Dialogues
EUROPEAN UNION · BRAZIL

European Union

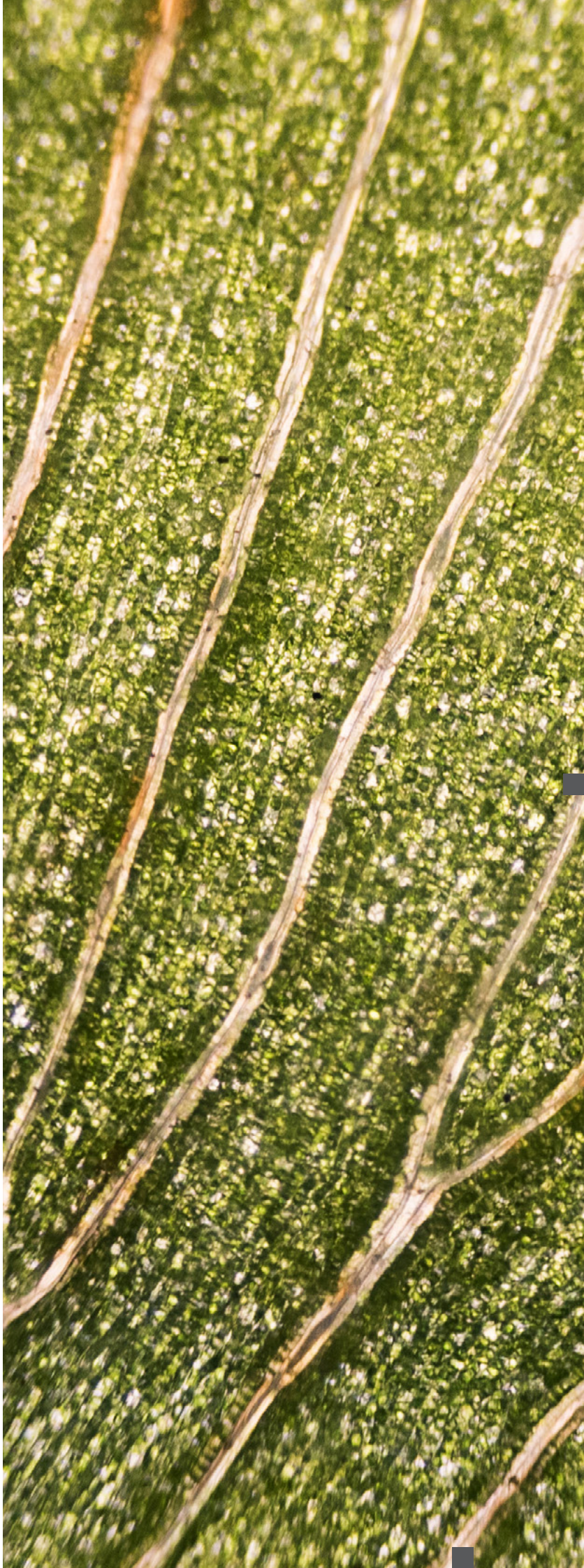
Brazilian Access and Benefit-sharing Rules

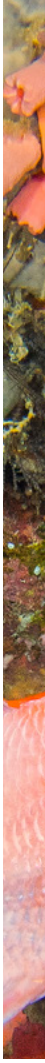
Procedural Clarifications & the Specific Case of in silico Genetic Heritage

BACKGROUND PAPER

Preparation of Brasilia workshop
10-12th December 2019

Fulya BATUR &
Paulo HOLANDA





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CESO Development Consultants/WYG/ Camões, I.P.

AUTHORS

Fulya BATUR
Paulo HOLANDA

TECHNICAL REVIEW

Alicja KOZLOWSKA
Chris LYAL
Francine FRANCO
Leticia PIANCASTELLI
Manuela DA SILVA
Thiago ZEIDAN

CONTACTS

National Directorate for the Initiative
dialogos.setoriais@planejamento.gov.br
www.sectordialogues.org

CONTEXT OF THE PROJECT

This background paper has been developed as a document to help participants in preparation of the international Workshop taking place in Brasilia from 10-12th December 2019 in the framework of the Brazil-EU Access & Benefit Sharing (''ABS'') dialogue. 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.

This background paper therefore builds upon the work undertaken during the project's past rounds, considering notably the recommendations formulated during the workshops held in London1 and Brasilia2 in 2016 and articulated in the 2016 project booklet3. This document has been drafted and developed by external consultants, having been reviewed by a team of experts from the European Union and Brazil, who the main authors would like to wholeheartedly thank for their involvement, time, and precious contributions.

1. Christopher HC LYAL, ''Workshop report : Utilisation of Brazilian Genetic Resources in the EU – understanding ABS expectations and legal requirements'', 27-28 June 2016 Natural History Museum, London

2. Kate DAVIS and Paulo HOLANDA, ''Brasilia workshop report: International exchange of genetic resources between Brazil and the European Union: building bridges to facilitate the path of research and development'', 7-10 June, Embrapa, Brasilia.

3. 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 project report, 2016. All project documents are available online at http://nagoyaprotocol.myspecies.info/node/23 (accessed September 2019).

PURPOSE AND CONTEXT OF THE BACKGROUND PAPER

This background paper aims to provide participants of the 2019 Brasilia workshop with contextual guidance regarding the practical issues raised by the implementation and articulation of the ''Brazilian ABS Rules''4 and the ''EU ABS compliance rules''5, with a clear focus on the notion of Brazilian notion of genetic heritage, defined as information, and thus directly encompassing an immaterial dimension. The document seeks to provide background information to ensure that participants can co-design practical solutions and explore bridges between Brazil and the EU, addressing existing uncertainties calm. Brazilian ABS Rules defines access as research and technological development, and regulates 'genetic heritage', defined as ''genetic information'', rather than ''genetic resources'' (terminology used in the Convention on Biological Diversity (''CBD'') and of the Nagoya Protocol) and covers both information and material acquired through ''in situ, ex situ and in silico sources''. That is why this document will focus on the practical implications of access to genetic heritage, more specifically those relating to access to genetic information held in computer storage, including information obtained from databases.

In order to guide the workshop discussions, this background document will (1) provide a summary of procedural requirements for carrying out research with Brazilian genetic heritage; (2) address the legal framework & practical implications of the inclusion of in silico genetic heritage in Brazilian ABS Rules; and prepare more in depth discussions for the workshop by (3) identifying open questions, especially with regards to access to genetic heritage found in silico, and (4) outlining four scenarios that participants will be asked to resolve in groups.

Building upon the results of the workshop, an electronic booklet will be developed to explore potential solutions and develop tools to enhance the understanding of Brazilian ABS Rules & the EU ABS compliance system, in order to ensure a swift implementation of the legal frameworks and identify areas where further work is needed. This booklet will inter alia offer a survey of key issues regarding the practical implementation of accessing Brazilian genetic heritage held in silico, and monitoring compliance with Brazilian ABS Rules.

4. For the purposes of this background document, the ''Brazilian ABS Rules'' are understood to comprise all applicable laws, decrees and implementing decisions. This includes inter alia the ABS Law no 13.123 dated as of 20.05.2015 (Lei n° 13.123, de 20 de maio de 2015. http://www.planalto.gov.br/ccivil_03/_ato2015- 2018/2015/lei/l13123.htm), and its implementing Decree no. 8772 dated as of 11 May 2016 (Decreto n° 8.772, de 11 de maio de 2016 http://www.planalto.gov.br/ccivil_03/_ato2015-2018/2016/decreto/d8772.htm).

5. For the purpose of this document, the ''EU ABS Compliance Rules'' will be understood as comprising of the EU Regulation 511/2014 of 16 April 2014 on compliance measures for users from the Nagoya Protocol, JOL 150, 20.5.2014, p. 59–71 & of the European Commission Implementing Regulation 2015/1866 of 13th October 2015 laying down detailed rules for the implementation of Regulation 511/2014, JOL 275, 20.10.2015, p. 4–19.

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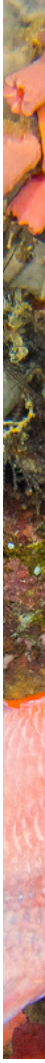

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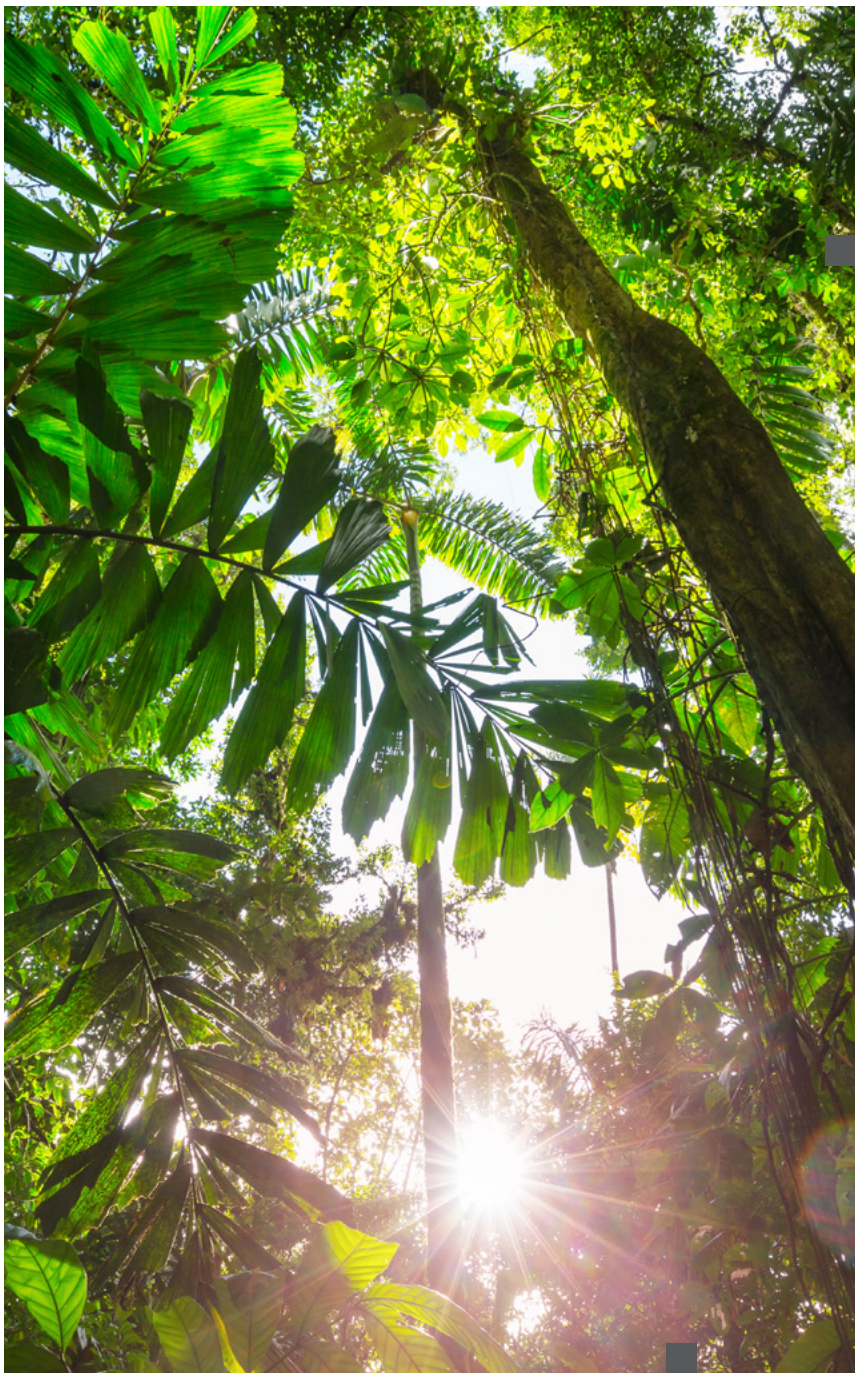

SECTION 1. PROCEDURAL & LEGAL CLARIFICATIONS: RESEARCH ON BRAZILIAN GENETIC HERITAGE WITH EU ENGAGEMENT

Without delving into the general rationale and details of applicable Brazilian law, which were thoroughly addressed in the past stages of this project6, and that we invite participants to read, we will seek to identify existing uncertainties and potential misunderstandings through a short analysis of institutional practice.

