Dialogues
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# Brazil-EU Dialogue on in silico Genetic Heritage in Brazilian ABS Legislation

*Diálogo Brasil-UE sobre patrimônio genético in silico na Legislação Brasileira de ABS*

**April 2020**

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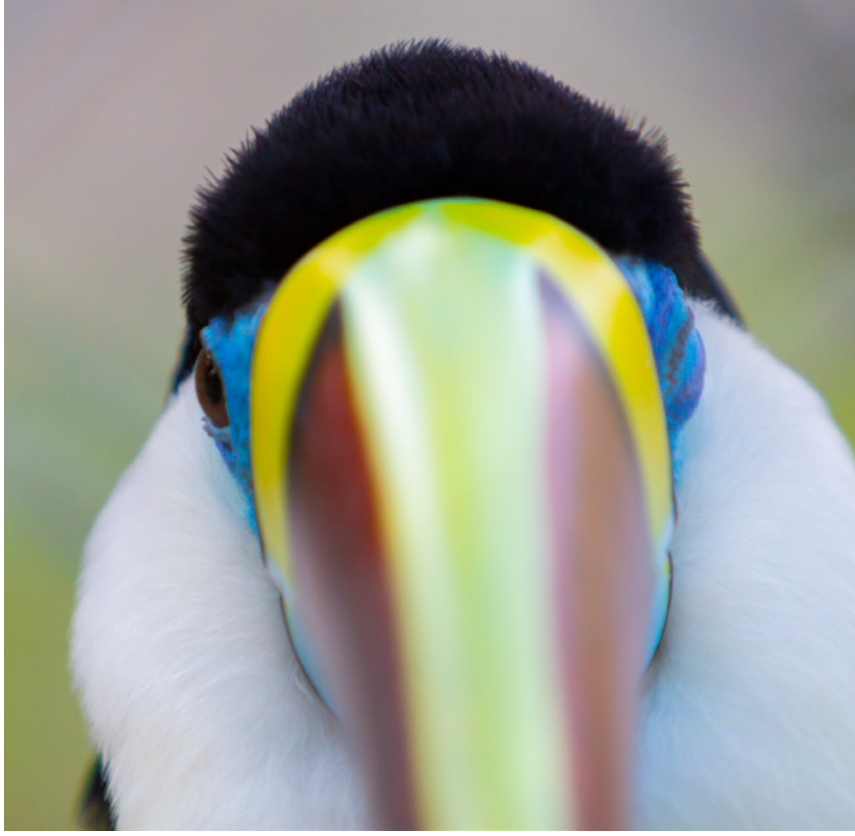
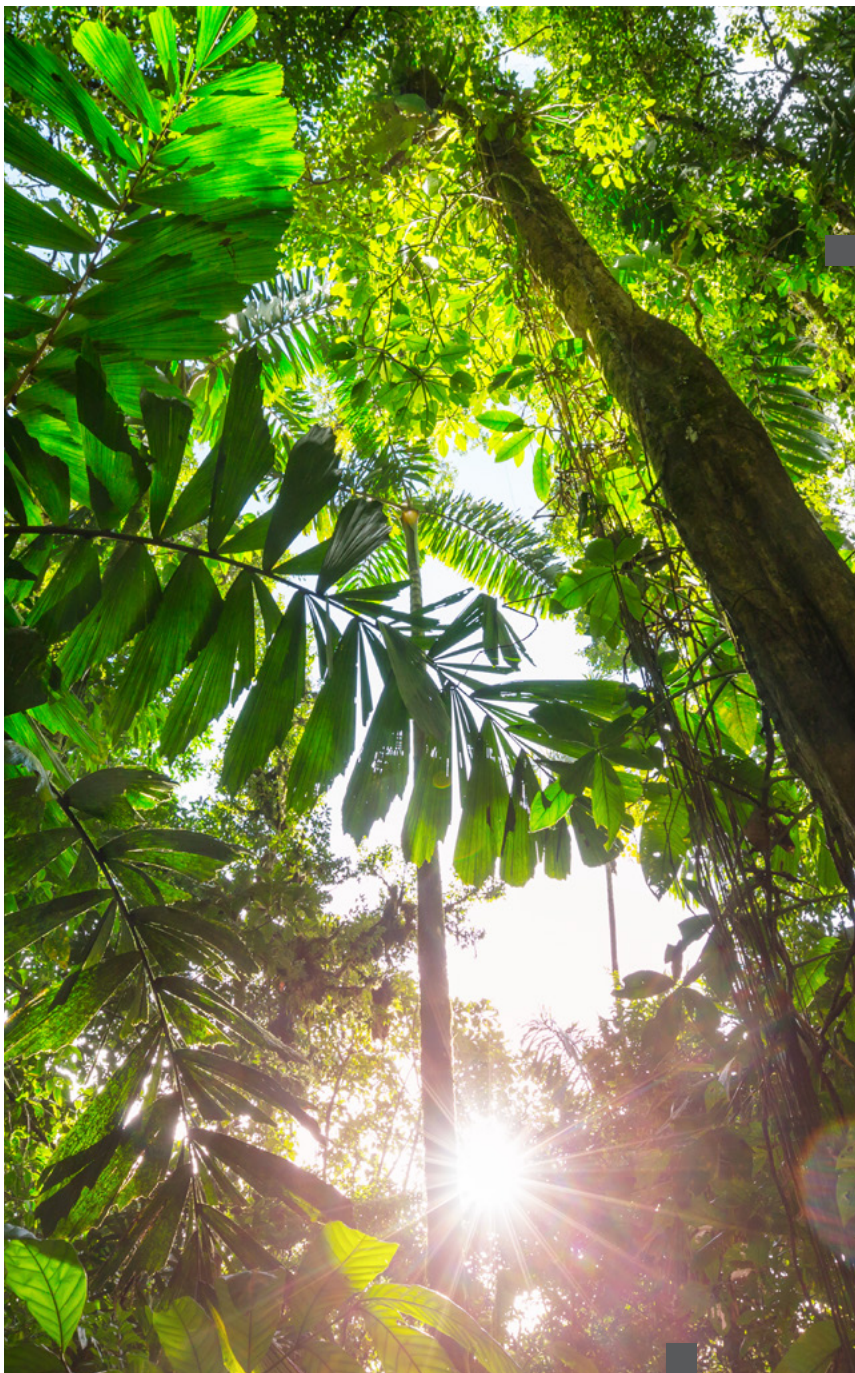
# ACRONYMS AND ABBREVIATIONS

| | |
|---|---|
| **ABS** | Access and Benefit Sharing |
| **ATK** | Associated Traditional Knowledge |
| **CAR** | Certificate of Access Regularity |
| **CBD** | Convention on Biological Diversity |
| **CGen** | Genetic Heritage Management Council |
| **CNPq** | National Council for Scientific and Technological Development |
| **DSI** | Digital Sequence Information |
| **EU** | European Union |
| **GH** | Genetic Heritage |
| **IBICT** | Brazilian Institute of Information in Science and Technology |
| **ICMBio** | Chico Mendes Institute for Biodiversity Conservation |
| **INPI** | National Institute of Industrial Property |
| **INSDC** | International Nucleotide Sequence Data Collaboration |
| **MCTI** | Brazilian Ministry of Science, Technology and Innovations |
| **MMA** | Brazilian Ministry of Environment |
| **MTA** | Material Transfer Agreement |
| **NP** | Nagoya Protocol |
| **SisGen** | National System of Genetic Heritage and Associated Traditional Knowledge Management |





# I. CONTEXT

## THE PROJECT

Access to genetic resources is of major importance to non-commercial and commercial research, supporting biodiversity conservation, environmental management, scientific excellence, product development and delivery. Because of Brazil's very high biodiversity, there is considerable interest for biodiversity studies and commercial activities, and many stakeholders both in Brazil and the European Union (''EU'') have long mutually profited from active research projects and collaborations in the context of complex and challenging ABS legislations.

