of global or regional relevance but are also essential vehicles for capacity building and the exchange of knowledge and expertise. Countries also benefit from the technologies and products resulting from research supported by open exchange of GRSD, wherever this research takes place. Widespread regulation of GRSD is likely to result in a dramatic reduction in information being made available in public databases. There is therefore a danger that the significant non-monetary benefits which are currently being delivered to developing

⁴ “As a member of INSDC (International Nucleotide Sequence Database Collaboration) maintaining the international GRSD database, we found that a total of 172 countries were using the database during the period from 2014 to 2016 (Europe 46, Asia 43, South/Central America 35, Africa 32, Oceania 14, and North America 2; Website access: 1,621,300) upon investigating the state of the use from outside Japan of DDBJ (DNA Data Bank of Japan) operated by National Institute of Genetics”- *Extract from the Submission by the Government of Japan on the “Current state of the use of digital sequence information on genetic resources in the biodiversity field”*.

countries could be diminished in the process. Considering the number of accessions from public databases by developing countries, small research institutions in developing countries would be especially burdened by additional obligations.

4. Numerous legal interpretations have confirmed that the definition of genetic resources refers to tangible material and does not include immaterial information. Negotiations to change this definition would require years, or even decades, as well as resources that would be better spent on efficient implementation of effective and workable measures that achieve the three objectives of the CBD, including capacity building to ensure sustainable use.

In short, imposing ABS obligations on the access, use and/or dissemination of GRSD, other than through the existing mechanism of mutually agreed terms, would substantially jeopardise the creation and sharing of benefits, which contribute to achieving the objectives of the CBD and the Nagoya Protocol, and ultimately support managing some of society's biggest challenges such as food security and human health.

In order to provide additional insights on the well-functioning of the current system of open exchange of data, ICC is currently also working on detailed case studies, which will be provided in due course to further enhance the informed discussions on this topic in the context of the CBD and the Nagoya Protocol.



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