1. GOVERNANCE ASPECTS

1.1. Applicable law & institutional considerations

The "Brazilian ABS Rules" are understood to comprise of the ABS Law no 13.123 dated as of 20th May 2015 (ANNEX 1)7 and its implementing Decree no. 8772 dated as of 11th May 2016 (ANNEX 2). In this background paper, they are also understood as including the high number of currently applicable implementing norms, mostly Normative Instructions, CGen Resolutions and Technical Orientations, which define the national ABS system's practical aspects. It is also worth noting that Brazil is a party to the Convention on Biological Diversity but is yet to ratify the Nagoya Protocol. The lack of ratification has implications in the reach of compliance measures established in other countries when implementing the Protocol. In this context, the EU ABS Compliance Framework will only be of partial assistance in the implementation of Brazilian ABS Rules within EU Member States. For instance, the general due diligence obligations established in the EU ABS Compliance Framework applies only to genetic resources which come from countries that have ratified the Nagoya Protocol and have adopted access measures. Only a portion of overarching measures set out by EU Regulation 511/2014 will be applicable, and only to some limited

6. 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 project report, 2016, available on http://nagoyaprotocol.myspecies.info/node/23 (accessed September 2019).

7. Both Annex 1 and 2 are the latest unofficial translations (still under review) of the Law 13.123 and Decree 8772.

extent, such as the recognition of best practices and recognized collections. Violations of Brazilian ABS Rules by users in the EU would be addressed through specific measures that may exist in each country's national laws that do not specifically address ABS8, but rather regulate violations of foreign laws in the framework of private international law, contracts, torts or administrative law9.

The Brazilian ABS Rules are carved around a registration and notification system regulating access to genetic heritage, with different triggers at different stages of valorisation of Brazilian genetic heritage. In the Brazilian law, access does not mean acquisition of genetic heritage, but research and technological development activities carried out with the genetic heritage. The ABS Electronic Registry, the National System of Genetic Heritage and Associated Traditional Knowledge Management (Sistema Nacional de Gestão do Patrimônio Genético e do Conhecimento Tradicional Associado – SisGen), is the system's centralized pillar, which is overseen and managed by 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. Alongside coordination and management duties as the entity monitoring access to genetic heritage whether through SisGen registrations or notifications, CGen also adopts technical norms and guidelines for all stakeholders. These norms and guidelines target potential users of the system (as holders or providers of genetic heritage, or as users wishing to undertake research or to develop a product based on genetic heritage), and also regulators, whether within Brazil or from other countries. Its large mandate makes it the master architect of the Brazilian ABS system, and CGen Council Resolutions considerably shape the practical implementation of the Brazilian ABS rules, as epitomized by Resolution no.12 adopted on 18th September 2018 ratifying the minimum standards to be included in Material Transfer Agreements10 (ANNEX 3), which is mandatory for shipment of genetic heritage, and to which additional provisions can be foreseen.

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8. Even in Denmark, where the Danish ABS law considers that any violation of foreign ABS laws will be considered as a violation of its own national corpus, this strong stance is only applicable if the country having enacted ABS laws is a Party to the Nagoya Protocol see Veit KOESTER, "the ABS Framework in Denmark", in Brendan COOLSAET, Fulya BATUR, Arianna BROGGIATO, John PITSEYS and Tom DEDEURWAERDERE (eds.), Implementing the Nagoya Protocol: Comparing Access and Benefit-sharing Regimes in Europe, Brill, 2015, pp.54-76, and remarks to Danish ABS law.

9. See for instance CHIAROLLA, Claudio, "The Role of Private International Law under the Nagoya Protocol", in Elisa MORGERA; Matthias BUCK, and Elsa TSIOUMANI (eds.), The 2010 Nagoya Protocol on Access and Benefit- sharing in Perspective: Implications for International Law and Implementation Challenges, Martinus Nijhoff, 2012, pp. 423-450.

10. Minimum requirements to be included in the MTA is provided in CGen Resolution 12/2018, available at: https://www.mma.gov.br/images/arquivo/80043/resolucoes/Resolution_12_TTM_english_version_nova.pdf, and also replicated here under ANNEX 3.

1.2. Procedural considerations

a. Registration of Access

In the Brazilian ABS Rules, prior informed consent for access to genetic heritage, i.e. research and technological development with such heritage is predicted in Law 13.12311, but there is no need to carry out any administrative procedure prior to access activities12, which happens rather at different trigger points. The acquisition of genetic heritage samples in situ nonetheless requires the prior obtention of a permit or authorisation in certain cases13. Institutions involved include the Chico Mendes Institute for Biodiversity Conservation14 - ICMBio, the National Defence Council or the Maritime Authority. 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.

As a rule, no foreign entity can submit an access or shipment registration on SisGen. Any legal entity located abroad needs to partner with a Brazilian institution, whether public or private and the latter will be responsible for the registration and update of the SisGen access registration entries. As this requirement has caused some difficulties, a new institutional system is being elaborated, whereby the Ministry of Science, Technology, Innovation and Communication (IBICT) would be the default Brazilian partner for foreign entities wishing to access genetic heritage, i.e. perform research and development on Brazilian biodiversity. The SisGen registration would in this new procedure be filled in by the foreign entity, but IBICT would validate the information and the form15.

The legal entity submitting the SisGen registration needs to indicate whether the access concerns genetic heritage and/or traditional knowledge associated with genetic heritage, the exact type of genetic heritage along with its scientific genus, name, (although the

11. Article 9 of Law 13.123

12. Article 12 of Decree 8.772

13. Such permits are required for "I - collection of biological material; II - capture or tagging of wild animals in situ; III - temporary maintenance of wild-life specimens in captivity; IV - transport of biological material; and V - conducting research in a federal conservation unit or in a natural underground cavity", for more detailed information, see Kate DAVIS et al, op.cit., p.22.

14. See ICMBio Normative Instruction no. 03/14, available at: www.icmbio.gov.br/sisbio/destaques/46-instrucao-normativa-03-14-e-retificada.html

15. Manuela DA SILVA, "The Brazilian Legislation on Access and Benefit-Sharing", presentation, May 2018.

system can accommodate for unidentified specimens) indicating whether it concerns a local or creole variety or breed, and also the source of the heritage, whether obtained in situ, ex situ, in silico, or through an intermediate product16. The procedures surrounding access to associated traditional knowledge are different whether such knowledge has an identifiable origin or not, i.e. whether it is possible to link the knowledge's source to at least an indigenous population, traditional community or traditional farmer or peasant. In the former case, additional Prior Informed Consent from the concerned communities is required, and the potential benefit-sharing arrangements will be directed towards them, while in the latter no specific consent is required.

The Brazilian ABS Rules require a SisGen registration at different trigger points17, which are:

- The **sending**18 of genetic heritage for the "provision of services abroad as part of research or technological development" 19 (for example for sequencing or identification), where the liability for ABS compliance is not transferred to the recipient, and where the signature of a Material Transfer Agreement is not required but a legal document addressing the specific use of genetic heritage and the prohibition of third party transfers is sent together with the samples;

- The **shipment**20 of genetic heritage samples with the intent of conducting research and development on such samples21 (where liability for ABS compliance is transferred to the recipient, including the obligation to continue the chain of information and liability to third party users);

- The **release or publication of research results**, whether partial or final, in scientific or communication circles, including the publication of any research data (whether sample is shipped or sent);

- The claim of any type of **intellectual property rights** (in all jurisdictions);

16. 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.

17. Article 12 of Law 13.123.

18. Sample Sending is the sending of sample(s) that contain(s) GH for services provided abroad, as part of research or technological development, in which the responsibility for the sample is held by the person who performs the access in Brazil.

19. Article 2 § XXX of Law 13.123: "sending of samples containing genetic heritage for services abroad as part of research or technological development, in which the responsibility for the sample is kept by the Brazilian user".

20. Sample Shipment is the transfer of GH sample to an institution located outside the country with the purpose of access, in which responsibility for the sample is transferred to the receiver.

21. Article 2 XIII of Law 13.123: shipment is defined as the "transfer of a sample of genetic heritage, intended for access, to an institution located abroad, in which responsibility for the sample is transferred to the recipient institution".

- The **commercialisation of an intermediate product**, i.e. a product used in the production chain as an input, excipient or raw material for the development of another intermediate or a finished product.

- The **notification of a finished product or reproductive material**, i.e. a product that does not need any additional processing, being ready for use by the final consumer, whether a natural or a legal person.

b. Notification of Economic Exploitation & Benefit-Sharing

While the commercialisation of intermediate products only needs to be registered, the ''economic exploitation'' of finished goods or reproductive material must be notified to SisGen and is the trigger of benefit sharing under Brazilian ABS Rules. While the modalities of benefit-sharing ought to be indicated at the time of SisGen notification, the notifier has 365 days to present the benefit-sharing agreement that will regulate its detailed implementation. Different types of non-monetary benefit- sharing mechanisms are recognised by the Law, such as the establishment of projects for the conservation and sustainable use of biodiversity, technology transfer and training opportunities, or the free distribution of products in programmes of social interest. These actions ought however to be equivalent to 75% of potential monetary benefit-sharing amounts22. In parallel, the Brazilian ABS Rules set out clear and fixed thresholds for monetary benefit-sharing, requiring either the payment of the rate fixed in Law 13.123, i.e. 1% of annual net revenue obtained from the economic exploitation of said product (Article 20), 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 said revenue23. The identity of the legal person responsible for benefit-sharing obligations is also quite clear, as manufacturers of intermediate products and developers of processes originating from access are expressly exempted from such obligations24. Whichever the value chain that precedes it, only the manufacturer of the finished product is thus liable for benefit-sharing. When monetary benefits are chosen by the user, 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 genetic

22. Article 22 of Law 13.123.

23. Article 21 of Law 13.123.

24. Article 17 of Law 13.123.

heritage and associated traditional knowledge. The Fund also receives any fines that are imposed on users for non-compliance with Brazilian ABS Rules.

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, shipment, patent grant, commercialisation of intermediate product or economic exploitation of finished product). 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 or notified activity. This Certificate could potentially be used by regulatory authorities of States operating ABS compliance controls over entities having accessed Brazilian genetic heritage.

2. SCOPE OF THE BRAZILIAN ABS RULES

2.1. Material, geographic & temporal scope

a. Genetic heritage as genetic information

The Brazilian ABS Rules regulate access to 'genetic heritage', which is defined in Law 13,123/2015 as the "genetic information from plants, animals, and microbial species, or any other species, including substances originating from the metabolism of these living organisms"25. The focus of the Brazilian ABS Rules is thus on information, and not just the physical genetic resources that are the vectors of such information, and that can be or have been acquired within the limits of the country's territorial sovereignty. In a parallel fashion, traditional knowledge is defined as information or practices of indigenous/traditional communities or farmers on genetic heritage's properties, or its direct or indirect uses. By applying to information of genetic origin from plants, animals or microorganisms, including metabolic substances, the Brazilian ABS Rules cover both material (molecules or substances) and intangible (information taken from samples) elements linked to genetic resources.

The only limitation that is put on the type of information covered by the notion of genetic heritage is its "genetic" attribute. Would this attribute mean that genetic information is understood to be limited only to information on genes, i.e. units in the cells of a living organism that control its physical characteristics, thereby excluding phenotypic information on plants, animals and microbial species for example? Or does the "genetic" nature of information mean that any information that is simply connected to genes, including its physical manifestation, description, location, or its relationship to other organisms, would be included in this notion?

OPEN QUESTIONS: Does the concept of genetic heritage include all types of information on "plants, animals, and microbial species, or any other species, including substances originating from the metabolism of these living organisms", direct and indirect, and also extend to the physical genetic resources that are the vectors of such information?