This specific project takes place within the Sector Dialogue framework, seeking to further develop mechanisms and tools to facilitate scientific and technological exchange and cooperation in the area of access to genetic resources and benefit sharing (''ABS''), in accordance with the requirements of the Convention on Biological Diversity (''CBD''), and the Nagoya Protocol (''NP''); a Protocol which was ratified by the European Union but not yet by Brazil. Collaboration between the Parties is ongoing despite this asymmetry. Understanding of both legislations and of the challenges arising from their implementation has been growing, even if their implications for EU-Brazil collaborations are not yet fully explored.

This Dialogue aims to continue the work coordinated by the Directorate General Environment of the European Commission and the Ministry of Environment of Brazil, conducted in 2012, 2013, 2014 and 2016. Since the previous Dialogue1, the legislation both in Brazil and EU has been more fully implemented and considerable experience was gained in practical matters. Even though a lot of existing issues and uncertainties have been resolved during the last phases of the project, many industrial and academic stakeholders remained very uncertain about the specifics of the procedures to follow under the Brazilian ABS Rules2. Furthermore, the notion of genetic heritage (GH) extends

1. The previous project outputs, including the booklet produced from the last phase of the project (Kate DAVIS, Paulo HOLANDA, Chris LYAL, Manuela DA SILVA and Eliana M.G. FONTES, Implementation of the Nagoya Protocol on Access and Benefit-Sharing: Dialogue between Brazil and the European Union, Sector Dialogues), are available online at : https://www.embrapa.br/recursos-geneticos-e-biotecnologia/dialogo-protocolo-de-nagoya ; http://nagoyaprotocol.myspecies.info/node/23; https://portal.fiocruz.br/sites/portal.fiocruz.br/files/documentos/mmaa0019_ingles_web.pdf

2. Throughout this booklet, the ''Brazilian ABS Rules'' are understood to comprise of ABS Law no. 13.123/2015 dated as of 20th May 2015, its implementing Decree no. 8.772/2016 dated as of 11th May 2016, along with all the legally binding Resolutions and Technical Guidances issued by CGen, providing authoritative interpretations with regards to the content of the aforementioned Law and its Decree.

to "genetic information from plants, animal and microbial species, or any other species, including substances originating from the metabolism of these living organisms" (Art.2 of Law 13.123/2015) notwithstanding the source of such information, which can be *in situ*, *ex situ* or *in silico* (Art. 22 of Decree 8.772/2016). The regulation of research and technological development carried out on ***in silico*** GH in the Brazilian legislation, i.e. GH held in computer storage, provides additional interrogations and challenges for regulators, academia and industry.

That is why this project phase was focused on providing information on procedures for access to Brazilian genetic heritage (GH), more specifically from so-called *in silico* sources (a terminology used in Brazilian national legislation next to ex situ and in situ sources of genetic information and material). Building on previous phases of the Brazil-EU Sector Dialogues, this particular project had the chance to reflect on almost four years of experience on the implementation of the "Brazilian ABS Rules", comprising of ABS Law no. 13.123/2015 dated as of 20th May 20153 and its implementing Decree no. 8.772/2016 dated as of 11th May 2016. It was particularly designed to further investigate the practical implications of the regulation of genetic heritage information held in computer storage, i.e. from *in silico* sources according to the Decree, to maximise confidence and legal certainty on Brazil and EU partnerships.

## PROJECT ACTIVITIES AND DOCUMENTS PRODUCED

In order to provide contextual information on applicable law and practical aspects of *in silico* genetic heritage access, a background document was developed prior to the workshop held in Brasilia from the 10th to the 12th December 2019 at the premises of the Ministry of Science, Technology and Innovations (MCTI). The background document had identified a series of open questions on the scope, content and implementation of the Brazilian ABS Rules, which were discussed by workshop participants from both European and Brazilian public authorities and stakeholders, whether researchers, users or legal consultants. Through different presentations and group work, participants conferred on applicable Brazilian and European ABS Rules, with emphasis on the regulation of access to Brazilian genetic heritage obtained from *in silico* sources. An overview of the presentations given during the workshop, as well as the discussions on the open

3. A courtesy English translation of Law no. 13.123, 2015 is available on the ABS Clearing House at the following link: https://absch.cbd.int/database/record/ABSCH-MSR-BR-238963

questions and scenarios developed in the background document can be found in the workshop report.

Building on these two documents and on the discussions held during and following the workshop, this booklet aims to inform potential users of the Brazilian ABS system on the scope of the Brazilian ABS Rules. Enriched with the established institutional practice in the Rules' implementation, it hopes to bring further clarity to users on existing procedural obligations. Using analysis and examples both from the background document and the workshop report, as well as additional illustrative cases, this booklet compiles the clarifications brought during the workshop discussions, flags areas of uncertainty and potential change, while also listing potential pathways that could be further explored.

# II. KEY ELEMENTS OF THE BRAZILIAN ABS RULES

By confronting the Brazilian ABS Rules to the practical realities of users and generators of genetic heritage information, especially those held *in silico*, i.e. in computer storage, the project has successfully put the implementation Rules' into concrete perspectives, and identified some clear assets of the system, as well as outstanding issues and impending challenges. While the new institutional governance established by the Brazilian ABS Rules in 2015 have brought considerable legal certainty to users, a limited number of ambiguities remain with regards to the exact scope of the Rules, the definition of access, and the different procedural triggers.

## INSTITUTIONAL CONSIDERATIONS

The Brazilian ABS Rules have a unique governance structure, which is centralised around the Executive Secretariat of the Genetic Heritage Management Council (*Conselho de Gestão do Patrimônio Genético* – "CGen"), established under the auspices of the Brazilian Ministry of Environment (MMA). The Council has very broad competences, continuously developing or clarifying the Brazilian ABS Rules through its Resolutions[4] and Technical Guidances[5], that are both legally binding, giving authoritative interpretations of Law 13.123/2015 and Decree 8.772/2016 The adaptable and participatory nature of the Rules is ensured through different Thematic Chambers, which are temporary, and Sectoral Chambers, which are permanent:

- Sectoral Chamber of Indigenous Populations, Traditional Communities and Traditional Farmer(s) Holders of Traditional Knowledge Associated with Genetic Heritage;
- Sectoral Chamber of Academia;
- Thematic Chamber on dosimetry of the fines of the infraction notices;

4. CGen Resolutions are available at: https://www.mma.gov.br/patrimonio-genetico/conselho-de-gestao-do-patrimonio-genetico/nrmas-do-cgen.html#resolu%C3%A7%C3%B5es

5. CGen Technical Guidances are available at: https://www.mma.gov.br/patrimonio-genetico/conselho-de-gestao-do-patrimonio-genetico/nrmas-do-cgen.html#orienta%C3%A7%C3%B5es-t%C3%A9cnicas

- Thematic Chamber on the proposed definition of distinctive characteristics;
- Thematic Chamber on the concepts of excipients for the personal hygiene, perfumery and cosmetics sector, which is no longer active, since its (the activities of which have resulted in the adoption of CGen Technical Guidance no. 2, 2017);
- Thematic Chamber on the concepts of key elements of value adding to the product for the fragrance sector, which is also no longer active, since its activities resulted in the adoption of CGen Technical Guidance no. 6, 2018).

Brazilian ABS Rules have also established an Electronic ABS Registry in the unique National System of Genetic Heritage and Associated Traditional Knowledge Management (*Sistema Nacional de Gestão do Patrimônio Genético e do Conhecimento Tradicional Associado* – ''SisGen''), where Brazilian entities must register access activities (i.e. research and development) when one of the legally established trigger points (which are identified below) is reached.

# GENETIC HERITAGE AS INFORMATION

> Law 13.123/2015, Art.2, I.
>
> Genetic Heritage - genetic information from plants, animals, and microbial species, or any other species, including substances originating from the metabolism of these living organisms

## Broad material scope

The **notion of GH** in the Brazilian ABS Rules is broad enough to include **all types of information**, their physical and digital counterparts, as long as such information relates to plants, animals, microbial species and any other species, including substances originating from the metabolism of these living organisms. The Brazilian ABS Rules thus refer to access to genetic information, and not to genetic resources.

