

# DIGITAL SEQUENCE INFORMATION ON PLANT GENETIC RESOURCES

**Galina Mozgova**, Head of the National Coordination Biosafety Centre, Institute of Genetics and Cytology, NAS of Belarus, PhD

**Elena Makeyeva**, Head of the National Coordination Centre on Access to Genetic Resources and Benefit-sharing, Institute of Genetics and Cytology, NAS of Belarus, PhD, Associate Professor

**Abstract.** The Article considers the issues related to the Nagoya Protocol operation, including the fundamental principles of benefit-sharing arising from access to genetic resources.

**Key words:** the Nagoya Protocol, the Convention on Biological Diversity, genetic resources and technologies, genetic sequences, benefit-sharing, digital information, databases.

The country Parties to the Nagoya Protocol, including the Republic of Belarus, have held a number of important events since the Protocol entered into force in 2014. However, many issues related to the implementation of the provisions of this international instrument have not been addressed yet. This applies both to additional barriers in accessing genetic resources and international collaboration in the field of basic scientific research, especially



fundamental research, and deriving no benefits from the utilization of genetic resources and technologies associated with them in the case of uncontrolled access.

One of the results of genetic resources' research is the digital sequence information (DSI) related to them. Many countries have raised an issue that the DSI exchange should also

be regulated in accordance with the provisions of the Nagoya Protocol, which builds upon the fundamental principles of access and benefit-sharing set forth in the Convention on Biological Diversity. At the same time, a number of terms and formulations of such documents are ambiguous. In particular, “genetic resources”, pursuant to Article 2 of the Convention, means genetic material of actual and potential value. However, this interpretation covers any material of plant, animal, microbial or other origin containing functional units of heredity [2]. Since 2016, the term “digital sequence information related to genetic resources” (hereinafter referred to as “DSI-GR”) has been subject to broad discussions. Many countries are of a strong opinion that it should be considered as a resource the utilization of which may provide benefits, and therefore access to it should be regulated by the provisions of the Nagoya Protocol.

Since States may establish national regulatory mechanisms both in bilateral and multilateral agreements, in December 2016, at the 13th Conference of the Parties to the Convention and the 2nd Conference of the Parties to the Nagoya Protocol, they were invited to continue investigating the problem at the

national level during the intersessional period (2017-2018) and direct information to the Secretariat expressing their position [3] to ensure conceptual clarity with regard to DSI-GR.

Hand in hand with that, the Secretariat created an Ad Hoc Working Group of Experts, which in 2018 considered two analytical documents prepared by the Secretariat on the basis of information obtained from the country Parties to the Nagoya Protocol [3,4]. Specialists criticized the term “digital sequence information related to genetic resources”. At the same time, an agreement was reached on its use until a new definition more fully reflecting the relationship of this information with the Nagoya Protocol has been developed, and that the term “digital” refers only to the method used for data storing and transfer, and that new alternative forms of storing or transfer may give rise to issues.

At that stage of problem research, experts identified various types of information that may be relevant to DSI-GR, recognizing that this interrelation is full in a number of cases. The following information was referred to such types: nucleic acid nucleotide sequence and corresponding data; information about this, its annotation and genetic mapping (it can describe whole genomes; individual genes or their parts, including DNA barcodes; organelle genomes, or single nucleotide polymorphisms); data on macromolecules or cellular metabolites; information about the ecological interactions of the body and abiotic environmental factors; the functioning of organisms (e.g. behavioral data); structure, including morphology and phenotype; taxonomic data. In addition, it was proposed to consider digital information as its contextual form based on observational data believing that such approach can simplify its interpretation, and consequently, enhance the understanding of genetic resource properties [3].

When studying technical issues, as well as the legal and scientific implications of existing terminology use and discussing the relationship between the concept of “digital sequence information” with its definitions given in the Convention and the Nagoya Protocol, no consensus was reached on whether the Convention’s term “genetic resources” includes digital information on related sequences. However, everyone would agree that even if DSP is not included in this definition, it is still within the scope of the Nagoya Protocol, since it is the result of genetic resource use as a material object, and therefore, in the subsequent application and commercialization of this information, a benefit-sharing procedure should be put in place. At that, digital records of nucleic acid sequences and the corresponding data obtained as a result of genetic resources’ use are primarily considered as an object of such procedure.

