



# COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

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## SUBMISSIONS BY MEMBERS ON DOMESTIC ACCESS AND BENEFIT-SHARING MEASURES APPLYING TO DIGITAL SEQUENCE INFORMATION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

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## I. INTRODUCTION

1. The Commission, at its Nineteenth Regular Session, considered the role of digital sequence information (DSI) on genetic resources for the conservation and sustainable use of GRFA. It requested the Secretariat, building on previous work and avoiding duplication, to invite Members to submit information on domestic ABS measures applying to DSI and their actual or potential implications for the conservation and sustainable use of GRFA, including their exchange, access to them and the fair and equitable sharing of the benefits arising from their use, and to compile this information for the Commission.<sup>1</sup>

2. FAO invited through Circulate State Letter C/X/OCB-12 Members to submit the relevant information. This document compiles the three submissions received by the Secretariat, for information of the Commission.

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<sup>1</sup> CGRFA-19/23/Report, paragraph 30.

## II. SUBMISSIONS BY INTERNATIONAL INSTRUMENTS AND ORGANIZATIONS

### A. Brazil

#### Domestic Measures Applicable to Access and Benefit-Sharing Related to DSI

Brazil has adopted two main regulations related to the registration and access to Digital Sequence Information (DSI): the “Biodiversity Law” (Law No. 13.123/2015) and Decree No. 8.772/2016. The Brazilian ABS system covers research and development with “genetic heritage”, i.e. the “genetic information from plants, animals, and microbial species, or any other species, including substances originating from the metabolism of these living organisms”. This is the case even when the information is disengaged from the physical samples the information has been obtained from. The Brazilian ABS Rules do not mention the term “digital”, but rather refer to the expression genetic heritage when acquired from “*in silico* sources”. The expression appears in Article 22 of Decree 8.772, of 2016, which regulates the procedural aspects of registration under the National System for the Management of Genetic Resources and Associated Traditional Knowledge (SisGen), prescribing that the origin of the genetic heritage, in the sense of its georeferenced coordinates, should be indicated in the registration form, whether the heritage has been acquired from *ex situ* or *in silico* sources.

With this understanding, drawing from Article 2,I of Law 13.123/2015, genetic information found in digital format or accessed through “*in silico*” sources, is not merely a product of research and development, as it forms an integral part of the notion of genetic heritage. Genetic heritage found *in silico* would designate any genetic information from plants, animals, and microbial species, or any other species, including substances originating from the metabolism of these living organisms, obtained through molecular and computational biology, and/or stored in a computer environment.

The Brazilian concept of genetic heritage could thus be understood to include in a broad manner DNA and RNA sequences in all their forms, including assembled and annotated genomes and partial sequences; sequences of alternative forms such as cDNAs, codon optimized sequences; amino acid sequences, SNPs, STR counts, and epigenetic and molecular characterization information (e.g. structures, DNA methylation).

As a rule, Law 13.123/2015 provides that research utilizing genetic information obtained *in silico* can be carried out in an open manner, and that registration is required only at specific points in the utilization chain, in parallel to genetic information obtained in other forms<sup>2</sup>. Some differences of treatment between genetic heritage information found *in silico* vis-à-vis its counterparts *in situ* or *ex situ*, exist only due to its specific nature, such as the need for naming the gene bank or data bank from which it was obtained.

Decree 8.772, of 2016, explains further the understanding of “research and technological development” in the context of *in silico* genetic heritage. For instance, in its Article 107, the Decree explicitly mentions that the mere consultation or reading of information contained in a database should not be considered an activity that would trigger genetic heritage access obligations.

The provision also addresses the comparison of information: “Does not configure access to genetic heritage reading or consultation available in national and international databases, although they are an integral part of research and technological development. Comparison or extraction of genetic information from national or international databases is not considered access if not integral part of research or technological development” this means that with regards to the comparison of information, only its execution in a context of research and development would fall within the Brazilian ABS Rules, provided they reach the triggers for SisGen registration as defined in Article 12 of Law 13,123. That is, since there is no need for prior registration, if a given access activity such as the download and subsequent use of information in research and development activities does not have any results, any

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<sup>2</sup> As per Art.20, Paragraph 1 of Decree 8.772/2016, users must notify and register activities under SisGen after some “triggering events”, such as the transfer of genetic samples; publication of final or preliminary results in scientific publications or media outlets; a Patent Application; a By Product commercialization; or a notification on finished product or reproductive material arising from access;

intellectual property right applications, products or processes developed, that access activity does not reach the trigger for access registration.