## Distinctive characteristics of domesticated and cultivated species

Law 13.123/2015, Art.2, XXV

In situ conditions – conditions in which genetic heritage exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, including those forming spontaneous populations, in the surroundings where they have naturally developed their distinctive properties

Similar to the wording used in the CBD, Brazilian ABS Rules establish that domesticated and cultivated species need to have "**naturally developed their distinctive characteristics**" in Brazil as a threshold which determines whether they should be considered as GH:

- Two specific tools are envisaged within the Brazilian ABS Rules to guide this process, led by the Ministry of Agriculture: the list of domesticated or cultivated plants and animals, used in agricultural activities, that were introduced into Brazilian sovereign territory, indicating whether they have naturally developed distinctive characteristics in Brazil or not, which has led to a listing of species and varieties not to be considered as Brazilian genetic heritage (Article 113 of Decree 8.772/2016 and two Normative Instructions[6]), and the compilation of traditional and creole varieties that are considered as Brazilian genetic heritage (Article 114 of Decree 8.772/2016)

EXAMPLE

Access to Kappaphycus alvarezii, the elkhorn sea moss, a species of red algae, even sourced within Brazilian territorial sea would not be subject to a SisGen registration, as it is listed as a species introduced in Brazil without having naturally developed distinctive characteristics in the country.

6. The list of plant species introduced to Brazil and not considered genetic heritage was first published by Normative Instruction No. 23, of June 14, 2017, updated and expanded by Normative Instruction No. 3, of March 20, 2019 (https://www.gov.br/agricultura/pt-br/assuntos/sustentabilidade/tecnologia-agropecuaria/recursos-geneticos-1/arquivos/INn3de20demarode2019.pdf/view). The list of domestic animal species published by Normative Instruction No. 19, of April 16, 2018, updated and expanded with the inclusion of aquatic animal species and plant pest animals by Normative Instruction No. 16, of June 4, 2019.

- Complex or contentious cases would still require thorough comparative research, whether in publications or other types of information listing the biodiversity that exists in Brazil,

- The existence of a Thematic Chamber within CGen on the proposed definition of distinctive characteristics could prove to be a helpful mediating solution, as it could discuss contentious cases, or alternatively propose additional clarifications to be included in a future CGen Resolution or Technical Guidance.

EXAMPLE

Yerba mate plants that have been cultivated outside of Brazilian national territory for a considerable length of time, even if initially sourced in Brazil (not for access in the sense of the Brazilian ABS Rules but mere cultivation) would be considered as Brazilian genetic heritage held ex situ according to Brazilian institutional practice, and thus fall under Brazilian ABS Rules. However, if the plants had naturally developed distinctive characteristics in the country where they have been cultivated, they would potentially fall under the sovereign rights of that country.

## Microorganisms

Law 13.123/2015, Art. 2, sole para. and Decree 8.772/2016, Art. 1 §2

"For the purposes of this Act, a microorganism isolated from national territory, national waters, exclusive economic zone, or from the continental shelf substrates is considered part of genetic heritage existing in the national territory.

Microorganisms shall not be considered national genetic heritage when the user, urged by the competent authority, provides proof that (1) it was isolated from substrates that are not from the national territory [...], and (2) the lawfulness of its importation".

Brazilian ABS Rules include specific considerations with regards to *microorganisms*, stating that they would fall under their scope if isolated from substrates originating from territories falling under national sovereignty (i.e. internal land, territorial sea, exclusive economic zone & continental shelf). The Rules prescribe a general principle of qualification of microorganisms as Brazilian GH, assuming that they "originate from" sovereign Brazilian territory, shifting the burden of proof to users.

EXAMPLE

A microorganism isolated in Denmark from a pickled cabbage jar bought in a local market in Brazil would be considered as Brazilian genetic heritage by Brazilian authorities, but the user would be able to bring proof that the microorganism has originated in Denmark, where it has been isolated.

- In the Brazilian ABS Rules, the emphasis is put on the origin of the substrates where the microorganism come from, rather than the place of isolation of the microorganism as such.

- Research and technological development activities carried on microorganisms that have been isolated in Brazil but from substrates that do not originate from Brazilian sovereign territory would in theory not fall within the scope of the Brazilian ABS Rules. However, it would be up to users to prove the foreign origin of the microorganisms, for instance through documentations proving their lawful importation into the territory.

- Organisms that have been found and isolated inside sovereign Brazilian territory would be assumed to be Brazilian genetic heritage, and thus any organism isolated in Brazil would trigger a presumption regarding its origin in Brazilian substrates, according to a user's guide published by the Academia Sectoral Chamber of CGen[7].

- Furthermore, organisms isolated from Brazilian substrates but by a user outside of Brazil, would still be considered as Brazilian genetic heritage under the Brazilian ABS Rules.

7. The user's Guide ("CARTILHA PARA A ACADEMIA LEGISLAÇÃO DE ACESSO AO PATRIMÔNIO GENÉTICO E CONHECIMENTO TRADICIONAL ASSOCIADO E REPARTIÇÃO DE BENEFÍCIOS") adopted in May 2018 is available only in Portuguese at https://www.mma.gov.br/images/arquivo/80043/camara-setorial-academia/cartilha_para_a_academia_lei_13123_maio_2018.pdf

- However, as uncertainties are bound to exist on the exact origin of such microorganisms, and foreign countries where the isolation has taken place may consider the microorganism as falling within their own sovereign rights, the delineation of Brazilian GH qualification may not always be easy.

## Broad Geographical and Temporal scope

In the Brazilian ABS Rules, the date of acquisition of GH, whichever its source, has no relevance to the implementation of the Rules. In other words, it would not matter when the GH has actually been collected, acquired or came into the hands of a user; if **access** (i.e. research and technological development in the sense of the Brazilian ABS Rules, as detailed below) is **undertaken on Brazilian GH after 30th June 2000**, it would fall within the temporal scope of the Rules and warrant a SisGen registration (Article 37 of Law 13.123/2015)8.

Under Brazilian legislation, **specimens and information found in overseas collections** are to be considered as Brazilian GH, even if originating from organisms collected in the (distant) past, as long as access (research and/or technological development) activities are carried out after 30th June 2000. Therefore, all GH information and its physical counterparts, including any microorganism isolated from substrates originating from Brazil, whether held in Brazil or in (private or public) collections outside Brazilian national territory, would be considered in scope of the Brazilian ABS Rules.

EXAMPLE

Beetle specimens collected in a primary forest in Brazil in 1952 and conserved in a Natural History Museum abroad would be considered Brazilian genetic heritage.

8. This date is the date of entry into force of the Provisional Measure 2.186/2001, which was abrogated by the current Brazilian ABS Rules.

# ACCESS AS RESEARCH

**Prior informed consent** is needed for access to associated traditional knowledge, (Article 9 of Law 13.123/2015), but there is no need for any administrative procedure prior to other access activities on and with carried out on Brazilian GH (Article 12, § 2 of Law 13.123/2015).

The acquisition of **GH samples *in situ*** may require the prior obtention of an authorisation in certain cases (see Chico Mendes Institute for Biodiversity Conservation ICMBio Normative Instruction no 03/14 for further information). When the physical collection or sampling is carried out by foreign entities in sovereign Brazilian territory (including its territorial sea and continental shelf) for research purposes, a specific request ought to be made within the National Council for Scientific and Technological Development – CNPq. These administrative procedures are not linked to SisGen, which does not function as a checkpoint for compliance to these requirements, but the user shall comply with them before the acquisition of the GH.

Law 13.123/2015, Art. 2

VIII – access to genetic heritage – research or technological development carried out on genetic heritage samples''

IX- access to associated traditional knowledge – research or technological development carried out on traditional knowledge associated to genetic heritage that makes possible or facilitates access to genetic heritage, even if obtained from secondary sources such as: street markets, publications, inventories, films, scientific articles, registries and other forms of systematization and record of associated traditional knowledge;

X – research – experimental or theoretical activity carried out on genetic heritage or associated traditional knowledge with the objective of building new knowledge by means of a systematic process that creates and tests hypothesis, describes and interprets fundamentals of observed phenomena and facts;

Brazilian ABS Rules concern **all types of research, whether experimental or theoretical, conducted on Brazilian GH, without exception** (Article 2, X and XI of Law 13.123/2015). Even if basic research activities relying on GH information (found in physical or digital formats) would fall within the definition of ''access'' under Brazilian ABS Rules, a number of research activities have been exempted from SisGen registration obligations, while a simplified procedure has been established for other basic research activities. Access rules apply to phylogeny, taxonomy, systematics, ecology, biogeography and epidemiology, with a **simplified registration** procedure detailed in CGen Resolution no. 10, dated as of 03rd August 2018.