The dual definition of genetic heritage, encompassing both material and immaterial aspects, comes with specific practical interrogations, mostly with regards to the frontiers

25. Article 2, I of Law 13.123.

of this concept, especially with regards to derivatives, and also to the access of purely informational components of genetic heritage in the digital realm, which will be addressed in Section 2 of this document. The term ''derivative'' is not found in the Brazilian ABS Rules, but it seems clear that all substances derived from the metabolism of living genetic heritage samples are included in the notion of genetic heritage, especially when read together with the notions of intermediate and finished products, which we shall touch upon in Part 2.C of this paper. Law 13.123 also addresses the issue of microorganisms and specifies that Brazilian genetic heritage includes any and all microorganisms isolated from substrates originating from territories falling under national sovereignty (internal land, territorial sea, exclusive economic zone & continental shelf)26. In terms of geographic scope, it thus seems that genetic heritage needs to originate from Brazilian national territory, indifferent of the location where the sample (whether a plant, animal or a microorganism) or the information is being held at the moment of access.

> OPEN QUESTION: Would all genetic heritage information and its physical counterpart, including any microorganism isolated from substrates originating from Brazil, but is held in collections outside Brazilian national territory, be considered in scope of the Brazilian ABS Rules?

c. Genetic heritage and native species

To be considered as Brazilian Genetic Heritage, genetic information needs to relate to native species, although non-native species are also regulated if they have developed their distinctive properties in Brazil. In order to clarify the material scope of the Brazilian ABS Rules, competent Ministries ''periodically prepare, publish and revise reference lists of domesticated or cultivated animal and plant species that have been introduced into the national territory and used in agricultural activities, [also indicating] the species that form spontaneous populations and the varieties that have acquired distinctive characteristic properties in the country''27. Another act would ''publish a list of traditional local or Creole varieties and locally adapted or Creole breeds''28. As a result, ''access, shipping or product notification records should be cancelled whenever [...] the genetic heritage described as the object of access or shipment refers exclusively to species listed [...], which

26. Article 2, final paragraph Law 13.123, and Article 1§2 of Decree 8772: ''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''.

27. Article 113 of Decree 8772/2016, courtesy translation.

28. Article 114 of Decree 8772/2016, courtesy translation. User obligations with regards to local or creole breeds and varieties begin from the date of publication of such act, see CGen Resolution no.16, 9th October 2018.

do not form spontaneous populations or that have not acquired distinctive characteristics of their own in the Country''29.

> OPEN QUESTION: When would a plant or other living material originating from another country considered to have developed distinctive characteristics in Brazil?

d. Temporal considerations

When it comes to the temporal scope of the Brazilian ABS Rules, the issue is not directly addressed in Law 13.123. However, it provides for rules on the regularisation of access to genetic heritage operated after the 30th June 200030. This would mean that no ABS requirements are required for research and development activities undertaken with Brazilian genetic heritage and associated traditional knowledge before 30th June 2000, which is the date of entry into force of the Provisional Measure that was applicable prior to the adoption of Law 13.123. Furthermore, as the trigger of the Brazilian ABS Rules is access defined as research and development, and not acquisition of genetic heritage, the latter date has no incidence on the implementation of the Rules. In other words, it does not matter when the genetic heritage has actually been collected, acquired or came into the hands of a user; if research and development in the sense of the Brazilian ABS Rules has been undertaken on such heritage after 30th June 2000, such access activities would fall within the temporal scope of the Rules.

> OPEN QUESTIONS: What is the clear temporal trigger of Brazilian ABS Rules? Does a recent date of access trump the fact that a Brazilian genetic heritage resource had been acquired before 30th June 2000?

2.2. Accessing genetic heritage

a. Access as research and development

The Brazilian ABS Rules concern all types of research, whether experimental or theoretical, conducted on and with Genetic Heritage, without exception31. Access rules thus apply to

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29. CGen Resolution no. 20, dated as of 7th August 2019, courtesy translation.

30. Article 37 of Law 13.123.

31. Article 2 X and XI of Law 13.123, courtesy translation.

basic research such as phylogeny, taxonomy, systematics, ecology, biogeography and epidemiology32, as long as they produce the appropriate events triggering an access registration. Some activities and tests are however exempt from obligations under the Brazilian ABS Rules, when they are not conducted for research and development. These activities include inter alia, ''DNA analysis and other molecular analyzes 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''33. Further interpretation to the Rules has been given by CGen itself, and ''(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''34 are equally found to be out of scope of the Rules.

In the Brazilian ABS rules, although the conduct of ''research and technological development'' is the general criteria upon which ABS obligations are born, the actual criteria for the implementation of access registration procedures is not the beginning of these activities. It rather relies on a number of moments that presuppose that research and development will occur downstream, i.e. the shipping of samples of genetic material; and additionally on different moments that presuppose access has occurred upstream, i.e. the application of intellectual property rights, the commercialization of intermediate or by-products, the publication of final or partial results in scientific or communication circles, or the exploitation of finished products.

e. Terms of access

The sending of genetic heritage samples ought to be registered with SisGen but does not

32. CGen Resolution no. 10, dated as of 03rd August 2018, courtesy translation.

33. The full list of tests and activities is found in Article 107 of Decree 8771/2015.

34. CGen Technical Orientation, no. 9, dated as of 18th September 2018, courtesy translation.

require the signature of an ad hoc material transfer agreement, especially if such sending is for the purposes of genetic sequencing. A signed legal instrument is a mandatory requirement of the SisGen when filling a sending registration form35. However, when the sending is for genetic sequencing, there is no need of a legal instrument, a formal communication of the institution about the obligations and prohibitions is considered sufficient in this specific case36. Even though there is no obligation to sign a formal contract, practice tends to ensure more solid paper traces.

Material Transfer Agreements are required for the shipment of genetic heritage (while the sending can only be accompanied by a notice)37. The Brazilian ABS Rules set out minimum elements that ought to be referred to in the Termo de Transferência de Material (''TTM''), which ought to address ownership, liability, third party uses and applicable law in dispute resolution, amongst other elements38. Following its mandate, CGen has adopted a number of mandatory clauses with regards to contracts to be signed for the ABS compliant shipment of genetic heritage, accompanied by the SisGen registration receipt and the shipment invoice. CGen adopted Resolution no.5 on 20th March 2018 ratifying a standard Material Transfer Agreement for all shipment of genetic heritage, which has been revoked and replaced by Resolution no.12 of 18th September 2018(ANNEX 3). MTA's issued and signed following the model from Resolution no.5 remain valid, but new agreements that are being signed should now follow the new model provided for by Resolution no.12.

The mandatory clauses remind the receiver of genetic heritage of applicable legal obligations, like the obligation to partner with a national Brazilian scientific and technological research institute, or to notify SisGen in case of economic exploitation of a finished product. The MTA also sets specific rules for the shipment of ''traditional local or Creole varieties or locally adapted or Creole breeds, [in which case] a copy of this MTA and its respective Shipment Invoice shall be sent by the sender to the provider, if the latter is properly identified'', thus formally identifying local farmer and peasant communities as holders of traditional knowledge in the implementation of Brazilian ABS Rules. Reminding users of applicable sanctions under Law 13.123, the mandatory clauses also set Brazilian law and courts as the applicable law and competent jurisdiction. Additional contractual provisions

35. Decree 8772, Art 24 §6° and §10.

36. Decree 8772, Art 24 §7°.

37. Article 2 XXIII of Law 13.123 defines material transfer agreement as ''a document signed by sender and recipient for shipping abroad samples containing genetic heritage accessed or available for access, which indicates if access to associated traditional knowledge was carried out and establishes the commitment of benefit-sharing according to the provisions in this Act'', courtesy translation.

38. Article 6 of Law 13.123, and Article 25 of Decree 8772, courtesy translation.

can be foreseen, which is especially useful to adapt the terms to the sectors and contexts in which the heritage is used, even though these additional terms cannot contradict the standard mandatory clauses of the MTA, like change applicable law for instance.

The main difference brought by CGen Resolution no.12 is that it explicitly recognises the possibility to sign a single MTA for a maximum period of ten years between two institutions concerning multiple genetic heritage samples. A SisGen registration would have to be made for each sample prior to its shipment, including an invoice generated with a sequential number order, together with the description of the samples to be shipped according to the standard document in Attachment 2 of the Resolution. The Shipment Invoice thereon requires an identification to the most specific taxonomic rank possible, information on the origin of the samples (either the in situ collection/acquisition, or the ex situ source of the genetic heritage, with the information contained in the deposit record), the intended use of the samples, allowing for a further change of intent with authorisation of the sender. Transfer 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. Under Brazilian ABS rules, the regulation of third-party transfers is left to the mutually agreed terms. Although the terms of the contract itself are not viral in their entirety, the obligation to enter into a contractual agreement with Brazilian authorities is a viral one, by law.

> OPEN QUESTIONS: How is the question of third-party transfers of genetic heritage approached in Brazilian ABS Rules and in particular in its model MTA? How is institutional practice dealing with such?

2.3. Sharing the benefits of accessed genetic heritage

a. Economic exploitation of a finished product

In the Brazilian ABS Rules, benefit-sharing requirements include the obligation to notify SisGen of economic exploitation and the signature of a benefit-sharing agreement. They also bring legal clarity as to the percentage of revenue that will be shared with the FNRB. Benefit sharing is only due when access to genetic heritage leads to economic exploitation

of finished products or reproductive material in certain conditions: the products need to be apt to be used by the final consumer (whether it is an individual or legal entity), they should be derived from access, whether or not it was produced in the country or abroad, and finally Brazilian Genetic Heritage needs to be one of the main elements adding value to the product. This means that non-commercial research on and with Brazilian genetic heritage falls completely outside the scope of notification obligations, and also the signature of benefit-sharing agreements, unless the results of such research have led to the development of a finished product that is intended to be commercialised, whether by the same entity or another one.

In the Brazilian ABS Rules, ''economic exploitation of a finished product or reproductive material'' is the necessary pre-condition for benefit-sharing obligations. Although the term ''economic exploitation'' is not defined in Law 13.123, it is stated as the goal of ''technological development'', which is defined as ''systematic work on genetic heritage or associated traditional knowledge [...] for economic exploitation''39. Additional clarification is given by the Decree 8772, which states that ''economic exploitation shall be considered initiated when the first sales invoice of the finished product or reproductive material is issued''40. Indeed, benefit-sharing rules only concern commercial products that are defined as ''finished product or reproductive material''. Contrary to a finished product, an intermediate product is ''used in the production chain as an input, excipient or raw material, for the development of another intermediate product or a finished product''41. On the other hand, finished products are ready for the ''final consumer'', and have received a significant contribution from Brazilian genetic heritage.

> OPEN QUESTION: How would the distinction between intermediate and finished product operate in complex and cumulative value chains?

f. Genetic heritage's contribution to the finished product

An important criterion for the application of benefit-sharing obligations under Brazilian ABS Rules is that the finished products ought to be developed with Brazilian genetic heritage having added significant value to the product. Genetic heritage ''must be one of the key elements of value adding to the product''42. In this context, ''the main elements of

39. Article 2, XI, Law 13.123.

40. Article 33 of Decree 8772/2016, courtesy translation.

41. Article 2 XVII Law 13.123.

42. Article 17 Law 13.123.

value addition are considered to be the elements whose presence in the finished product is crucial for the existence of functional characteristics or for the formation of marketing appeal''43. These concepts are further defined as the ''characteristics that determine the main purposes, enhance the product action or broaden its range of purposes'', and the marketing appeal means that the ''reference to genetic heritage or associated traditional knowledge, 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 on the product label''44. In order to trigger benefit-sharing obligations, Brazilian genetic heritage thus needs to be completely essential to the product's characteristics, or its marketing potential. CGen has issued a couple of Technical Orientations providing for a specific sectoral interpretation of this threshold that triggers benefit-sharing in the Brazilian ABS Rules45. As a result, ''the use of genetic heritage, 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''46.

> OPEN QUESTION: When is Brazilian Genetic Heritage ''one of the main elements adding value to the product'' and how is this expression to be interpreted in different contexts?

