

## **CABI response on potential implications of the use of digital sequence information (DSI) from genetic resources for the three objectives of the Convention, and for the objective of the Nagoya Protocol.**

At its thirteenth meeting, the Conference of the Parties to the Convention on Biological Diversity (CBD) considered the issue of digital sequence information on genetic resources and adopted decision XIII/16, in which it decided to consider, at its fourteenth meeting, any potential implications of the use of digital sequence information (DSI) on genetic resources for the objectives of the Convention on Biological Diversity.

### **Summary statement**

CABI believes that amendments to the Nagoya Protocol are **not** necessary in respect to Digital Sequence Information (DSI) as it is already captured in the definition of the genetic resources and genetic material covered by the Convention on Biological Diversity (CBD). “Genetic resources” means genetic material of actual or potential value. “Genetic material” means any material of plant, animal, microbial or other origin containing functional units of heredity. CBD 19 Mar 2010; <https://www.cbd.int/doc/meetings/abs/abswg-09/information/abswg-09-inf-01-en.pdf>. DSI describes the resource or material and in a functional form would be a “derivative” and its use and benefits can be treated at a country level at the point of access to genetic material. However, it would be helpful to have a common agreement on the generation of DSI and how it can be used in order not to impede innovation in the life sciences.

### **CABI position**

- Generating and publishing sequence data is considered by CABI as the production of descriptive information on the organism and therefore not utilisation. As such, it is out of Nagoya Protocol regulatory scope.
- Publishing the sequence as electronic data is an act of sharing such descriptive information and thus meets any benefit-sharing commitment required from access to sequence the organism.
- DSI can be used at many non-exploitative levels: for example, it is used to confirm identification and in the CABI understanding this is an observation; in most cases the sequence is published.
- if DSI is used for financial benefit then this could be considered utilisation and the full benefit sharing aspect would be negotiated with the provider country as would be done for access to the organism
- The generation and use of DSI must be considered at the point of access and be expressed in the Mutually Agreed Terms (MAT) and presented in any Material Transfer Agreement (MTA) for clarification on what can and cannot be done regarding DSI.

### **CABI reasoning**

The debate continues within the regulator and stakeholder communities, on whether access to Digital Sequence Information (DSI) should be treated in the same way as would accessing the genetic resource or material (organism) itself. It is obvious they are not the same thing as currently more can be done with the organism than with a partial sequence or even an entire genome. In essence, generation of a sequence requires the genetic resource, itself, to be accessed; the DSI is a product of that access, a “derivative”. However, generating and publishing sequence data is considered by CABI as descriptive information and therefore not utilisation and, as such, it is out of regulatory scope. Publishing the sequence as electronic data is an act of sharing such descriptive information with the wider community – including the provider country. DSI can be used at many non-exploitative levels; for example, it is used to confirm identification and in the CABI understanding this is an observation; in most cases the sequence is published. European draft guidance indicates that taking the

sequence information and using it to develop a product or tool is out of scope but we are aware that other countries are not of that opinion (this is still in debate at COP). However this does not negate the need for benefit sharing and in this case it is the actual publication of the DSI that shares the benefits of access to the genetic resources from which it was generated.

Selected DSI are becoming standard tools for identification and phylogenetic characterisation of species and populations: mitochondrial CO1 'barcodes' for animals; plastid matK and rbcL barcodes for plants; 16S ribosomal DNA for bacteria, and ITS for many eukaryotes (including Fungi), have become standard tools in modern taxonomy and identification, although the real power of this approach becomes most obvious when sequences from multiple individuals and sources (countries) is freely shared and duly acknowledged. In the future, whole genome sequencing will, without any doubt, have a similar impact on taxonomy. We argue strongly that DSI generated for taxonomic or descriptive purposes needs to be freely shared in the public domain to help address the taxonomic impediment that the CBD recognises, as well as to meet the needs of agriculture and other sciences.

### **Conclusion**

Generation and use of DSI should be considered when accessing the genetic resource to the extent that benefit-sharing is required under the CBD. However, the generation and publishing of such data is not "utilisation" and should not trigger the Nagoya Protocol. Further, we suggest that such generation and publishing of DSI should be considered as part of a country's responsibilities under Article 7 (Identification and Monitoring) and 17 (Exchange of Information) of the CBD. As new technologies develop, DSI may have additional uses that could trigger benefit-sharing and this should be subject to equitable sharing of benefits. Requirements will vary from country to country but should include placing the DSI in the public domain and its subsequent use can be defined in standard Material Transfer Agreements. Likely benefits could include sharing the developed tool or enabling access to the generated product but in most cases the benefit is likely to be facilitating access to the published data and no more. It would be preferred that a single common global understanding was reached to ensure full compliance and thereby reduce confusion.

NOTE FOR SUBMISSION IN UK and to EC: In Europe there is an additional problem because the EU in their guidance documents are using the Frascati definition of research and development [http://www.oecd-ilibrary.org/science-and-technology/frascati-manual-2002\\_9789264199040-en](http://www.oecd-ilibrary.org/science-and-technology/frascati-manual-2002_9789264199040-en) to help define "utilisation" and this includes the generation of knowledge. In this case generating DSI would consequently be "utilisation" and trigger benefit-sharing. However, the guidance documents go on to describe sequencing as a descriptive step or confirming identity which is NOT utilisation – there is still work needed to clarify.