Furthermore, some activities and tests are considered out of scope of the Rules or **exempt** from access registration and other obligations:

- ''DNA analysis and other molecular analysis aimed at identifying a species or specimen, diagnostic tests and clinical examinations for the direct or indirect identification of etiological agents or hereditary pathologies in an individual; physical, chemical and physicochemical characterization for the determination of the nutritional information of foods'' (Article 107 of Decree 8.772/2016).

- When they are ''not an integral part of research and development'', ''(1) technical reports that include inventory, survey or monitoring of genetic heritage, for the purposes of environmental licensing, assessment of potential for exploitation of natural resources or actions for environmental restoration and restoration of degraded areas; (2) identification or confirmation of the taxonomic identification of genetic heritage to be incorporated into the collection of an ex situ collection; (3) physical, chemical, physicochemical or biochemical characterization of extracts, waxes, butters and oils; (4) quality control tests of products derived from access to genetic heritage or associated traditional knowledge, as well as proficiency tests performed in laboratories; and (5) tests that use genetic heritage exclusively as target organisms'' would not be considered as access to genetic heritage under Brazilian ABS Rules (CGen Technical Guidance, no. 9 of 18th September 2018).

EXAMPLE

DNA barcoding carried out in 2016 linked to beetle specimens collected in a primary forest in Brazil in 1952 and conserved in a Natural History Museum abroad would not require a SisGen access registration on its own. However, if the barcoding efforts are part of a larger research project that goes beyond the identification of a species or specimen (or the other exceptions listed in corresponding articles 107 of the Decree 8.772/2016, and Technical Guidance no.9, 2018), then it would require a SisGen registration at any of the trigger points that will be mentioned below.

## PROCEDURAL TRIGGERS

Even though the Brazilian ABS Rules have quite a comprehensive view of ''access to genetic heritage'', research and technological development is viewed as a continuum where SisGen access registration is required only at specific trigger points, as opposed to the start of the research and/or technological development activities themselves. A number of activities cannot occur before SisGen registration has been made. These strict trigger points, which will be detailed below, are the shipment of genetic heritage, the commercialisation of an intermediate product, the request of intellectual property rights, the publication of access activity results, and the notification of a finished product or reproductive material. Only the sending of samples, as opposed to their shipment, may be registered after it has occurred in practice.

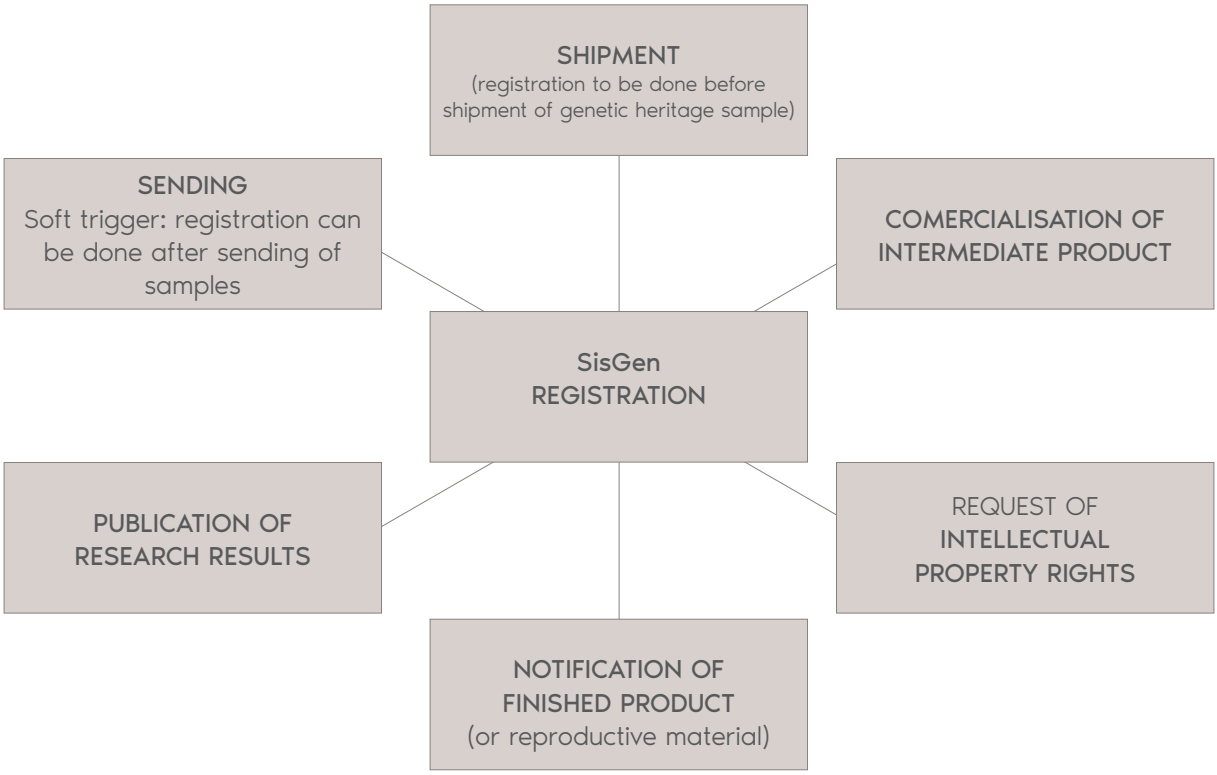
The legal entity or the Brazilian natural person submitting the SisGen registration needs to indicate whether the access concerns GH and/or traditional knowledge associated with GH, the exact type of GH along with its scientific genus, name, (although the system can accommodate for unidentified specimens) indicating whether it concerns a local or creole variety or breed, and also the source of the genetic heritage, whether obtained in situ, ex situ, *in silico*, or through an intermediate product.

SisGen will automatically issue a receipt that proves the submission of requested information, which allows the entity to carry out the activity for which a registration or a notification has been asked for (i.e. publication of research results, sending, shipment, any

intellectual property right application or patent grant, commercialisation of intermediate product or economic exploitation of finished product or and reproductive material).

Upon request of the user, CGen may issue a Certificate of Access Regularity (''CAR''), whereby CGen declares compliance with Brazilian ABS Rules for the purpose of the registered access activity (but not for the notification of finished product (Art 2, XXII, Law 13.123/2015 and Art. 42, Decree 8.772/2016). This Certificate could potentially be used by regulatory authorities of States operating ABS compliance controls over entities having accessed Brazilian GH.

## Trigger Points




Trigger points for SisGen access registration

## Sending or Shipment of Samples

**Sending of GH** is the movement of samples for the provision of services abroad as part of research or technological development, for example for sequencing or identification, where the liability for ABS compliance is not transferred to the recipient but remains with the entity that performs the access in Brazil (Article 2 § XXX of Law 13.123/2015). In these cases, the signature of a Material Transfer Agreement (''MTA'') is not required but a legal document addressing the specific use of GH and the prohibition of third-party transfers is sent together with the samples. The sending of GH can be viewed as a softer trigger point for SisGen registration, since the actual sending can occur before the registration itself, which is not the case for the other trigger points. It should be noted that the ''sending of samples'' is always part of an access activity, therefore its registration can occur after the ''sending of samples'' itself, but not after any of the other access activity registration trigger points.