43. Article 43 of Decree No. 8.772/2016, courtesy translation.

44. Ibidem.

45. For instance, ''For the personal hygiene, perfumery and cosmetics sector, the use of genetic heritage 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''. As for the fragrance sector, ''main elements of added value to the product'' are considered as ingredients derived from access to genetic heritage that determine the predominant olfactory family of the fragrance used in the finished product, when the purpose of the genetic heritage in the formula is solely for the formation of its smell'', respectively CGen Technical Orientation no.2, dated as of 28 June 2017, courtesy translation, and CGen Technical Orientation no.6, dated as of 20th June 2018, courtesy translations.

46. Article 43 §5 of Decree No. 8.772/2016, courtesy translation.

SECTION 2. *IN SILICO* GENETIC HERITAGE IN BRAZILIAN ABS RULES: STATE OF PLAY & PRACTICAL IMPLICATIONS

The Convention on Biological Diversity refers to sovereign rights of States on genetic resources, a right which is being implemented through the notion of genetic heritage by Brazil, which, as aforementioned, refers not only to physical genetic resources but also directly includes informational and immaterial elements. This understanding of "genetic heritage" as "genetic information" does not differentiate where, how, and under which format this information is found. The Brazilian ABS Rules nonetheless cite three sources where such information can be found (1) in situ, (2) ex situ, and (3) in silico.47 It should be noted that the terms in silico, although used in the Brazilian ABS Rules, are not defined in the national legal framework. Some elements to define the scope of "Brazilian genetic heritage found in silico" can nonetheless be highlighted through publications and institutional practice, which will be done in Chapter 1A below. The Merriam-Webster dictionary defines the expression in silico, as meaning "in or on a computer; done or produced by using computer software or simulation". The focus of this particular section will thus be on genetic heritage information as defined in the Brazilian ABS Rules, which can be found on a computer, or has been produced using a computer.

The dematerialization of genetic resources is a growing concern for the effective implementation of ABS systems worldwide, and poses many great challenges, from the boundaries of ABS rules themselves, to the implementation of concrete rights and obligations in a faster and wider digital context. Discussions on both aspects of the issue have been quite intense the last few years, leading to different processes since 2016. The thirteenth meeting of the Conference of the Parties to the Convention (COP 13) and the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol (COP-MOP 2) adopted specific decisions on digital sequence information ("DSI") on genetic resources48. These decisions have asked for the submission of views and information on the potential of DSI for the three objectives of the Convention

47. Article 22 of Decree No. 8.772/2016, courtesy translation.

48. CBD COP decision 13/16 (available at https://www.cbd.int/doc/decisions/cop-13/cop-13-dec-16-en.pdf) and NP COP-MOP Decision NP-2/14 (available at https://www.cbd.int/doc/decisions/np-mop-02/np-mop-02-dec-14-en.pdf) related to "digital sequence information on genetic resources".

(1) the commissioning of a fact-finding study49, (2) the undertaking of analysis by an Ad Hoc Technical Expert Group (AHTEG), and (3) the adoption of recommendations to the meetings of different Parties to the Convention and the Protocol. During this fourteenth meeting of the Conference of the Parties to the Convention and the third meeting of the Parties to the Nagoya Protocol, signatories agreed to set up another AHTEG on Digital Sequence Information on Genetic Resources to (1) consider the compilation and synthesis of views and information and a number of peer-reviewed studies50; (2) develop options for operational terms and their implications to provide conceptual clarity on digital sequence information on genetic resources51; and (3) identify key areas for capacity-building52. The outcomes of the AHTEG will be considered by the open-ended inter-sessional working group established to support the preparation of the post-2020 global biodiversity framework53, and then by the Conference of the Parties at its fifteenth meeting in 2020.

Notwithstanding the discussions held under the CBD, our focus in this section will solely be the regulation of in silico genetic heritage as defined in the framework of the Brazilian ABS Rules. According to the latest Brazilian submission to the CBD process in 2019 (ANNEX 5), out of the 47,000 access activities that have been registered since the implementation of the SisGen system, 449 activities were linked to genetic heritage of in silico origin, and within this figure, 64 activities were declared to have commercial intention, in a ''technological development'' approach54. An example of such in silico genetic heritage registration, which includes a commercial exploitation intention, 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 database55.

49. Sarah A. LAIRD & Rachel P. WYNBERG, ''A Fact-Finding and Scoping Study on Digital Sequence Information on Genetic Resources in the Context of the Convention on Biological Diversity and the Nagoya Protocol'', 10th January 2018, CBD/DSI/AHTEG/2018/1/3, available at https://www.cbd.int/doc/c/079f/2dc5/2d20217d1cdacac787524d8e/dsi-ahteg-2018-01-03-en.pdf

50. Different studies have been commissioned by the CBD COP and the Secretariat, one addressing the concept and scope of digital sequence information on genetic resources, another on DSI in public and private databases and DSI traceability, and a last one on domestic measures. While the former is still waited upon, the latter two have been published for peer-review, and can respectively be found in https://www.cbd.int/abs/DSI-peer/Study-Traceability-databases.pdf, and https://www.cbd.int/abs/DSI-peer/Study4_domestic_measures.pdf, (only to be cited as draft for review at the time of writing of this Background Paper).

51. These recommendations will be discussed during the next meeting of the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources will tentatively be held from 17 - 20 March 2020 in Montreal, Canada.

52. CBD COP Decision 14/20 on ''Digital sequence information on genetic resources'', available at https://www.cbd.int/doc/decisions/cop-14/cop-14-dec-20-en.pdf, which is referred to by COP-MOP NP-3/12 (available at https://www.cbd.int/doc/decisions/np-mop-03/np-mop-03-dec-12-en.pdf)

53. CBD COP decision 14/34 on the Comprehensive and participatory process for the preparation of the post-2020 global biodiversity framework, available at https://www.cbd.int/doc/decisions/cop-14/cop-14-dec-34-en.pdf

54. Brazil notification 2019-012 to the CBD, 03 June 2019, p.6 (available on https://www.cbd.int/abs/DSI-views/2019/Brazil-DSI.pdf)

55. Personal communication from Brazilian authorities, referring to registration A23BA95 ''Aplicação do peptídeo PnPP19 sintetizado racionalmente a partir da toxina PnTx2-6 do veneno da aranha armadeira Brasileira (Phoneutria nigriventer) como novo candidato para o tratamento da disfunção erétil'', with reference to https://www.uniprot.org/uniprot/P29425 This communication also gives the most recent figures of almost 50.600 registered access activities in the SisGen by now, 524 declared in silico origin, from which 75 declared commercial intention activities, through the registration of

1. LEGAL CLARIFICATION: NATIONAL BRAZILIAN LEGAL FRAMEWORK FOR "*IN SILICO* GENETIC HERITAGE"

The rights and obligations that surround access of genetic heritage from in silico sources are identical to those applying to Brazilian genetic heritage obtained from other sources (i.e. in situ and ex situ), albeit with a few practical differences. Like other types of genetic heritage, the acquisition of genetic heritage information on a computer (or produced by a computer) does not require prior informed consent in Brazil56; but its access, understood as utilization in research and development, triggers the aforementioned registration and notification obligations, depending on the results of these activities. The Brazilian ABS Rules do nonetheless take into consideration the specific inherent characteristics of genetic heritage available from in silico sources and have provided for specific interpretations of their legal framework in this particular context.

1.1. Definition: What is "in silico genetic heritage"?

The Brazilian ABS system covers acquisitions and uses of "genetic heritage", 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". This is the case even when the information is disengaged from the physical samples the information has been obtained from. However, as aforementioned, the Brazilian ABS Rules do not mention the term "digital", but rather refer to the expression genetic heritage acquired from "in silico sources". The expression does not appear in Law 13.123, but in Article 22 of the Decree 8772, which deals with the procedural aspects of SisGen registration, 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.

Technological Development activities arising from the utilization of digital sequence information/genetic information on Genetic Resources.

56. The Brazilian approach is thus different than other national ABS legislation which regulates access in the sense of acquisition of genetic information found in digital format, as some countries have domestic measures in place requiring prior informed consent when such information is acquired, even if independently from the physical material to which the information relates to. The latest CBD study cites Bhutan, Bolivia, China, Colombia, Kenya, Malaysia, Mozambique, Oman, Peru and Uganda amongst these countries; see Margo BAGLEY, Elizabeth KARGER, Manuel RUIZ MULLER, Frederic PERRON-WELCH, and Siva THAMBISETT, "Fact-finding Study on How Domestic Measures Address Benefit-sharing Arising from Commercial and Non-commercial Use of Digital Sequence Information on Genetic Resources and Address the Use of Digital Sequence Information on Genetic Resources for Research and Development", 25th October 2019, Draft for peer review compiled according to Decision 14/20 of CBD COP, available at https://www.cbd.int/abs/DSI-peer/Study4_domestic_measures.pdf, pp. 14-16.

Coming from the Latin term ''in silicon'', referring to the use of silicon chips in computer systems, the expression seems to indicate that either (1) the information is found on a computer, or that (2) the scientific experiment or research that generates the information has been conducted or produced by means of computer modelling or computer simulation, usually modelling a natural or laboratory phenomenon. 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, it forms an integral part of the notion of genetic heritage. In its submission to the CBD consultation on ''DSI'' in 2017, the Environment Division of the Brazilian Ministry of the Foreign Affairs states that ''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]57. In the context of the discussions on DSI before the Commission on Genetic Resources for Food and Agriculture (CGRFA)58, the Brazilian submission states that ''digital sequence information'' should be regarded as data information contained in a digital file with a precise order of nucleotides or amino acids. Such digital sequence information is however considered to be only a clipping of Brazilian genetic heritage, which is a broader concept that includes sequence information. 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 computational biology and simulations, and/or stored in a computer environment.

The nucleotide sequence is the main structure of nucleic acid molecules, DNA and RNA, whose main function is the storage and transmission of genetic information. Depending on the interpretation, the Brazilian concept of genetic heritage could thus be understood to include in a broad fashion 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); but also all sequence associated metadata (e.g. 'passport' data, phenome-genome data, etc), similar to the definition provided by the draft explanatory fact-finding scoping study on ''digital sequence information'' on genetic resources for food and agriculture

57. 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

58. Submission of information received by the Commission on Genetic Resources for Food and Agriculture on the use of ''digital sequence information on genetic resources for food and agriculture'' and potential implications for the conservation and sustainable use of genetic resources for food and agriculture, including exchange, access and the fair and equitable sharing of the benefits arising from their use, September 2017, available at https://www.cbd.int/abs/DSI-views/CGRFA-DSI.pdf

presented in 2018 at the Commission for Genetic Resources for Food and Agriculture59. Brazilian genetic heritage could as a result of such understanding, cover the presentation and description of nucleic acid molecules, as well as all aggregate information and data found in in silico forms.

OPEN QUESTION: Does genetic heritage found *in silico* sources cover all information on genes, genetic sequences, protein expressions, metabolites, but also phenotypic and associated data?

1.2. Access to in silico genetic heritage: specific considerations

As a general rule, Law 13.123/2015 provides that research utilizing genetic information obtained in silico can be carried out freely, and that registration is required only at specific points in the utilization chain, in parallel to genetic information obtained in other forms. Some differences of treatment between genetic heritage information found in silico vis-à-vis its counterparts in situ or ex situ, exist due to its specific nature.

a. Actions that would require registration

Decree 8,772/2016 specifies that the understanding of "research and technological development" needs to be adapted to 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 GH access obligations. The provision also addresses the comparison of information: "Does not configure access to genetic heritage reading or information of genetic consultation available in banks of national and international data, 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 part of research or technological development"60.

These thresholds regarding the consultation and comparison of information could prove tricky to assess for researchers involved in the frontiers of identification. However, combined

59. HEINEMANN, Jack and CORAY, D., Draft Exploratory Fact-Finding Scoping Study on "Digital Sequence Information" on Genetic Resources for Food and Agriculture. Commission on Genetic Resources for Food and Agriculture, 2018, CGRFA/WG-AqGR-2/18/Inf.10 (http://www.fao.org/fi/static-media/MeetingDocuments/AqGenRes/ITWG/2018/Inf10e.pdf)

60. Article 107 of Decree 8772/2016, courtesy translation.

with the wide definition of research in Brazilian ABS Rules, it seems like only the consultation and reading of information falls outside of its access procedures. With regards to the comparison of information, its execution is a context of research and development would fall within the Brazilian ABS Rules (provided they produce the results defined as triggers for SiSGen registration). For instance, the comparison of genetic heritage information for educational purposes would theoretically not require a registration, as this would not be considered as part of research or technological development. Would this also be the case even if such information is used in an undergraduate molecular biology class to demonstrate the possibilities offered by synthetic biology or make inoculations using Agrobacterium to transfer a transgene obtained from Brazilian genetic heritage in a host plant, but without any publication of research data or contribution to a symposium? Registration with SisGen would arguably be required in the framework of a doctoral dissertation making the same manipulations, at the moment of publications or presentations linked to the thesis.