Regarding the transfer of downloaded or produced information via digital means (for example file transfer through a email or USB stick), Technical Guidance number 8 from the Genetic Heritage Management Council (CGe) specifically excludes access registration obligations at the moment of the transfer itself, but rather explains that those obligations are only needed further down the chain to the usual trigger points of the Brazilian ABS Rules. “The transfer abroad, by digital means, of information relative to genetic heritage, regardless the purpose, does not fall within the concepts of shipment and sending of samples aforementioned.”

With regards to the registration procedure on SisGen, the information required from entities declaring access to genetic heritage includes information on the digital sources it comes from, i.e. “the genetic heritage origin database with the information in the deposit record, when it comes from an *in silico* database.”

The SisGen system contains specific fields to be filled out by users regarding the source of the genetic heritage subject to the registration. It is thus mandatory to indicate (i) the database that has been consulted; (ii) the genetic heritage access code from the database; and (iii) the electronic address of the information provided on genetic heritage. Also, in an additional optional layer, the user may also add information such as (iv) the State, municipality, geographic coordinates, biome and date of data collection, if they are available. The Brazilian ABS Rules thus assume that the georeferenced coordinates of the *in situ* sampling of genetic heritage should be made available in *in silico* databases with regards to genetic heritage that has been physically acquired (and not necessarily accessed in the sense of the Brazilian law) after the entry into force of Law 13.123. The Brazilian ABS rules also address the situation where the mentioned information is erroneous, or is no longer available on the indicated *in silico* source: “if it is detected, at any time, the unavailability of access to information in the indicated databases, repositories or information systems, or to the standard resource locator (URL), or equivalent, referred to in paragraph 3, the user will have 60 days after becoming aware of this fact to rectify the information presented, or to register in the standard form of SisGen the identification and origin of the genetic heritage object of access, under penalty of cancellation.

It should be noted that SisGen also foresees situations when access activity is carried out from samples of substrates containing non-isolated microorganisms, such as metagenomics/metabolomics analysis, in which case the user may register the higher taxonomic level and update the information later when results with specific taxonomic information is available.

Specifically for agricultural activities, Decree 8.772/2016 provides that the national system must collect and provide information relevant to the traceability activities arising out of access to genetic resources and associated traditional knowledge, as follows:

**Article 5:** Without prejudice to the system provided in Chapter IV of this Decree, the Genetic Heritage Management Council (CGen) must maintain its own traceability system for activities resulting from access to genetic heritage or associated traditional knowledge, including those related to economic exploitation.

**§1:** Pursuant to Article 7 of Law No. 13.123/2015, the system mentioned in the main clause will be managed by the Executive Secretariat of the Genetic Heritage Management Council (CGen) and will contain the necessary information for the traceability of activities resulting from access to genetic heritage or associated traditional knowledge in the databases of the following systems:

I – systems of protection and registration of cultivars, seeds and seedlings, products, establishments and agricultural inputs, information on the international movement of agricultural products and inputs from the Ministry of Agriculture, Livestock, and Supply.

Finally, as per May 2024 approximately 1700 registered activities on SisGen have declaration of access to genetic heritage obtained from *in silico* sources.

## Implications for the Conservation and Sustainable Use of GRFA

The use of DSI is becoming more relevant and holds great transformative potential regarding the use of genetic resources in agricultural research, including for conservation and sustainable use of agrobiodiversity and benefit-sharing from its utilization. The use of DSI provides opportunities for accessing a wide range of genetic resources during the early stages of research by using *in silico* DNA sequences to introduce genes of interest into products, inputs, or for the development varieties. It is important to note that Brazilian legislation, particularly Law No. 13.123/2015 and Decree No. 8.772/2016, introduces certain requirements for *in silico* access to DSI for the use of species of genetic heritage. The requirements are the same as those applicable to access to physical samples of genetic resources. Other possible requirements are related to obtaining Prior Informed Consent (PIC) when there is associated traditional knowledge (ATK) linked to the genetic sequences used, and a Material Transfer Agreement (MTA) when transferring genetic material between institutions, detailing the conditions of use and benefit-sharing.

In this regard, we note that, according to information from the Management Committee of the National Benefit-Sharing Fund (CG-FNRB), it is estimated that the National Benefit-Sharing Fund has collected until 2023 a total of R\$ 7,438,596.49 (seven million, four hundred and thirty-eight thousand, five hundred and ninety-six reais and forty-nine cents), of which approximately 1.2 million (21% of the total) are derived from earnings remunerated at the SELIC rate (Brazilian federal funds interest rate). Since its operationalization in 2020, the FNRB has received deposits from 65 companies, with about 60% of the amounts resulting from Benefit-Sharing for access to Genetic Heritage; 30% from access to identifiable ATK, and the remaining 10% divided between Benefit-Sharing for access to *ex situ* Genetic Heritage and access to non-identifiable ATK.