**Shipment of GH** is the transfer, (only from Brazil to abroad,) of samples with the intent of access, where the responsibility for the sample (including further ABS compliance) is transferred to the recipient institution with the obligation to continue the chain of information and liability to third party users (Article 2, XIII of Law 13.123/2015). As opposed to sending, the shipment of GH requires a SisGen registration before the shipment itself and is made through a specific form in the system. Shipment requires the signature of a Material Transfer Agreement – MTA:

- The contract ought at minima to address ownership, liability, third party uses and applicable law in dispute resolution (Article 6 of Law 13.123/2015, and Article 25 of Decree 8.772/2016). The MTA model approved by CGen, which is understood by CGen as a ''minimum required content'', can be found in CGen Resolution no.12 of 18th September 2018[9], with an English version of the MTA model.
    - According to Article 2, sole paragraph of the CGen Resolution no.12, 2018, ''Additional clauses of specific interest to the sender or to the recipient'', may be included as attachments to the MTA, provided they do not conflict with the provisions of this Resolution or any other applicable law.

9. An English version of the model MTA can be found at https://www.mma.gov.br/images/arquivo/80043/resolucoes/Resolution_12_TTM_english_version_nova.pdf

- CGen Resolution no. 12, 2018 explicitly recognises the possibility to sign a single MTA between two institutions concerning multiple GH samples, for a period of maximum ten years, which may be renewed, characterising regular institutional cooperation in biodiversity science.

    - A SisGen registration would have to be made for each sample prior to its shipment, including a "Shipment Invoice" with an identification of the sample, information on its origin, the intended use of the samples, allowing or not for a further change of intent, that may require an authorisation of the sender.

    - Transfer of samples under a Shipment Invoice to third parties can be allowed, but in such case, the initial MTA signed between the institutions becomes viral, as all subsequent recipients down the chain are required to "sign a new MTA containing all the terms of this MTA, including the Shipment Invoice identifying the samples, in accordance to the standard document ratified by the CGen", and CGen is notified by email of the new MTA and its accompanying Shipment Invoice.

    - All samples submitted through shipment registrations relating to a single long-term MTA remain valid even at the end of the MTA validity period, notwithstanding whether the MTA is reconducted, or is terminated. Users engaging in research and technological development on the Brazilian GH covered by those shipment registrations or invoices would need to register their research or technological development activities "access", whether it occurs within or outside the MTA validity period.

## Publication of Research Results

Another important trigger point is the publication of research results, understood as a disclosure or release of results, whether partial or final, in scientific or communication circles, including the written publication of any research data or its presentation in symposium or conferences.



## Request of Intellectual Property Rights

Access registration in SisGen must be done prior to the request of any type of intellectual property rights resulting from access to GH or ATK, in Brazil or abroad (Article 12 of Law 13.123/2015 and Article 20, §1, II of Decree 8.772/2016). The Brazilian patent authority (National Institute of Industrial Property - INPI) requires a proof of access registration in the application of intellectual property process involving GH and/or ATK.

## Intermediate product

An intermediate product is defined as ''a product used in the production chain as an input, excipient or raw material for the development of another intermediate or a finished product'' Article 2, XVII of Law 13.123/2015.

SisGen registration needs to be done before the commercialisation of intermediate products based on genetic heritage. To the contrary of finished products, there is no legal threshold regarding the contribution of Brazilian GH to such a product.

EXAMPLE

An enzyme discovered on Brazilian genetic material, whose utility in washing powder development has been identified (and patented) would be considered an intermediate product, the commercialisation of which would trigger an access registration (but not benefit-sharing obligations). In this case, the washing powder developed with the enzyme would rather be considered a finished product, provided the formal thresholds of the Brazilian ABS Rules are met.

## Finished Product

The ''economic exploitation of a finished product or reproductive material'' not only has to be notified to SisGen, it is also the (only) trigger of benefit sharing obligations under Brazilian ABS Rules. In order to trigger the obligation under the Brazilian ABS Rules, a finished product should not require any additional processing, being ready to be used by the final consumer, and to have been developed with Brazilian GH or ATK, which ''must be

one of the key main element of value adding to the product'' (Article 17 Law 13.123/2015). SisGen notification needs to be done prior to the issue of the first bill of sale.

- Two thresholds determine whether **Brazilian GH is the ''value-adding''** element to the finished product: GH or ATK needs to contribute to the product's functional characteristics or be crucial to its marketing appeal (Article 2, XVIII of Law 13.123/2015):

    - Functional characteristics are those ''that determine the main purposes, enhance the product action or broaden its range of purposes''. The use of GH, exclusively as excipients, vehicles or other inert substances, which do not determine functionality shall not be considered determinant for the existence of functional characteristics, just as the substance originating from the metabolism of a microorganism shall not be considered [in scope] when it is identical to the substance of fossil origin already used and used instead. (Article 43, §§ 3 and 5 of Decree 8.772/2016)

    - The contribution of GH or ATK to the product's marketing appeal means that there is reference to GH or ATK, its origin or the differentials arising therefrom, related to a product, product line or brand, in any visual or audio media, including marketing or highlighting campaigns or the product label. (Article 43 § 3, of Decree 8.772/2016)

- Recognizing that the distinction and interpretation of these thresholds could prove challenging when faced with products based on multiple components, or in certain sectors, CGen has already adopted a number of Technical Guidances providing for specific **sectoral interpretation** of this crucial criteria, which trigger benefit-sharing obligations under the Brazilian ABS Rules:

    - For the personal hygiene, perfumery and cosmetics sector : the use of GH when used exclusively for the structuring of the formula will not be considered determinant for the existence of functional characteristics, being responsible for stability, consistency or physical appearance, which do not determine functionality'' (CGen Technical Guidance no.2, dated as of 28th June 2017)

    - As for the fragrance sector, ''main elements of added value to the product'' are considered as ingredients derived from access to GH that determine the

predominant olfactory family of the fragrance used in the finished product, when the purpose of the GH in the formula is solely for the formation of its smell'' (CGen Technical Guidance no.6, dated as of 20th June 2018).

The modalities of benefit-sharing ought to be indicated at the time of SisGen notification of economic exploitation of a finished product falling within the criteria of Brazilian ABS Rules:

- Non-monetary benefit-sharing initiatives, in some cases, need to be equivalent to 75% of monetary benefit-sharing amounts, i.e. for projects aiming at the conservation and sustainable use of biodiversity, providing training opportunities, or ensuring free distribution of products in programmes of social interest; Article 22 of Law 13.123/2015).

- Monetary benefit sharing operates through clear and fixed thresholds: either the payment of 1% of the annual net revenue obtained from the economic exploitation of said product (Article 20 of Law 13.123/2015), or the diminished rate fixed by a sectoral agreement recognised by the Federal Government of Brazil, which can be as low as 0,1 % of the total net revenue obtained from economic exploration (Article 21 of Law 13.123 / 2015).All payments done as a result of economic exploitation of a finished product or plant reproductive material are deposited in the National Benefit Sharing Fund (FNRB), which is established for the valorisation and the promotion of sustainable use of GH and ATK.

EXAMPLE

A shower cream developed using Brazilian nut oil, as well as its extract derived from nuts acquired and accessed in Brazil, labelled and sold as ''Brazilian Nut Cream'' would be considered a finished product, the commercialisation of which would trigger a SisGen access registration and notification, and the signature of a benefit-sharing agreement with Brazilian authorities and/or ATK holders, if applicable.

## Distinction between an intermediate and finished product

Even in the presence of defined thresholds and guidelines that help to differentiate between an intermediate and a finished product, practical difficulties do remain when

it comes to determine which procedure to follow when a single product is marketed as a final product for a specific value chain, without knowing whether, how, and when it would or could lead to the development of another finished product.

EXAMPLE

Patented ATP kits developed on the basis of access to Brazilian genetic heritage, and used in the development of medicine in the pharmaceutical sector, could be viewed as intermediate products in the value chain leading to the development of such medicine (then leading solely to an access registration for the commercialisation of the ATP Kits). However, since the final consumer of the ATP kits, which could be a natural or a legal person, would be the researcher or product developer using it as a tool in its research and technological development process, the ATP kits would rather need to be viewed as a finished product, provided that Brazilian genetic heritage's added value to the finished product is crucial for the existence of the product's functional characteristics or its marketing appeal. A SisGen product development notification would be required in this case by the ATP kit developer next to the access registration. The medicine developer would need to file an access registration with SisGen, and a product notification if Brazilian genetic heritage's added value to the finished product is crucial for the existence of the product's functional characteristics or its marketing appeal, which is unlikely to be the case if the ATP Kits are the only tool where Brazilian genetic heritage would be found.