> OPEN QUESTION: Would the consultation of genetic heritage information by email, by Brazilian and/or foreign entities trigger a registration obligation?

Due to its purely non-physical character, the notions of sending and shipping are difficult to translate to the in silico world. One needs to therefore assess whether the publication and downloading or other types of procurement of genetic heritage information in digital formats would trigger any legal obligations as such under the Brazilian ABS Rules or not. Some information point to the fact that the mere publication or download of genomic sequence information or other types of genetic heritage information from databases or websites would not trigger any access registration obligation, even if the information that is being acquired can be identified as being ''genetic heritage'' under Brazilian ABS Rules. As confirmed by the Brazilian Ministry of Environment in its submission to the CBD consultation on DSI, ''since there is no need for prior registration, if a given access activity [such as the download and subsequent research on genetic information] does not have any results, any intellectual property right applications, products or processes developed, that access activity doesn't have to be registered''61. It would nonetheless be useful to discuss whether the download of genetic heritage information would be regarded as shipment of genetic heritage or not.

61. Brazil notification 2019-012 to the CBD, op.cit., p.4.

OPEN QUESTION: Would the publication or the download of genetic heritage information by Brazilian and/or foreign entities trigger a registration obligation? Would the download of genetic heritage by a foreign entity trigger an obligation to enter into association with the Brazilian institution?

Another tricky point relates to the transfer of downloaded or produced information via email (or other digital means, for example file transfer through a USB stick); a point which is addressed by CGen Technical Guidance no 8. The Guidance specifically excludes access registration obligations at the moment of the transfer itself, but rather pushes those obligations 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.''62 This Guidance provides useful clarifications as to the actual procedural elements that apply to the access of genetic heritage in silico, and it would be useful to clarify its content and confirm its reach during the workshop.

OPEN QUESTION: Would the transfer of genetic heritage information by email, by Brazilian and/or foreign entities trigger a registration obligation?

b. Procedural aspects for SisGen registration and notification related to in silico genetic heritage

With regards to the registration procedure before the National System for Genetic Heritage – 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.''63

Additional rules have been adopted to establish an alternative way of registering access in the electronic form with SisGen has been established exclusively in cases of research or technological development in which genetic heritage has been obtained in silico in CGen Resolution 13 of 18th September 2018 (ANNEX 4). As a result, ''(1) The identification of genetic heritage and its origin in the caption may only refer to databases, repositories or information systems in which the information has already been recorded; (2) The databases, repositories or information systems must be open and unrestricted to the Brazilian State;

62. CGen Technical Orientation no.8, dated as of 18th September 2018, courtesy translation.

63. Article 22 of Decree 8.772/2015, courtesy translation.

(3) The indication referred should be made by presenting the access numbers, registration numbers, unique indicators or the standard resource locator (URL), or equivalent, in which information is recorded in the databases, repositories or information systems'' 64. The second criterion raises the question whether information systems that cannot be consulted by the Brazilian State, like private databases such as a company's own breeding pool or microorganism collection, would thus be implicitly excluded from the scope of the Brazilian ABS Rules, or whether they would not be accepted as alternative ways of registering access to genetic heritage, or whether they would be considered in the scope of the Brazilian Rules, and non-compliant with them.

> OPEN QUESTION: Would genetic sequence information from an organism clearly originating from within Brazilian territorial borders accessed from a privately held database fall within the scope of the Brazilian ABS Rules? What would be the consequence of the absence of registration of access to such genetic heritage?

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 presuppose that the georeferenced coordinates of the in situ sampling place 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 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 of the

64. CGen resolution no.13, dated as of 18th September 2018, courtesy translation.

registration''65. Would the lack of information regarding the in situ sampling place for such genetic heritage acquired after 30th June 2000 be considered in direct violation of Brazilian ABS Rules, triggering its sanctions mechanism set out in Articles 27 and 28 of Law 13.123, i.e. administrative penalties and sample interception or confiscation? In the absence of specific rules on the burden of proof in these situations, it is unclear who the sanctions would apply to, either those who access genetic heritage information, or to those who provide such information.

> OPEN QUESTIONS: What are the exact consequences of accessing (i.e. in a context of research and development) heritage in digital format without accompanying information as to its geographical origin? Would the sanctions system target access of *in silico* Brazilian genetic heritage only if a link with Brazilian sovereign territory can be established in existing documentation in computer format?

Another challenge relates to products with multiple different genetic sequences, and the use of sequences with multiple different origins. It is not clear how the system would deal with the registration of results, intermediate products and especially the notification of finished products (which triggers benefit-sharing), when they contain and rely on a wide range of different genetic information for the expression of their essential characteristics. It remains therefore difficult to address obligations surrounding products derived from several multi-origin gene sequences, i.e. sequences that have can be found in different species originating from different territories, especially in sectors where incremental innovation prevails rather than unique findings. Brazilian authorities themselves recognise the existence of ''difficulties for traceability [due to the fact that] genomes are composed by repetitive regions and those regions are even conserved between species from different kingdoms, which the vast majority is not endemic to a single country. In this way, identical DNA sequences can exist in several organisms originated from different regions of the world''66.

> OPEN QUESTIONS: How would the Brazilian ABS Rules adapt its access and benefit-sharing triggers to products developed with the use of multiple different genetic sequences, and especially the use of sequences from multiple different origins? How would the origin of sequence information be traced back to Brazil

65. Cgen Resolution no 13, courtesy translation.

66. Commission on Genetic Resources for Food and Agriculture, 7th Regular Session, April 2018, ''Submissions by Members and Observers on ''Digital Sequence Information'' on Genetic Resources for Food and Agriculture'', available at http://www.fao.org/3/my613en/my613en.pdf, p.4.

faced with identical information stemming from another organism that cannot be considered Brazilian genetic heritage?

1.3. Monitoring Compliance in the context of in silico genetic heritage

a. Notice of infraction & sanctions

In case of non-compliance, in parallel to general violations of Brazilian ABS rules, 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, the Ministry of Agriculture and other supervisory agencies by Decree 877267. According to the compliance rules adopted in the Brazilian ABS Rules, 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 supporting documents attesting the regularity of access to the Brazilian genetic heritage, if the user has no means of attesting the regularity of access, 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.

g. Third party transfers & declaration of origin

The Brazilian ABS system for monitoring access and further uses of Brazilian genetic heritage does not target each and every movement of such heritage, but rather relies on the establishment of a constant enough flux of information between the origin and an end point, i.e. the commercialization of a finished product or reproductive material. With regards to the information to be provided by those that access in silico genetic heritage, the Brazilian ABS Rules require the identification of genetic resources and their origin, including geo-referenced coordinates of the location where the physical sample was collected in situ, even if obtained from ex situ or in silico sources. Monitoring tools include the contractual clauses that have a viral character and address third party uses, and the control mechanisms set up in the Law. Together with the registration procedure, conditions are put forward to surround research on and with Brazilian genetic heritage obtained from in silico sources. Under Brazilian ABS rules, the regulation of third-party

67. Decree 8772, Article 93.

transfers have been left to the mutually agreed terms. When it comes to shipment of genetic heritage, third party transfers may be authorized in the MTA that needs to be signed prior to the shipment, with a viral clause extending the application of contractual terms to third parties and to the information obtained through the research undertaken on genetic heritage.

> OPEN QUESTIONS: Should contractual terms dealing with third-party uses and transfers be addressed to ensure compliance with Brazilian ABS Rules? If so, how?

Another set of tools that is relied on the check compliance with Brazilian ABS Rules relates to the establishment of so-called checkpoints. All national authorities involved in product authorisation have the obligation to ask product manufacturers for an express statement, whether positive or negative, regarding compliance with the access and benefit-sharing requirements of Brazilian ABS Rules. This declaration of origin would be required whether the product has been developed on the basis of physical genetic heritage samples, or of genetic heritage information found in digital and non-physical formats. These statements (or declarations) seek to respond to three questions: ''(1) Did the product use genetic resources, genetic heritage or derivatives of genetic material in its composition or elaboration?, (2) If so, were the legal requirements of the country of origin of the appeal observed and met?, (3) Which is the country of origin of the genetic resource?''68. The answers are then sent to the ABS authority, which checks the statements with existing registrations. The notorious requirements that relate to the disclosure of origin in the field of intellectual property rights thus extend in Brazil to the different stages of value chains in all existing biodiversity-linked product authorisation procedures. With specific regards to in silico genetic heritage; from the point of view of Brazilian authorities, ''development agencies should require from databases of genes, proteins, secondary metabolites and other genetic information to implement the declaration of origin requirement of the information used, even if the initial access was not made by the person /company /university that deposits the information in the database''69. For the purposes of Brazilian ABS legislation, the declaration of origin may be limited to the country of origin, without further details.

> OPEN QUESTIONS: How would the declaration of origin requirement be implemented in practice? Which organisations would require it? Does the

68. Personal communication, Ministry of Environment, courtesy translation.

69. Ibidem

declaration envisage situations where the origin of information is unknown? What would be the consequences of such ''unknown origin''?

h. International dimension

With regards to users found outside the borders of Brazil, its ABS Rules can today only rely on the foreign country's private international law system, or its own ABS user compliance rules, if those refer to other countries' national laws, without relying on the Nagoya Protocol itself, as Brazil is not a signatory to the Protocol. For instance, users of genetic resources found in the European Union have a general due diligence obligation to seek ABS related information on the resources they are utilising in the sense of EU Regulation 511/2014, but compliance measures established at European level apply to genetic resources accessed in countries having ratified the Nagoya Protocol70. In this context, due diligence declarations need to be filled according to EU Regulation 511/2014 at the final stage of product development, and the process is centralised around the ABS competent national authorities. In addition, a number of national legal systems require disclosure of origin (or a more limited disclosure of source) in their national patent systems, such as Belgium Germany, Spain and France. The General Guidance document to the EU ABS Regulation71 (which is not legally binding) indicates that ''the use or publication of [sequence] data might be covered by conditions set in the mutually agreed terms, which should be respected. In particular, those who accessed the genetic resources and obtain sequence data from them should respect the conditions of the agreement entered into, and inform subsequent actors about any rights and obligations attached to the data obtained and related to any further uses of it.''. But as aforementioned, the entire array of EU user compliance monitoring rules apply solely to ABS laws of countries having ratified the Nagoya Protocol, and also does not apply to access activities carried out solely on in silico genetic heritage. The EU ABS Compliance rules would indeed 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.

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70. Article 4 of the EU Regulation 511/2014.

71. Commission Notice (2016/C 313/01). Guidance document, op.cit., point 2.3.3. It should be noted that the Guidance document is currently being reviewed, albeit this particular guidance is not part of this review process.

Monitoring the implementation of Brazilian ABS Rules with regards to in silico genetic heritage will not be easy, considering the wide array of information that needs to be gathered, the high number of providers, and its large range of potential uses. However, some mechanisms are currently being developed to try to "capture evidence of the generation and utilisation of genetic information found in digital format, through different information technologies"72. An example of such initiatives is the ABS-Monitoring System (ABS-MS) that has been developed by experts associated with the ABS Capacity Development Initiative (implemented by GIZ) in India. Launched in 2019, the System is a machine-learning tool that integrates information on patents, scientific literature and taxonomic data from relevant data sources across the world, identifies that are of Indian origin, generating reports, statistics and even alert mechanisms73. "The ability to integrate data, including relating to "DSI" from major data sources coupled with scanning of complex documents to track the use of biological resources having Indian origin, should make it a useful tool for the Indian NBA to detect non-compliance (i.e., utilization without seeking approval) with ABS regulatory requirements"74. Brazilian authorities have also openly talked in favour of the Global Multilateral Benefit-Sharing Mechanism in order to resolve challenging situations in which prior informed consent cannot be obtained, such as lack of origin information, transboundary situations or products and reproductive material resulting from multiple access from different origins75.