Regarding *in silico* access, between 2017 and 2023, these represented 0.2% of the number of access registrations in PG included in SisGen. To date, only 4 notifications of finished product or reproductive material resulting from DSI access have been registered, according to a report by the Institutional Relations Directorate of National Industry Confederation, presented during the 36th ordinary meeting of the Genetic Heritage Management Council (CGen).

In light of the requirements applicable to the utilization of DSI under Brazilian legislation, there is a need to further develop technologies that may enhance and facilitate compliance with Brazil's national ABS system, such as blockchain and others. However, those technologies may prove costly in terms of development and maintenance, besides having a significant environmental footprint.

Resources from benefit-sharing derived from the use of DSI could provide a tool to address those technological gaps, by unlocking investments in capacity building and technology transfer, as well as developing the necessary infrastructure. Such initiatives could be carried out through joint technological development, international cooperation, and scientific research programs aimed at conserving agrobiodiversity, in line with Target 20 of the Kunming-Montreal Global Biodiversity Framework.

Given the scale of activities across the agricultural sector, open access to DSI is particularly vital for agricultural research, allowing for rapid and preventive responses to diseases and pathogens of economic importance, as well as facilitating studies on mitigation and adaptation to climate change and the exchange of crucial data for genetic improvement and agricultural research, which significantly contributes to global food security.

At the same time, the specifics of DSI may lead to "forum shopping". Because a specific genetic sequence might be found in different varieties or species with different "countries of origin," developers might try to circumvent benefit-sharing obligations by claiming the same sequence from materials available in multilateral or unregulated sources, including varieties and species available in the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA/FAO). On top of that, potential users may decide to seek sequences from countries that do not apply or enforce tracking mechanisms in their national legislation. That said, there is a need to improve coordination amongst countries to ensure a "level playing field" and address loopholes that may enable users to bypass benefit-sharing obligations. There is also a need to identify best practices that could help countries address compliance costs and facilitate the implementation of national legislation from the user perspective.

## **B. Canada**

Canada has provided several submissions through the FAO and the Convention on Biological Diversity on “Digital Sequence Information (DSI) / Genetic Sequence Data (GSD)”, its relevance to GRFA, and impacts on Access to Genetic Resources and Benefit-Sharing (ABS). These submissions include:

- Response to an invitation to submit views from the Commission Secretariat (submission can be found in CGRFA-17/19/4/Inf.1).
- Responses to relevant invitations from the Secretariat of the International Treaty on Plant Genetic Resources for Food and Agriculture (submissions can be found in IT/GB-8/19/16.1/Inf. 1 and IT/GB-9/22/17.2/Inf.1).
- Response to CBD notification 2017-037 (can be found in CBD/SBSTTA/22/INF/2 and CBD/DSI/AHTEG/2018/1/2), and response to CBD notification 2019-012 (can be found in CBD/DSI/AHTEG/2020/1/INF/1).

In addition, Canadian ABS experts provided input to the authors of the recent study prepared for the Commission titled “The role of digital sequence information in the conservation and sustainable use of genetic resources for food and agriculture: opportunities and challenges”. As such, Canada’s national ABS measures have been taken into account within this study.

Evaluating and compiling measures relevant to DSI is challenging without an agreed definition of DSI. Canada’s interpretation of the term DSI can be characterized as Genetic Sequence Data (GSD) or Nucleotide Sequence Data, and not equivalent to Genetic Resources. The Canadian agricultural sector is mindful of DSI issues, and sees DSI/GSD as central to the conservation and sustainable use of genetic resources.

Canada has been and remains actively engaged in DSI/GSD discussions within the Commission, the ITPGRFA, the CBD, and other fora. Given the rapidly changing status of DSI/GSD negotiations and agreements, Canada is evaluating its domestic ABS framework in the light of the Kunming-Montreal Global Biodiversity Framework, the Enhancement of the Functioning of the Multilateral System under the ITPGRFA, and the Multilateral Mechanism on Benefit-Sharing from the use of DSI on Genetic Resources in development under the CBD.

**C. Japan****I. Introduction**

Japan welcomes the opportunity to provide information on domestic ABS measures applying to DSI regarding the decision made by the 19<sup>th</sup> Regular Session of Commission on Genetic Resources for Food and Agriculture.

- (1) Japan does not apply any measures on ABS from the use of DSI.
- (2) As noted above, Japan does not apply any domestic ABS measures on DSI.