Some elements might be useful in the evaluation of a particular product's legal status under Brazilian ABS Rules:

- Faced with the combination of two value chains, a prevalent ''business to consumer'' value chain, and a parallel ''business to business'' chain (for example like cocoa butter sold in pharmacy as a cosmetic product to be used by individuals, but also sourced to food processing businesses for use in the manufacturing of another product in the food industry), those accessing GH would need to distinguish between the two value chains, ensuring the notification of a finished product in the ''business to consumer'' value chain (provided Brazilian GH is a main value-adding element to the product, or to its marketing appeal), and maintaining the

access registration for the "business to business" value chain, if the product is to be defined as an intermediate product under Brazilian ABS Rules.

- As a rule, a product would be viewed as intermediate if the full commercial product development chain is not finished, and if it does not reach the final consumer, whether a natural or legal person.

## Obligation for foreign researchers to enter into a partnership with Brazilian entity

- Only Brazilian nationals (whether natural or legal persons) are allowed to register access activities on SisGen. Foreign entities thus need to enter into a **partnership with a Brazilian institution** to carry out their procedural obligations for access registration and/or finished product notification.

- An additional remaining point of uncertainty relates to the **exact moment at which a foreign entity needs to enter into such a partnership**, whether at the start of access activities themselves, or before the access registration trigger point.

    - At the moment of writing, this issue was being debated within the CGen Academia Sectoral Chamber, which should bring clarity on the articulation of the two obligations (i.e. association with a Brazilian national at point of access in the sense of research, and registration of this access activity at a specific trigger point) not to hamper the generation and publication of knowledge on Brazilian biodiversity.

# III. PRACTICAL CONSIDERATIONS REGARDING ACCESS TO *IN SILICO* GENETIC HERITAGE

The inclusion of genetic information sourced *in silico* within the Brazilian ABS Rules is undisputed in the national legal framework, confirmed by the fact that out of 51,162 access activities registered in SisGen, 530 declared that the genetic heritage was obtained *in silico*[10]. However, a number of questions remain with regards to the scope and limits of such inclusion, especially outside of Brazilian sovereign territory, considering the dominant practice of data generation and use worldwide. The project presented an extensive opportunity to dialogue about the types of information that fall under the Brazilian notion of genetic heritage, including *in silico* genetic heritage, how such information moves around the globe, and how it is used in different sectors, as well as about aspects of the governance structures surrounding the Brazilian ABS Rules, bringing procedural and legal clarifications, and highlighting the practical implications of the inclusion of *in silico* genetic heritage in Brazilian ABS Rules.

## NOTION OF *IN SILICO* GENETIC HERITAGE

### An integral part of the broad notion of GH

The notion of *in silico* GH appears in the Brazilian ABS Rules in the provisions that relate to the different sources of GH, that ought to be indicated in the SisGen registration form.

10. These figures were used in the presentation by the Brazilian Ministry of Environment during the Brasilia project workshop, as an update to those cited in Brazil's submission to the Convention on Biological Diversity (Brazil Position on Digital Sequence Information, Notification 2019-012, available at https://www.cbd.int/abs/DSI-views/2019/Brazil-DSI.pdfhttps://www.cbd.int/abs/DSI-views/2019/Brazil-DSI.pdf

Decree 8.722/2016, Art. 22

"For the registration of access to genetic heritage or associated traditional knowledge, the national individual or legal person shall fill in the SisGen electronic form which will require: [...]

1. Source of genetic heritage, including georeferenced coordinates in the degree, minutes and seconds format, "in situ" locality (even if they were obtained in "ex situ" or "*in silico*" sources)"

- Genetic information found in digital format or accessed through "*in silico*" sources, is thus in the Brazilian ABS Rules not merely a product of research and development, it forms an integral part of the notion of GH. "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 fulfilment of [access and benefit-sharing obligations][11].

- The limits of *in silico* GH are thus set by the limits of the notion of GH itself, i.e. "all types of "genetic information from plants, animals, and microbial species, or any other species, including substances originating from the metabolism of these living organisms" (Article 2, Law 13.123/2015).

- Genetic heritage found *in silico* thus designates any genetic information from plants, animals, and microbial species, or any other species, including substances originating from the metabolism of these living organisms, which originated from Brazilian national territory (or from Brazilian substrates in the case of microorganisms), obtained through computational biology and simulations, and/or stored in a computer environment.

11. Ministry of Foreign Affairs of Brazil- Environment Division, submission to the Secretariat of the Convention on Biological Diversity following Notification 2017-37, in response to COP Decision XIII/16 on the submission of views and relevant information on any potential implications of the use of DSI on genetic resources for the three objectives of the Convention, available at https://www.cbd.int/abs/DSI-views/Brazil-DSI.pdf

## What could this mean in practical terms?

Although there is no officially accepted definition of the exact scope of Brazilian notion of genetic heritage information, especially when sourced *in silico*, some guidance can be given on the basis of existing SisGen access registrations and/or finished product notifications. It is understood that under Brazilian ABS Rules, both the presentation and description of nucleic acid molecules, as well as all aggregate information and associated data found in *in silico* forms could all be considered as *in silico* GH:

- Nucleotide data, metabolites, protein data, 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, etc).

- Considering the lack of direct reference to sequence information in the notion itself of ''genetic heritage'', information found *in silico* which corresponds to sequence associated metadata (e.g. 'passport' data, phenome-genome data, etc), or other types of information held in computer storage might all potentially be considered as genetic heritage.

EXAMPLE

An actual illustration of *in silico* GH which includes a commercial exploitation intention, stemming from the SisGen system itself is '' the application of PnPP19 peptide synthesized rationally from PnTx2-6 toxin from the venom of the Brazilian Armadeira spider (Phoneutria nigriventer) as a new candidate for the treatment of erectile dysfunction'', which cites the *in silico* source of genetic heritage as the Uniprot database.

# IMPLEMENTATION OF ACCESS RULES TO *IN SILICO* GENETIC HERITAGE

## Trigger of Access registration for *in silico* GH

Given the wide scope of the notion of access as research under Brazilian ABS Rules, and the broad notion of genetic heritage held in computer storage, but also the distinctive features and wide sources of *in silico* genetic information, some guidance and clarity has been given with regards to the implementation of the different access registration **trigger points** under Brazilian ABS Rules.

## Reading or Consultation of GH *in silico*

> Decree 8.722/2016, Art. 107
>
> The following tests, exams and activities, when not an integral part of research or technological development, do not configure access to genetic heritage as referred to in Law No. 13,123, 2015: VI - Comparison and extraction of genetic origin information available in national and international databases
>
> Sole paragraph. Does not configure access to genetic heritage the reading or querying of information on genetic origin available in national and international databases, even though they are an integral part of research and technological development.

- Although they are an integral part of research and technological development, **reading or consulting genetic information** available in national or international databases, is not considered access in accordance to Brazilian ABS Rules, and would thus not trigger a SisGen registration.

- The **comparison or extraction of genetic information** from national or international databases is not considered access in Brazilian ABS Rules, if not part of research

or technological development. Even if such actions were to be part of a research and technological development process, they would not require a SisGen access registration unless they include the aforementioned access triggering events (i.e. shipment, publication of research results, request of intellectual property rights, etc..).

- It is thus safe to say that the **consultation or download** of genetic information in digital format would not lead to an access registration under Brazilian ABS Rules.

EXAMPLE

Performing a search in a database, even when comparative in nature, through the use of BLAST tools for instance, would not necessitate registration, unless it leads to formal access registration trigger points (i.e. the publication or disclosure of research results, the development of an intermediate or final product, or the application for any of intellectual property rights,..).

## Transfer of GH *in silico*

CGEN TECHNICAL GUIDANCE NO.8

''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''.