> OPEN QUESTION: Which type of system could be envisioned in order to facilitate monitoring of compliance with Brazilian ABS Rules?

The Brazilian ABS Rules rely on the willingness and capacity of entities providing genetic information data to require standardised ABS-relevant information for each of their new submissions, as well as a review of the comprehensiveness of existing data vis-à-vis their in situ origin. The information that is needed for such compliance to be operational would thus at minimum include the date and place of acquisition of the physical material or sample (whether from a collection from the ground, purchase or gifting) to which the genetic sequence data is linked. This is why we will now attempt to quickly describe how the potential in silico sources of genetic heritage information operate and seek to identify questions to be debated further during the workshop.

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72. Margo BAGLEY, et al, op.cit., p.21.

73. Detailed information on how the ABS-MS is intended to work can be found here http://indo-germanbiodiversity.com/pdf/publication/publication07-06-2019-1559912567.pdf

74. Margo BAGLEY, et al, op.cit., p.21.

75. Brazil Ministry of Foreign Affairs submission to the CDB, 2017 & Ministry of Environment's submission in 2019, op.cit.

2. WORKFLOWS & SECTORAL CONSIDERATIONS

Science has made considerable leaps ever since the discovery of the building blocks of life by James D. Watson and Francis Crick, so much so that we have entered a new era where the amount of data generated by scientists, researchers and product developers, has reached absolutely gigantic proportions, and has never been easier to get hold of. A working Internet connection, or a simple user profile created thanks to a valid email address now opens the door to a fountain of knowledge on biodiversity, about which the likes of Charles Darwin would be flabbergasted. Coupled with sound scientific knowledge and a good deal of curiosity and inventiveness, information on genetic resources found online could very well be at the heart of the solutions to the serious challenges faced by humankind and all ecosystems. The technology of DNA sequencing and synthetic biology is highly decentralized, as the sequencing, synthesis, storage, assembly, screening and other activities are conducted by different actors, some very specialised in portions of the sequencing chain, and some that operate in multiple jurisdictions. Scientific bodies, universities and sequencing companies play a pivotal role in generating information on genetic heritage and associated resources.

Understanding the concrete practical implications of the inclusion of genetic heritage held in silico within the Brazilian ABS Rules requires a thorough examination of sectoral practices of actors providing such types of information, and of actors using them, whether in a non-commercial research setting or a technological development perspective. Our analysis will as a result distinguish between actors whose main aim is to provide information on genetic diversity (in its broadest term) in in silico conditions, and the good practices that address ABS elements in these sources, as well as the actors who mainly use such information for research and development (and thus generate more information, which will be shared in the platforms provided for by the providers). For the purpose of this section, and notwithstanding the more detailed interpretation of the notion of genetic information that may arise from the workshop based on the questions listed above, we will purposefully describe workflows involving the widest range of information that could potentially be considered as Brazilian genetic heritage, in order to show the impact of the widest understanding, from which it would be easier to derive a more restrictive analysis, if needed.

2.1. Provision of information on genetic diversity in "in silico" conditions

Information that could fall within the scope of Brazilian ABS Rules could take very different forms. from passport data (which describes the identity and origin of the material), to management data (which describes storage conditions, quality of samples and their geographical distribution), to phenotypic data (when applicable, regrouping the characterisation and evaluation data), to genomics data (which includes information on DNA sequence, but also the results of phenomics experiments)76. The recent CBD study on DSI traceability opts for a two-fold approach, distinguishing "Nucleotide sequence data", which designate the different DNA bases, i.e. the nucleotides A,C,G,T uploaded in databases, from "Subsidiary Information", when these datasets extend beyond mere sequence information77. We will maintain this dual terminology in these sections for the sake of clarity, acknowledging that the data falling within the scope of Subsidiary Information can be quite diverse and could warrant further classification. Indeed, genetic heritage information would be found in a very wide array of documentation, from encyclopaedias, compendiums, scientific articles, supplementary files linked to published papers, large-scale scientific collaborative reports, project results and deliverables, to more specific kinds of information like traditional knowledge logs, or online portals of physical specimen collections, or genetic sequences and aggregate data. This information is also held by a large variety of actors, whether private or governmental, in public research institutes' collections or in private companies' laboratories78, and thus adhere to different values, adapting their modus operandi accordingly, whether sheltered in confidentiality or administered by policies of open access.

a. International public DNA sequence databases

As DNA sequence data was beginning to accumulate in the scientific literature on account of technological developments, public databases were set up in the 1970's in order to store and organize the knowledge collected, and common scientific practice started to dictate the publication of DNA sequences in parallel to the publication of scientific articles79. We

76. This useful differentiation is made by Theo VAN HINTUM & Martin BRINK, "Technological and policy challenges to utilization of plant genetic resources', in Robert ZEIGLER, Sustaining Global Food Security: the Nexus of Science and Policy, CSIRO publishing, 2019, p. 37

77. Fabian ROHDEN, Sixing HUANG, Gabriele DROGE, Amber HARTMAN SCHOLZ, et al, CBD combined study on DSI in public and private databases and DSI traceability, Draft for peer review as requested by Decision 14/20 of the CBD COP, available https://www.cbd.int/abs/DSI-peer/Study-Traceability-databases.pdf, p. 1.

78. Sarah A. LAIRD & Rachel P. WYNBERG, op.cit., CBD/DSI/AHTEG/2018/1/3, Executive Summary, pp.9-10.

79. Ibidem, p.10.

have today reached an estimated gigantic volume of 1.500 publicly accessible databases, of very different sizes, focus and data use policies, but that generally-speaking 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 proteins80.

Amongst these public databases, the largest are found under the umbrella of the International Nucleotide Sequence Database Collaboration (''INSDC''), which comprises of the DNA Data Bank of Japan (''DDBJ'', based at the National Institute for Genetics in Japan), the European Nucleotide Archive (''ENA'', based at the European Bioinformatics Institute, ''EMBL'', in the United Kingdom), and GenBank (based at the National Center for Biodiversity Information ''NCBI'' in the United States). These three organizations exchange data on a daily basis. Within the INSDC universe, the most well-known DNA sequence database is GenBank. It releases considerable amounts of genetic sequence data, from the sequence identifiers to their annotations, and makes it available free of charge for every and anyone from the ftp site, updating the release every two months. There are several ways to search and retrieve data from GenBank, either through ''ENTREZ Nucleotide'', or through the use of the BLAST tool (''Basic Local Alignment Search Tool'', which aligns the database sequences to a query sentence and can in the case of GenBank dig into the different information resources of CoreNucleotide, dbEST, and dbGSS independently), or programmatically through the different NCBI e-utilities. In addition, the ASN.1 and flatfile formats are available at NCBI's anonymous FTP server81.. GenBank's sister in the European continent is the European Nucleotide Archive, with its different tools, ranging from the PRIDE (proteomics data), the Immuno Polymorphism – Major Histocompatibility Complex, the European Variation Archive (species genetic variation data) and ENSEMBL (genome browser).

The INSDC is an inescapable actor for the provision of DNA sequence information, as ''95% (705 out of 743) of NSD databases directly link to or download NSD 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''82. As a result, even the very little portion of public databases that are seemingly independent from the INSDC and thus may possess different nucleotide sequence data, adopt the same internal structure for the

80. Ibidem, p.28.

81. NCBI FTP sites: ftp://ftp.ncbi.nlm.nih.gov/ncbi-asn1 and ftp://ftp.ncbi.nlm.nih.gov/genbank.

82. Fabian ROHDEN, et al, op.cit.

identification of accessions. This reliance on a unique identifier, the ''Accession Number'', is an extremely useful for researchers around the globe.

With regards to their policy on data, the INSDC policy, reiterated in 2016, is clearly one of free, unrestricted and permanent access to information83. Its long-established and broadly adopted data infrastructure is also as a result completely oriented towards the open sharing of sequences84. As the database's goal is to provide and encourage full and open access to the most up-to-date and comprehensive DNA sequence information within the scientific community, no restrictions are put by NCBI on the use or distribution of the GenBank data. This does not however mean that no restrictions actually exist on the use of the data provided online. Indeed, the NCBI itself recognises such reality, and even though its disclaimer does not mention ABS requirements as such, the Institute expressly states that it cannot provide comment or unrestricted permission concerning the use, copying, or distribution of the information contained in the molecular databases85. The attachment to the value of open access is extremely strong in all INSDC tools. Even if the release of new submissions can be withheld for a specified period of time at the request of the user for confidentiality, if the accession number or sequence data appears in print or online prior to the specified date of release, GenBank would for instance releases the sequence before the agreed date.

Other more specialised databases also gather sequence information, albeit of a more specific type, like UniProt for example. Developed as a consortium regrouping the aforementioned EMBL-EBI, the Swiss Institute of Bioinformatics and the Protein Information Resource, UniProt's core data is divided into four parts : UniProtKB (knowledge base), UniRef (sequences clusters), UniParc (sequence archive), and proteomes (protein sets expressed by organisms). Uniprot allows queries on regions of origin, although the information will not unequivocally be present in each of its entries. As aforementioned, the database has already been cited in a SisGen registration as a source of in silico Brazilian genetic heritage information used in the development of a finished product. It also uses the BLAST tool, which finds regions of local similarity between sequences. Another example is RNAcentral, which is described as the ''non-coding RNA sequence

83. COCHRANE, G., KARSCH-MIZRACHI, I., TAKAGI, T., and International Nucleotide Sequence Database Collaboration, ''The International Nucleotide Sequence Database Collaboration'', Nucleic Acids Res., 2016, pp.48-50.

84. Ilene MIZRAHI, on behalf of the INSDC, Submission to the CBD call for views and information on Digital Sequence Information on Genetic resources, 01 June 2019, available at https://www.cbd.int/abs/DSI-views/2019/INSDC-DSI.pdf

85. NCBI in this context recognizes that ''some submitters of the original data (or the country of origin of such data) may claim patent, copyright, or other intellectual property rights in all or a portion of the data (that has been submitted). NCBI is not in a position to assess the validity of such claims and since there is no transfer of rights from submitters to NCBI, NCBI has no rights to transfer to a third party'', see Molecular Data Usage policy, https://www.ncbi.nlm.nih.gov/home/about/policies/#disclaimer

database'', coordinated by EMBL-EBI, which provides an integrated view of such sequences by gathering information from various databases that publish data on general RNA sequence information (NCBI RefSeq, ENA, PDBe, Rfam), genomic resources (Ensembl, Gencode, HGNC, CRS), other RNA types (GtRNAdb, snoopy miRbase, TarBase, tmRNA, Modomics, SRP DB), rRNA (GreenGenes, RDP, Silva), lncRNA (Noncode, Lncma, LNCpedia), and model organisms (dictybase, SGD, PomBase, WormBase, FlyBase, RGD, MGI, tair) from an astounding number of different databases. The sequences of RNAcentral all contain functional annotations, which would arguably also be considered part of in silico genetic heritage in the sense of Brazilian ABS Rules.

