

DIGITAL SEQUENCE INFORMATION

1. DEFINITION

Digital Sequence Information (DSI), in general terms, is the information that originates from the analysis of the data contained in a digital file with a precise order of nucleotides (A-T-C-G), amino acids, or molecular structure of proteins. The sequence of nucleotides or amino acids forms nucleic acid molecules, DNA and RNA - (U), and proteins, whose main function is the storage and transmission of genetic information.

The term "Digital Sequence Information on Genetic Resources" as used in Decisions CBD XIII/16 and NP-2/14, should be carefully considered. In particular, whenever possible the term should be harmonized with the terminology used in other international treaties. Currently, there is a multitude of correlate terms currently being used in different forums, including "genetic sequence data", "genetic information", "dematerialized genetic resources", "*in silico* utilization", and "natural information".

2. INSERTION OF THE TOPIC IN THE SCOPE OF THE CONVENTION

According to Article 1 of the CBD, one of the three objectives of the convention is the fair and equitable sharing of the benefits arising from the utilization of genetic resources. The Nagoya protocol defined the term "utilization of genetic resources" as the conduction of research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology. Article 2 of the CBD defines "biotechnology" as any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

Article 5 of the Nagoya Protocol also clarifies its scope when it states that "(...) benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms."

The CBD defines "genetic material" as any material of plant, animal, microbial or other origin containing functional units of heredity. Moreover, according to the Oxford Dictionary, the word "material" can be defined as "*information or ideas for use in creating a book or other work*". On the other hand, the definition of the word "matter" is "*physical substance in general, as distinct from mind and spirit; (In physics) that occupies space and possesses rest mass, especially as distinct from energy*". The term "material" should not be confused with the term "matter". The definition of the word "material" allows the interpretation of the term to include the set of information associated with the genetic resource, that is, the substrate information or working material.

Even if genetic information obtained digitally is to be considered as excluded from the concept of genetic material, a systemic interpretation of the Convention on Biological Diversity and the Nagoya Protocol leaves no doubt that the use of this information is subject to benefit sharing. The means of transmission of genetic information, whether in the form of matter from a DNA sample or as information stored *in silico*, is irrelevant to the fulfillment of this obligation. Since

there was a "utilization" of a physical sample to access this type of information, its application and subsequent commercialization should be shared in a fair and equitable way, in line with Article 5 of the Nagoya Protocol. To exclude the use of genetic information, whether obtained digitally or otherwise, in the mechanisms provided for in the Nagoya Protocol, which seeks precisely to operationalize one of the three objectives of the CBD, would compromise the achievement of its general purpose and observance of its principles, especially in megadiverse and developing countries.

Therefore, the discussion of digital sequence information within the scope of the convention ultimately does not impact the effective application of the CBD and Nagoya Protocol objectives. It is also worth mentioning that, in the context of the Brazilian regulatory framework, this issue is considered settled.

It is also important to highlight that the CBD and the Nagoya Protocol, especially its Article 8, recognize the need for access facilitation for the progress of science. The exchange of digital sequence information is essential to achieve the objectives set out in Article 12 of the CBD, which are to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, *inter alia*, in accordance with decisions of the Conference of the Parties taken in consequence of recommendations of the Subsidiary Body on Scientific, Technical and Technological Advice.

In order to contemplate the provisions of Article 12 of the CBD and Article 8 of the Nagoya Protocol, the benefit sharing obligation should not impact the speed of research and development using digital sequence information. Parties should consider facilitated rules for access and use of these sequences in the development of their national legislation, so as to provide for the fair and equitable sharing of the benefits that originate from the commercialization of new products obtained from the utilization of genetic information.

3. TRACEABILITY

For provider countries and countries of origin of genetic resources, traceability is crucial for the full implementation of the Nagoya Protocol in the context of the utilization of digital sequence information. Traceability is also fundamental for countries that utilize this information, since a consolidated legal framework is considered favorable by institutions that study the possibility of investing in research in their domestic contexts.

Although genetic sequence databases require the provision of several different pieces of information regarding the submitted sequences, in many cases the necessary data for its traceability is not required or the requirement of information is not mandatory, which makes the precise determination of its source very difficult.

Therefore, once rules for the use of digital sequence information are established in the context of the CBD and the Nagoya Protocol, it is important to ensure the traceability of sequences submitted in databases. Thus, it is necessary to: (i) establish mechanisms to ensure that the genetic databases require standardized information necessary to the traceability of submitted sequences; (ii) establish differentiated treatment for cases of sequences submitted in genetic databases prior to the definition of this mechanism and whose traceability is not possible.

The implementation of "disclosure of origin or source" in both patent applications and the deposit of digital sequences in databases could make possible the creation of verification points, as envisioned in Article 17 of the Nagoya Protocol. Although this mechanism has not

yet been established as a rule for all databases, it could potentially facilitate the establishment of *prior art* for the analysis of patent applications, inhibit misappropriation, create mutual trust among all stakeholders and make traceability possible.

4. BRAZILIAN LEGISLATION

In Brazil, Law 13,123/2015 defines genetic resources (or genetic heritage) as the genetic information from plants, animals, and microbial species, or any other species, including substances originating from the metabolism of these living organisms (Article 2, I). Furthermore, Decree No. 8,772/2016, in what concerns registration in the National System for Genetic Heritage - SisGen - requires that the origin of the genetic heritage found in *in situ* conditions be informed, even if obtained from *ex situ* or *in silico* sources. Therefore, the Law and Decree that regulate access and benefit sharing in Brazil have already recognized access to dematerialized genetic resources in its framework, without the need for access to the physical sample as such. Thus, the regulation of Law 13,123/2015 provides that research utilizing genetic information obtained *in silico* is to be carried out freely, and that registration is required only at the time of publication of the results, or upon application for a patent, or before introduction of a product on the market.

Some other solutions found in the Brazilian legislation could be considered for the implementation of the use of genetic information in the CBD and in Nagoya, such as: facilitated mechanisms for access to genetic resources, causing a shift in the focus of regulation, previously focused on the access control, to the control of results; special considerations for scientific research, for food and agriculture, for public health emergencies and for technologies that foster sustainable development; economic exploitation as the point of incidence of benefit sharing obligation; the establishment of a benefit-sharing fund.

Similarly to the National Benefit-sharing Fund created by Law 13,123/2015 in Brazil, Article 10 of the Nagoya Protocol provides for the establishment of a useful mechanism for benefit sharing in the case of genetic resources occurring in transboundary situations or for which prior informed consent cannot be obtained. It remains to be further analyzed how benefit sharing should be carried out in the cases of: (i) access to multiple genetic resources, including cases in which the genetic information was obtained from genetic databases, and may come from different species or regions, and (ii) use of conserved sequences, since these sequences can be found in hundreds or even thousands of different species, which makes traceability difficult.