- The **transfer** of GH information would not trigger an access registration either, as the action is not listed as a triggering event, and as it has been further detailed in **CGen Technical Guidance no.8**. An exchange of emails containing GH information would thus not trigger a SisGen registration. A review of the Guidance is nonetheless being considered at the time of writing.

## Upload of GH *in silico*

- Different scenarios ought to be identified with regards to the **upload** of GH information to a database or another *in silico* platform. The underlying principle is that such upload would not trigger an access registration with SisGen, unless it constitutes the publication of the access activity results:

    - The upload of GH information on a database, when triggered by a written scientific publication would unquestionably require a prior SisGen registration.

    - The upload of information solely on a private database internal to the research and technological development institution (without written publication of research results) would not require a SisGen registration.

    - However, uncertainties remain regarding the obligations that would accompany an upload of GH information on public databases that would not have been triggered by a more formal publication of research results in a scientific article for example.

## Access registration formalities for *in silico* GH

When the use of GH falls within the scope of access in the sense of Brazilian Rules and requires a SisGen registration, the system contains **specific fields to be filled in by users** regarding the identification of the *in silico* 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.

# MONITORING ACCESS TO *IN SILICO* GENETIC HERITAGE

## Key sectoral considerations on the production and publication of digital sequence data

Data that can be considered within the definition of *in silico* GH is generated by a wide range of scientists, can be found in varied sources (which remain highly interconnected in the case of digital sequence data), and is transferred globally at a very large speed and scale.

- **A wide range of scientific disciplines** generate data that could be considered within the notion of *in silico* GH. The publication of this data in journals or monographs is a mandatory condition for the receipt of research grants and academic positions, while the uploading of digital sequence data into databases is required by journals, often time also the funding agencies.

- A **diverse yet interconnected landscape of databases** holds potential GH information in computer storage:

    - Estimated gigantic volume of 1.500 publicly accessible databases, of very different sizes, focus and data use policies, but that generally strive for the easy availability of free data on the building blocks of life.

    - The information gathered in these public databases, whether comprehensive or specialised, ranges from sequence data on nucleic acids, model organisms, RNA types, and known proteins.

    - The International Nucleotide Sequence Database Collaboration (''INSDC''), plays a central role in the global data infrastructure : ''95% (705 out of 743) of nucleotide sequence data databases directly link to or download data from the INSDC [and] the remaining 5% of databases allow direct submissions, but [...] require the use of Accession Numbers, which are generated by the INSDC''

(2019 CBD Study on Traceability and Databases)[12]; the INSDC is based on free and open access to data, without user registration requirements.

- The bulk of data transfer is not operated manually, but rather automatically and programmatically, at quite a large scale.

- There is no link with ABS requirements or information within most of the digital sequence databases and other potential sources of *in silico* GH.

**The presence and accuracy of ABS information in** ***in silico*** **GH sources** would need to be greater to ensure better implementation of the Brazilian ABS Rules, and higher user awareness levels with regards to their obligations under this set of national rules:

- **ABS disclaimers in databases** could be a possible path forward, which would involve the inclusion of ABS requirements in the existing database system, whether through a mandatory country tag or a provision of link to articles, publications, or a system providing ABS information. However, some consider the **database systems to be outside of ABS information chains**, necessitating the development of different tools to gather ABS related information on genetic heritage found *in silico*.

- **Practical issues** with regards to the implementation of ABS-related obligations within the database systems include the fact that they would, pose challenges with regards to:

  - the interoperability of data (information linked to the Internationally Recognised Certificate of Compliance (''IRCC'') is for instance currently not completely transferrable into Information Technology infrastructures because of the written format and lack of coding of the certificates' substantial contents, while many countries currently do not issue such IRCCs, and there is no requirement under the Nagoya Protocol to include all elements of PIC and MAT in the IRCC), ;

  - data accuracy problems, as the databases would not be in positions to check the accuracy of uploaded ABS information;

  - governance problems due to the fact that ABS information would be needed solely for a limited set of data uploaded to databases; and

12. This study can be accessed at: https://www.cbd.int/abs/DSI-peer/Study-Traceability-databases.pdf

- avoidance practices of users that could potentially get genetic heritage information with no direct link made to its Brazilian origins for example.

- Any parallel system that would be hypothetically developed for ABS in the digital world would thus definitely need to take into account technical inter-operability issues vis-à-vis nucleotide sequence databases, as currently done with oceanographic datasets that are linked up to such databases, but operate outside of the bio-informatics realm.

**Practical challenges** relating to the regulation of *in silico* GH access also come from the common practice of accessing multiple sequences from different origins or the existing possibilities to access the same sequence from multiple origins, which is especially common in the case of **"highly conserved sequences"** related to universal biological functions for example.

- Bilateral ABS regimes show their limits in dealing with such cases, and that discussions at the international level regarding digital sequence information would be important to bring workable solutions for users and public authorities.

There is a fundamental need for targeted trainings, in order to **raise awareness-levels** of both uploaders and downloaders of *in silico* GH information, considering that these actors are often different than those usual users of genetic resources, who have grown more accustomed to the ABS paradigm. Trainings on minimum information that ought to be uploaded; with the possible involvement of grant donors and funders, could prove highly beneficial to ensure the flow of more accurate and complete *in silico* GH information.

## Existing Compliance Tools in Brazilian ABS Rules

In case of non-compliance, a "notice of infraction" will be drawn up by authorities according to Decree 6514/2008, while powers to supervise and verify the existence of administrative offences are expressly given to Ibama, the Naval Command, and the Ministry of Agriculture and other supervisory agencies by Decree 8772/2016 (Article 93). The supervisory bodies may, at any time, promote a complete inspection in the companies, evaluating the entire product portfolio, as well as evaluating scientific publications, media in general, among others. Thus, in case of inspection, the user must

present the access registration receipt to demonstrate compliance with Brazilian ABS Rules, or other supporting documents, attesting the regularity of access to the Brazilian genetic heritage. If the user has no means of attesting compliance with the SisGen registration requirements, it may be reported. A quite significant list of sanctions is envisaged in both the Law 13.123 and Decree 8772 in case of non-compliance, most of them relating to the lack of proper SisGen registration.

Additional avenues are also considered to ensure greater user compliance with Brazilian ABS Rules: these include model contractual terms and the involvement of product authorisation authorities. In this context, the Brazilian Patent Authority (INPI), has a central role in ABS Compliance in Brazil, as it is established as a formal checkpoint for the declaration of origin. Furthermore, CGen has a strong statutory empowerment that allows the institution to ask for information to any authority involved in product authorization procedures in Brazil.

## Implementation of Brazilian ABS Rules beyond national territorial borders

**Compliance monitoring** possibilities of Brazilian authorities remain limited, especially if the patenting and commercialisation take place outside of Brazilian territory:

- The launch of civil litigation procedures abroad based on the application of private international law principles and national civil law, the adoption of soft measures like best practices, awareness-raising, education and training activities, resource-heavy checks of publications, awareness raising activities carried out by EU ABS authorities (on their own accord and without a legal obligation to do so) could potentially have beneficial side-effects to ensure better knowledge of Brazilian ABS Rules by European users.

- The full breadth of ABS compliance rules adopted in foreign countries (such as the EU and its Member States, Japan, or Switzerland) would not enter into play, as Brazil is not a party to the Nagoya Protocol. It should be carefully noted that, even if such ratification would take place in the future, the EU ABS Compliance rules would only apply when *in silico* GH is combined with research on the same biochemistry (subject of the *in silico* GH) on the physical genetic resources themselves, or when *in silico* GH is generated from physical genetic resources in the project. Access to and use of nucleotide data from a database would neither trigger due diligence obligations for users in the EU, nor a control by EU ABS authorities.

# IV. CONCLUSIONS

## LEGAL CERTAINTY AND FLEXIBILITY THROUGH THE CGEN STRUCTURE AND THE SISGEN SYSTEM

### Legal Certainty: a simpler system built on trust with specific registration trigger points

- The new Brazilian ABS Rules, and their unique governance structure, centralised around the Executive Secretariat of the Genetic Heritage Management Council (*Conselho de Gestão do Patrimônio Genético* – CGen), established under the auspices of the Brazilian Ministry of Environment, have brought about greater legal certainty and simpler obligations for users of Brazilian GH, compared to the provisional regime applicable prior to 2015.