> OPEN QUESTIONS: What would be the consequence of the absence of link between the genetic sequence and the Brazilian national territory in the database entry? Should data about the origin of ''genetic information'' be provided for by every single entity that publishes information linked to the broad concept of genetic heritage? How could this obligation work in practice? What is the role of databases, if any, in transmitting Brazilian legal requirements?

i. Digital Interfaces of Physical Collections

The second largest repository of genetic heritage information are the digital interfaces of physical collections, whether microbial, germplasm, and other structural or thematic components of genetic diversity. Most germplasm collections today possess an online interface, with information of different types, both on the resources themselves, and on their origin, depending on the objective of the collections, and their capacity. These interfaces generally regroup passport data as a minimum, at times coupled with genomics data, and relatively lengthy phenotypic data86. The largest of these is the United States' Germplasm Resources Information Network (GRIN)87 web server. The US Department of Agriculture's Agricultural Research Service's platform is one of the most complete sites, and provides germplasm information about plants, animals, microbes and invertebrates. The origin of each accession is generally indicated for each entry, and Brazil is identified as the origin of 484 accessions, being cited in the description of an additional 16 accessions. For each accession, the reader is provided with relatively detailed taxonomic data, common names, economic importance, distributional range, references, along with the details of the

86. Theo VAN HINTUM and Martin BRINK, op.cit., p. 38.

87. GRIN : https://npgsweb.ars-grin.gov/gringlobal/search.aspx

specific repository where samples may be available from. The database user can search accessions that have genomic data or have a NCBI link provided for in their description. Such data is available for 64 accessions mentioning Brazil (either as a place of cultivation or as the origin of the sample), with a specific link to ENTREZ, NCBI's search engine for PubMed citations & GenBank sequences. The link to NCBI is however only made on the higher taxa level, not on the specific sample.

Microbial collections also provide directly some genetic sequence information, coupled with other data about the microorganisms found in their collections. The World Data Centre for Microorganisms (''WDCM''), set up as a data centre by the World Federation for Culture Collections (''WFCC''), regroups a wide array of information resources, whether related the management data, passport data, and genomics data stemming from microbial culture collections. The most relevant resources in the context of the Brazilian ABS Rules are probably the ATCC reference strain databases, the GCM Type strain genome database, and the gcMeta Microbiome Research Platform, which all provide quite detailed genomics data on each organism, compared to the Global Catalogue of Microorganisms, which compiles information on the date of isolation, the history of the deposit, the organism's geographic origin, its optimum temperature for growth and associated literature88. Going into much further detail, the ATCC Bacteriology Collection is a diversified assemblage of prokaryotes, containing more than 18,000 strains in over 750 genera, and holds more than 3,600 type cultures of validly described species, and nearly 500 bacteriophages. It has an online database for bacterial genome sequencing strains89, where you can find information on genomic sequences of the strains that can be ordered from the collection itself. The data provided on the database is governed by the ATCC Data Use Agreement90, and downloaders of the data expressly agree to use it for non-commercial research only. Furthermore, they cannot share or publicly post the data, nor transfer it to third parties, nor aggregate it for use in any public database. Information about the origin of the strains can be provided for, but its presence is not uniform, as the person consulting the data is often faced with incomplete or missing data. Within the ATCC system, a product name with a unique identifier is given to each entry.

88. Global Catalogue of Microorganisms: http://gcm.wfcc.info/ Although the geographic origin of organisms is indicated when the information is available, it cannot be searched

89. ATCC Reference Strain Collections : https://genomes.atcc.org/genomes

90. The ATCC Data Use Agreement can be found in https://www.lgcstandards-atcc.org/Documents/Product_Use_Policy/Data_Use_Agreement.aspx?geo_country=tr (accessed October 2019)

Currently the only registered collection in the framework of EU Regulation 511/2014, the Leibniz Institute DSMZ-German Collection of Microorganisms and Cell Cultures (''DSMZ'') has set up quite a complete system, that also accommodates for the potential restrictions that could be put on the use of material held in their collections in research and development through foreign legislative measures or even contractual terms. The DSMZ catalogue includes all documents relevant for Nagoya Protocol compliance (even for material that could theoretically be outside the scope of EU Regulation 511/2014), including PIC, MAT, Internationally Recognised Certificates of Compliance (IRCC) and/or additional (depositor-originated) MTAs91. DSMZ relies on clear institutional terms and conditions for the use of their material and data, establishes mechanisms to transfer obligations stemming from signed contractual arrangements, but also ensures transparency in their catalogue. Its online catalogue regroups bacteria, archaea, plasmids, fungi, bacteriophage and cyanobacteria, includes available GenBank accession numbers, and more interestingly a specific item on each product page on ''known Nagoya Protocol restrictions'' on the use of the strain. It should however be noted that as the EU ABS Compliance Rules only apply to national ABS laws of Parties to the Protocol, no reference would need to be made under this specific item of DSMZ product pages to restrictions that may derive from national ABS laws of countries that are not Parties to the Protocol, like Brazil.

> OPEN QUESTIONS: How would the digital interfaces of material collections be integrated into the notion of Brazilian genetic heritage? Are their obligations the same as the International public sequence databases?

j. ''Subsidiary Information'': associated, aggregate data & research results

As the notion of Brazilian genetic heritage is potentially considerably broad, the Brazilian ABS Rules would not solely regulate access to genome sequence databases, they would extend to all databases compiling information on genetic diversity in its broadest understanding, including research results on genetic samples as such and the interfaces compiling information on the genetic heritage's environment and the ecosystems where it evolves.

Databases that compile subsidiary information on genetic diversity are too many to try to compile exhaustively in this document, which will only provide some illustrative examples. In the field of agriculture, several databases are maintained by the United Nations' Food and

91. Margo BAGLEY, op.cit., pp.50-51.

Agricultural Organisation (''FAO''). Brazilian ABS Rules do not set up a specific system for genetic heritage used in food and agriculture, but do not require Prior Informed Consent at the acquisition of such heritage, and provide for an in-built mechanism for benefit-sharing in case of change of intent and use of agricultural genetic heritage for industrial purposes. All data that relates to Brazilian genetic heritage, whichever the context in which they are created, would indeed fall within the remit of Brazilian ABS Rules92. As an example of these food and agricultural science databases, one can cite AGRIS93, the International Information System for the Agricultural Science and Technology, which is a collaborative network of more than 150 institutions from 65 countries, containing more than 7 million records covering all areas of interest to FAO, including food, nutrition, agriculture, fisheries, forestry, environment etc. Arguably, the use of genetic information found in AGRIS relating to plants of Brazilian origin, if used in a context of research and development could fall under the realm of the Brazilian ABS Rules. GARDIAN, the Global Agricultural Research Data Innovation & Acceleration Network94, an initiative of the Consultative Group on International Agricultural Research (''CGIAR''), brings together the incredibly wide data and knowledge resources produced by the different CGIAR centres. The ''Dataverse''95, the Agri-Environmental Research Data Repository managed by the University of Guelph in Canada is another smaller example. It compiles data on research projects carried out by university staff and affiliated researcher, and includes genomic data, SSR markers, soil quality and composition measurements. MetaCrop96 is a database maintained by Leibniz Institute of Plant Genetics and Crop Plant Research (IPK), that summarizes diverse information about metabolic pathways in crop plants and allows automatic export of information for the creation of detailed metabolic models. It includes 60 major metabolic pathways in various crop plants with special emphasis on the metabolism of agronomically important organs such as seed or tuber. Some information resources regroup the results of larger-scale research projects or contextualise them for better use of the scientific community. One can cite the Rice Annotation Project, which compiles the results of the International Rice Genome Sequencing Project, in order to facilitate the analysis of the genome structure97. Another example comes from the NCBI BioProject (formerly Genome

92. Henry Philippe Ibanez de Novion and Letícia Piancastelli Siqueira Brina, ''Brazilian National Implementation of Access and Benefit-sharing'', in Proceedings of the International Workshop on Access and Benefit-sharing for Genetic Resources for Food and Agriculture, CGRFA, Rome, 2018, http://www.fao.org/3/CA0099EN/ca0099en.pdf

93. AGRIS, https://agris.fao.org

94. GARDIAN, https://gardian.bigdata.cgiar.org/#!/

95. DATAVERSE, https://dataverse.scholarsportal.info/dataverse/ugardr

96. METACROP http://metacrop.ipk-gatersleben.de/apex/f?p=269:111

97. The RAP uses GBrowse, its own data tracker, but is also connected to NCBI Blast to search for relevant data : see https://rapdb.dna.affrc.go.jp/

Project), which is a collection of genomics, functional genomics, and genetics studies linking to their resulting datasets. This resource describes each project's scope, its material and objectives and aggregates diverse data types which are often stored in different databases, which usually makes them difficult to find due to inconsistent annotation and multiple independent submissions98.

Another large effort combining different data sets is the Global Genome Biodiversity Network (GGBN), formed in 2011 to make high-quality well-documented and vouchered collections storing DNA or tissue samples of biodiversity, discoverable for research through a networked community of biodiversity repositories. This is achieved through the GGBN Data Portal99, which links globally distributed databases and bridges the gap between biodiversity repositories, sequence databases and research results. It is useful to note that the "GGBN document library permits users to perform full text searches for documents including publications, example use case documents on material transfer agreements (MTAs) and codes of conduct related to ABS"100.

> OPEN QUESTIONS: Would associated data accessed through these databases be considered Brazilian genetic heritage if the link with the Brazilian national territory is made in the database entry?

2.2. Good practices that address access to in silico genetic information

Good practices for the storage, management and transfer of physical genetic resources in compliance with ABS laws have grown in number considerably in the past decade. However, most do not target the issue of genetic heritage information to be found in silico. Nonetheless, as they tend to address the daily practices and workflows of scientists and researchers active in a wide range of sectors, they will inevitably contribute to raising awareness of the significance of ABS-related information. This may include to the transfer of such ABS information at the time of upload and transfer of sequence data and/or subsidiary information. Amongst such best practices that address the issue of third-

98. NCBI Bioproject: https://www.ncbi.nlm.nih.gov/bioproject

99. GGBN Data Portal : http://data.ggbn.org

100. Gabriele DROEGE et al, "The Global Genome Diversity Network Data Portal", Nucleic Acids Res., 2014 Jan 1, p.42

party transfers, although not directly addressing processes that link ABS and sequence information, is the Consortium of European Taxonomic Facilities (''CETAF'') Code of Conduct and Best Practices101. Other notable efforts come from the Global Biodiversity Information Facility, an international network and research infrastructure based in Copenhagen, which provides data-holding institutions around the world with common standards and open-source tools that enable them to share information about where and when species have been recorded, most of which comes from museum collection or observations. It relies on the Darwin Core102, a standard file format that establishes a common language for data exchange and thus the collaborative effort of more than 1200 institutions in 123 countries that willingly share data.

Perhaps the most comprehensive good practices that address ABS elements stem from the world of microbiology. The role of microbial collections is to provide material, expertise and data that is not only fit for purpose, but also comes with legal certainty, which is why open access to data should be coupled with accurate identification of strains103. The TRUST (Transparent User-friendly System of Transfer) system has as a result been gradually established, with both legal and technical elements. Legal certainty and compliance aspects of TRUST are based on MOSAICC (Micro-Organisms Sustainable use and Access regulation International Code of Conduct)104, and the new e-TRUST optimises information flow, linking the ABS Clearing-House with sectoral databases. For instance, Minimum Data Set records in microbial culture collections include due diligence elements (on source & origin of organisms), contains administrative references (like PIC or IRCC) and is coupled by scientific data useful for the identification of the microorganism. As a result of these efforts, the TRUST system is associated with the Global Catalogue of Microorganisms (GCM)105, which is an automated powerful integrated data management and processing system able to provide much information related to microbial material. The GCM links the strain itself with detailed geographical information of its isolation, and thus establishes a clear geographic origin.

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101. CETAF Code of Conduct https://cetaf.org/sites/default/files/final_cetaf_abs_coc.pdf

102. GBIF Darwin Score : https://www.gbif.org/darwin-core

103. Philippe DESMETH, ''Open Science, Open Data & the Nagoya Protocol: Legal certainty in uncertain times'', presentation at the WDCM GCM 2.0 Type Strain Sequencing Project Workshop, November 2018, available at http://www.wdcm.org/wdcm2018/pdf-11-22/8.1%20Open%20Data%20and%20Nagoya.pdf

104. For the updated version of the MOSAICC: http://bccm.belspo.be/documents/files/projects/mosaicc/code2011.pdf

105. http://gcm.wfcc.info/

Another initiative worth mentioning with regards to international exchanges of genetic sequence data with an in-built benefit-sharing mechanism is the World Health Organisation's Pandemic Influenza Preparedness (''PIP'') framework. Adopted in 2011, the PIP framework's main objective is to improve preparedness and response against pandemic influenza, by sharing influenza viruses with human pandemic potential through the Global Influenza Surveillance and Response System's Terms of Reference. Although the framework does not directly target nor include genetic sequence data, and rather focuses on viruses, the PIP Review Group found in 2018 that many genetic sequences of ''novel influenza viruses with pandemic potential'' were rapidly shared in accordance with the aforementioned Terms of Reference, which include two types of benefit-sharing106.