The complexity of this issue is also associated with a multitude of variants in the disclosure of the terms “sequence”, “information” and “functional unit of heredity”. In this regard, Parties to the Convention and the Nagoya Protocol believe that discussions should continue with an eye to finding a balance between the terminology, which should be adaptive and dynamic enough from

the standpoint of modern scientific, technological, market and other changes, and at the same time clear and reliable enough to ensure legal certainty of DSI-GR.

The legal implications of recognizing digital sequence information as a genetic resource equivalent will be an obligation in providing prior informed consent and determining mutually agreed terms of the information use for benefit-sharing.

The issue under discussion results from an increased activity of the Parties in the implementation of the Convention and the Nagoya Protocol to ensure their sovereign rights over biological (genetic) resources. No doubt that the main objective of the Convention is the conservation of biological diversity, and the public access to digital sequence information is paramount in achieving it through the implementation of Articles 17 and 18 of the Convention, as well as Articles 8, 20, 22, 23 and the Annex to the Nagoya Protocol, and also in addressing the 19th Aichi Target of the 2011-2020 Strategic Plan for the Conservation and Sustainable Use of Biological Diversity and the 15th Sustainable Development Goal (SDG) [5, 6].

At the same time, in the reality of the high technology era that has come into biology, a digital product with genetic information is moving from the field of data exchange to its application in biological technology and other scientific and industrial sectors, including healthcare.

At the same time, a concern is raised about the fact that countries may limit access to their genetic resources, provided that there are no benefit-sharing rules with regard to possessed DSI-GR, and this will have negative implications on the conservation of biodiversity. In light of the general recognition of the DSI-GR value, as well as a fast changing character of the technology that constitutes the core of it, regular horizontal scans of future technological developments relevant to the objectives of the Convention and the Nagoya Protocol may be required for a deeper analysis of the relationship between biodiversity conservation, its sustainable use and DSI-GR.

Analysis of potential consequences related to the DSI-GR application showed that transformational changes in the use of genetic resources may occur, and this will affect the type of benefits and how they are distributed: on the one hand, access to information and in-kind (kind) benefits in the technology transfer, data exchange and capacity development is regulated and realized to conserve and use biodiversity, and on the other hand, and in particular in light of advances in sequencing technologies, DSI may in some cases cast doubt on the implementation of mechanisms for access to genetic resources and benefit-sharing. For example, the World Health Organization is discussing an issue related to a possible violation of the contingency reaction mechanism in cases of pandemic influenza, when laboratories and vaccine manufacturers are increasingly relying on genetic sequence data, which excludes the use of material genetic resources.

Normally, digital sequence information becomes a foundation of analytical research, however, it is also leveraged for subsequent materialization of genetic material and this directly relates to benefit-sharing and may lead to the need for the economic valuation of information as such.

At present, GenBanks and their databases are recognized as one of the important mechanisms for the DSI-GR exchange. There are various interpretations of what a public database is: they can range from databases that are fully accessible for all users (e.g. GenBank) to those that impose specific requirements (e.g. the Global Initiative on Sharing All Influenza Data (GISAID)) on user registration and access agreements for available data. Obtaining of data may also require benefit-sharing agreements, but public domain data may be an object of intellectual property rights or subject to the commitments under the Nagoya Protocol. The academia is increasingly emphasizing the need for including environmental information in the metadata as it contributes to the conservation and access to genetic resources for best research practices and benefit-sharing. At the same time, there is a need for additional data on the country of origin of genetic information – the resource whose sequences are located in databases, who it is presented by and the country users gain DSI access from.

Placing limitations on the use of data in the public domain is hardly desirable. However, there is information of the ownership nature, the content of which is not publicly available. At the same time, there are already examples when steps are being taken to comply with the Nagoya Protocol using both direct genetic material and digital sequence information related to genetic resources (e.g. the International Project “Barcode of Life”, Canada) [7-10].

The Republic of Belarus as a Party to the Convention and the Protocol should be actively involved in further discussions related to the elaboration of the definition “digital sequence information related to genetic resources” and the mechanism regulating access to such data and benefit-sharing. Currently, in our country, you can refer to the “Law on Information, Informatization and Information Protection” of November 10, 2008 to protect data on sequences.

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