- On account of a user-friendly ABS Electronic Registry, coined with the implementation of the National System of Genetic Heritage and Associated Traditional Knowledge Management (*Sistema Nacional de Gestão do Patrimônio Genético e do Conhecimento Tradicional Associado* – SisGen), most of the procedural bottlenecks experienced under the past ABS regime have been replaced by a unique system built on trust, where registration with the system is required at precise trigger points, centered at the end of the research and technological development process.

    - Access to GH is defined as research and technological development on GH, without exceptions, whether experimental, theoretical or practical. However, research in phylogeny, taxonomy, systematics, ecology, biogeography and epidemiology benefit from a simplified SisGen registration procedure, while a limited number of specific activities within these disciplines do not require a formal access registration (listed in Article 107 of the Decree and CGen Technical Guidance, no. 9).

    - However, the in situ acquisition of samples, in certain cases, may require a specific permit outside of the SisGen system (see Chico Mendes Institute for Biodiversity Conservation - ICMBio - Normative Instruction no. 03/14 for further information).

- The trigger points for SisGen access registration are defined as the shipment of GH, the publication of research results, the claim of intellectual property rights, the commercialisation of an intermediate product, or the notification of a finished product or reproductive material developed as result of the access. The sending of GH samples is a softer trigger point for access registration, since such registration can be done after the sending of the samples, contrary to the other trigger points, where SisGen registration needs to be done before the triggering event. It should be noted that the "sending of samples" is always part of an access activity, therefore its registration can occur after the "sending of samples" itself, but not after any of the other access activity registration trigger points.

- A benefit-sharing agreement is only required when an entity develops a finished product or reproductive material, which needs to be notified to SisGen prior to the issue of the first bill of sale. Brazilian GH needs to be a key element adding value to the finished product to trigger obligations under the Brazilian ABS Rules.

- Only Brazilian nationals (whether natural or legal persons) are allowed to register access activities on SisGen, which means that foreign entities need to enter into a partnership with a Brazilian institution (public or private) to carry out their procedural obligations. An automatic partnership with the Brazilian Institute of Information in Science and Technology (IBICT) or another Brazilian institution is being envisaged to ease the administrative burden that this obligation represents, but it is not yet implemented. An additional remaining point of uncertainty relates to the exact moment at which a foreign entity needs to enter into such a partnership: at the start of access in the sense of research and technological development, or at the registration trigger point.

## Flexibility: a double-edged sword

- The Brazilian ABS Rules are surrounded by **flexible governance structures**, with a unique master architect, CGen, which oversees the entire system, but also has considerable regulatory powers, adopting Resolutions and Technical Guidances, which can be used to bring further clarifications to the Brazilian ABS Rules, and also interpret them in a rapidly changing technological context.

- This flexibility also means that users need to go through a quite **sizeable amount of information scattered in different places.** A centralisation of all applicable rules would be beneficial to ensure full legal certainty for users.

- **Foreign users also face linguistic difficulties**, as even when they manage to gain access to the official texts, these are only published in Portuguese. Availability of information and reports in English on the exact content and implementing practice of Brazilian ABS Rules is therefore paramount to achieving higher awareness levels, and thus better compliance.

## PRACTICALITIES OF ADDRESSING *IN SILICO* GENETIC HERITAGE

- Brazilian ABS Rules govern access (in the sense of research and technological development rather than acquisition) to GH, defined as **genetic information** (and not genetic resources). As a result, the notion of Brazilian GH also extends to information held in computer storage or simply found in the digital realm, i.e. accessed from *in silico* sources, as mentioned in Decree no. 8772/2016 (Article 22).

- The **consultation and/or download of** *in silico* **GH** does not trigger a SisGen access registration, even if it may constitute the first stages of research in the sense of the Brazilian ABS Rules (Decree 8772/2016, Article 107). The **transfer of *in silico* GH** to another user is also currently not viewed as a trigger for access registration as such, although the applicable CGen Technical Guidance no.8, 2018, is under revision. When an **upload** of *in silico* GH is triggered by a formal publication of research results, such upload would trigger a SisGen registration, but uncertainties do remain when it is not the case.

- The regulation of access to *in silico* GH faces **noticeable practical limits**, especially in the face of the important volume of data that is put online and used by a wide range of actors around the globe, the prominence of highly-conserved sequences, lack of ABS information data and awareness of ABS obligations by users operating in a highly connected world, the thorny issue of products developed using multiple *in silico* (or digital) genetic information, and a general lack of awareness about ABS by data users (as opposed to genetic resources users).



# V. WAY FORWARD

## REMAINING BOTTLENECKS

- Uncertainties remain regarding the practical frontiers of the notion of Brazilian genetic heritage sourced *in silico* in the absence of a dedicated official document, whether a CGen Resolution or other useful documentation, outlining the range of genetic information covered by the Brazilian ABS Rules. Addressing this uncertainty is particularly important with regards to the wide range of information and data associated to organisms originating from Brazil held in computer storage.

- Additional sectoral guidance was requested for the articulation of obligations for foreign researchers engaged in activities considered as ''access'' before the different official registration trigger points, as well as for the distinction between intermediate and finished product in different sectors, building on the work already done by CGen and the Sectoral and Technical Chambers.

- The consequences of a transfer of *in silico* GH information, which today does not trigger access registration but remain uncertain since a revision of the regulatory interpretation is being discussed within CGen at the time of writing.

- The Brazilian ABS Rules' flexible governance structure leads to a considerable scattering of useful (and sometimes crucial) information on the scope and implementation of Brazilian ABS Rules, making it very difficult to navigate for users, especially foreign ones.

# AVENUES FOR FURTHER WORK

## Centralised information about Brazilian ABS Rules

- Centralisation of all issued Guidance and Recommendations on the Law and the Decree in one reference website
- Uploading of useful commentary documents like the Sector Dialogue Reports to ABS CH
- English translation of Decree 8772, CGen's Resolutions and Technical Guidances

## Education, training & awareness raising

- Brazilian ABS Rules are designed for a simple and accurate chain of information flow, where all users know their obligations and comply with them voluntarily, which could very easily be challenged by practical sectoral realities. This led participants to the conclusion that although the Brazilian ABS rules have explicit sanctions for non-compliance, the system viewed access activities as a continuum and relied on trust and on the users' willingness to participate, stressing the necessity for awareness-raising, education and training.
- For Brazilian ABS Rules to truly be operational, there is a clear need to explore feasible and practical tools to improve ABS functionality of the different *in silico* sources of GH information, as well as a clear need to develop trainings on the concept of ABS itself for data users, which are different than physical resource users, who are getting accustomed to ABS principles. It was also clear from the workshop that any tool developed in these directions would need to take into account the customary practices of scientists who both upload and use the data, and the scientific developments that are epitomized by the exponential growth in the number of sequences that can be part of a single research question, and that can be downloaded speedily.



## Case for multilateralism

- The need for global or multilateral solutions for a coherent regulation of access to *in silico* GH when faced with the scale of global data exchange, as well as the high proportion of highly conserved data, which would trigger avoidance of data where the link with Brazilian ABS Rules has been clearly acknowledged in the discussions, just as the obvious limits of national compliance measures in an interconnected and interdependent digital realm (as the limits of implementing Brazilian ABS Rules outside territorial borders are more significant when faced with *in silico* GH).

- The ratification of the Nagoya Protocol could allow Brazilian authorities to partially rely on user compliance measures adopted in different legal orders, and notably the comprehensive EU ABS compliance measures, provided nonetheless that the organisms are considered as Brazilian GH by EU national authorities and provided that the research on the *in silico* GH is combined with research on the subject of the *in silico* data on the physical genetic resources themselves.

# ANNEXES

Brazilian Law 13.123/2015 (translation made available on ABSCH)

Brazilian Decree 8772/2016 (courtesy translation)

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