OPEN QUESTION: How could communication about best practices be developed, and how can ABS functionality of databases be reinforced?

2.3. Use of in silico genetic information

In order to set a full picture of the stakeholders involved in the acquisition (by means of download and transfer) and in the access (experimental or applied research and product development), it is useful to delve into the different uses that can be made today with genetic heritage information acquired from in silico sources. Genetic information found in silico can be used for food security, safety and public health reasons, for instance in the context of diagnostics. It is also used across scientific disciplines to contribute to the conservation and sustainable use of biological diversity, generally by increasing knowledge on existing diversity, its ecosystem, accompanying threats, and also for the identification of species and taxonomy, which is crucial to feed into conservation policies and efforts107. In this context, DNA barcoding uses short genetic markers that represent either gene fragments, or non-functional elements of the genome, which are selected because they show rapid changes as species and populations diversify. This makes the markers ideally suited for species-level identifications, but these sequences have limited value except as part of a system of DNA barcodes to support species identification. Consortia such as the International Barcode of Life run projects, the most comprehensive one being

106. World Health Organisation, ''Approaches to Seasonal Influenza and Genetic Sequence Data under the PIP Framework'', December 2018, available at https://www.who.int/influenza/pip/WHA70108b_Analysis.pdf

107. CBD Secretariat, Synthesis of views and information on the potential implications of the used of digital sequence information on genetic resources for the three objectives of the Convention and the objective of the Nagoya Protocol, CBD/SBSTTA/22/INF/2, pp.5-10.

BIOSCAN, to develop biodiversity observation and monitoring protocols applicable to whole ecosystems, but it depends "for its effectiveness on the comprehensiveness and openness of the data included in the reference library"108. Biodiversity biobanks are much better suited for modern downstream molecular applications (e.g. second- and third-generation sequencing requiring high-quality DNA), as their focus lies explicitly on conserving the molecular structure of their samples. Such downstream applications can range from industrial biotechnology, which relies mostly on enzymes and micro-organisms to produce bio-based products, while in the healthcare realm the applications are even more far-reaching, as they contribute to the development of advanced gene and stem cell therapies, different diagnostic tools, but are also useful for more useful vaccines109. In agriculture and breeding (whether plant or animal), genetic information tends to be mined in the search for genes of interest, understanding interactions, and increasingly accelerate the breeding process itself to achieve targeted uses of genetic diversity110.

As a conclusion, it is safe to say that most platforms that publish and thus distribute in silico genetic information operate on an undeniable focus on open access to data. The submissions of several research institutes and organisations to the CBD process on DSI underline the universal values behind these practices: open access, cooperation, unfettered exchange and the transboundary flux of knowledge111. In large sequence databases, no restrictions are put on the download and transfer of data. The Brazilian authorities recognise that, "although genetic sequence databases require the provision of several different pieces of information regarding the submitted sequences, in many cases the necessary data for its traceability is not required, or the requirement of information is not mandatory, which makes the precise determination of its source very difficult"112. In digital interfaces of physical collections, the open access focus is accompanied by terms of use that are more relaxed for non-commercial research, with a more cautious approach to allow commercial research and development with the resources provided. Although ABS functionality is increasingly added to collection and database management systems, it is

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108. Paul HEBERT and Donald HOBERN, International Barcode of Life Consortium, Submission to the CBD process on DSI, 28th June 2019, https://www.cbd.int/abs/DSI-views/2019/iBOL-DSI.pdf

109. Sarah LAIRD, op.cit., pp. 24-25.

110. Submission of the Consultative Group on International Agricultural Research to the CBD process on DSI, available at https://www.cbd.int/abs/DSI-views/CGIAR-DSI-en.pdf

111. CBD Secretariat, Synthesis of views, op.cit., p.16-20.

112. Ministry of Foreign Affairs of Brazil- Environment Division, submission 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, op.cit.

very rarely structurally accommodated, and would require quite high levels of investments, both in terms of structural financing and in terms of human resources. TRUST, arguably the most advanced system which includes fields on the origin but also the terms of use of the data or the material in question, is not yet completely equipped to ensure compliance with ABS Rules. The draft CBD study on traceability of digital sequence information states that ''scientists could improve traceability during the submission process to INSDC by improving reporting on availability and country of origin, while the INSDC could stringently enforce country of origin requirements on new submissions and improve metadata fields for enabling a stable link from [Internationally recognised Certificates of Compliance] and information on when [genetic material] was accessed from the country of origin''113. However, the same study also underlines that even through traceability systems could be put in place for nucleotide sequence data, such an endeavour would be far more difficult and possibly technically impossible with regards to ''subsidiary information'' linked to genetic resources114.

> OPEN QUESTION: Which systems or tools could be envisaged (either within the database systems themselves or outside of their realm) in order to increase the linkages between ABS-related information and genetic information provided by the wide array of databases concerned by the notion of Brazilian genetic heritage?

113. Fabian ROHDEN, et al, op.cit. p. 4.

114. ''Although the tracing of NSD (nucleotide sequence date) is technically challenging and requires user awareness and compliance, it is technically feasible. SI (subsidiary information), on the other hand, is unlikely to be traceable or, in a best case scenario, would sometimes be traceable in some data formats under some conditions, i.e., there would be many different technical and scientific contingencies [leading to] an administrative nightmare of a patchwork of different data types, databases, contingencies, rules, etc'', Ibidem, p. 54.

SECTION 3. OPEN QUESTIONS & AVENUES FOR FURTHER DISCUSSION

Based on our analysis, there are numerous open questions and elements that would benefit from further discussion during the workshop.

These issues mainly touch upon (1) the notion of genetic heritage itself, (2) the different triggers of ABS obligations when acquiring and accessing genetic heritage information from in silico sources, (3) the availability of ABS information in the hands of the providers of in silico genetic heritage information (including the difficulties of establishing origin faced by complexity in research and development based on genetic diversity), and (4) the challenges linked to monitoring of compliance with Brazilian ABS Rules, especially in the in silico context.

1. THE NOTION OF GENETIC HERITAGE

- *Does the concept of genetic heritage include all types of information on "plants, animals, and microbial species, or any other species, including substances originating from the metabolism of these living organisms", and also extend to the physical genetic resources that are the vectors of such information?*
- *Does the notion of genetic heritage encompass all types of genetic sequences, protein expressions, metabolites, but also phenotypic and associated data? Is there a conceptual limit set to its reach?*
- *Would the term "genetic information", which defines the concept of genetic heritage, be interpreted restrictively to designate information on genes, and more particularly genetic sequences?*
- *When would a population originating from another country considered to have developed distinctive characteristics in Brazil?*
- *Is genetic heritage information (including its physical counterparts and microorganisms isolated from substrates originating from Brazil) held in collections outside Brazilian national territory, be considered in scope of the Brazilian ABS Rules?*

- *What is the clear temporal trigger of Brazilian ABS Rules? Does a recent date of access trump the fact that a Brazilian genetic heritage resource had been acquired before 30th June 2000?*

- *When is Brazilian Genetic Heritage considered to be "one of the main elements adding value to the finished product" (thereby triggering economic exploitation notification obligations) and how would this expression be interpreted in different contexts?*

2. TRIGGERS OF OBLIGATIONS FOR ACCESSING GENETIC HERITAGE FROM IN SILICO SOURCES

- *Would the consultation of genetic heritage information by email, by Brazilian and/or foreign entities trigger a SisGen registration?*

- *Would the publication or the download of genetic heritage information by Brazilian and/or foreign entities trigger a SisGen registration? Would the download of genetic heritage by a foreign entity trigger an obligation to enter into an association with the Brazilian institution?*

- *Would the transfer of genetic heritage information by email or another digital format, by Brazilian and/or foreign entities trigger a SisGen registration?*

- *Would genetic sequence information deriving from an organism clearly originating from within Brazilian territorial borders, but accessed from a privately held database, fall within the scope of the Brazilian ABS Rules? What would be the consequence of the absence of registration of access to such genetic heritage?*

- *How would the Brazilian ABS Rules adapt its access and benefit-sharing triggers to products developed with the use of multiple different genetic sequences, and especially the use of sequences from multiple different origins?*

- *How does the distinction between intermediate and finished product operate in complex and cumulative value chains?*

3. ABS INFORMATION IN POTENTIAL IN SILICO GENETIC HERITAGE INFORMATION SOURCES (AVAILABILITY AND TRANSFER)

- *Since genetic heritage information is being downloaded and used globally in silico format, at very high levels, frequently by automated or semi-automated systems, and often in sets that are geographically, temporally and taxonomically mixed, can users be made aware of the components that fall under the Brazilian legislation and, if so, how?*
- *What are the legal and practical implications of the publication and transfer of incomplete data considered as or associated with in silico genetic heritage?*
- *What would be the consequences of the absence of link between the genetic sequence and the Brazilian national territory in a database entry?*
- *What are the exact consequences of accessing (i.e. in a context of research and development) genetic heritage in digital format without accompanying information as to its geographical origin?*
- *Should data about the origin of "genetic information" be provided for by every single entity that publishes information linked to the broad concept of genetic heritage? How could this obligation work in practice?*
- *What is the role of databases, if any, in transmitting Brazilian legal requirements?*
- *How would the digital interfaces of material collections be integrated into the notion of Brazilian genetic heritage? Would their obligations be the same as the International public sequence databases?*
- *Would associated data accessed through these databases be considered Brazilian genetic heritage if the link with the Brazilian national territory is made in the database entry?*
- *How could communication about best practices be developed, and how could the ABS functionality of databases be reinforced (if it should be)?*
- *Which systems or tools could be envisaged (either within the database systems themselves or outside of their realm) in order to increase the linkages between ABS-related information and genetic information provided by the wide array of databases concerned by the notion of Brazilian genetic heritage?*

4. COMPLIANCE

- *How is the question of third-party transfers of genetic heritage approached in Brazilian ABS Rules and in particular in its model MTA? How is institutional practice dealing with such?*

- *Should contractual terms dealing with third-party uses and transfers be addressed to ensure compliance with Brazilian ABS Rules? If so, how?*

- *Would it be possible to monitor the use of Brazilian genetic heritage, especially information found in silico, and who would do this?*

- *Would the sanctions system of the Brazilian ABS Rules impact the publication, transfer and use of genetic heritage information found in silico? How?*

- *Would the sanctions system target access of in silico Brazilian genetic heritage only if a link with Brazilian sovereign territory can be established in existing documentation in computer format? If not, how would it deal with the lack of ABS information?*

- *How would the declaration of origin requirement in all Brazilian product authorization procedures be implemented in practice? Does the declaration envisage situations where the origin of information is unknown? What would be the consequences of such "unknown origin"?*

- *How could compliance mechanisms set out by signatories to the Nagoya Protocol be used for monitoring compliance with Brazilian ABS Rules (whether Brazil ratifies the Protocol or not)?*

- *Which type of system could be envisioned in order to facilitate monitoring of compliance with Brazilian ABS Rules?*

SECTION 4. SCENARIOS

Participants will collectively discuss and resolve these scenarios during the Brasilia workshop. Working in groups of 5 to 6 persons, ideally with a geographical, gender and background balance, participants will be asked to identify the legal and procedural obligations that are incumbent upon each actor present in the specific scenario and respond to the specific questions asked below. They will identify key dissenting points and common understandings, and report back to plenary in the format provided for by the consultants. The entire group will then be invited to compare each groups' approach and their answers in an open debate guided by moderators.

1. PERFECT DAY

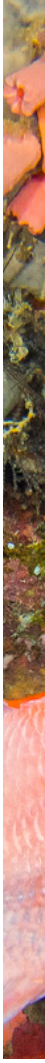
Ilona, a Latvian doctoral researcher based in a public University in Riga (Latvia), wishes to better understand the pigmentation process of common beetles through phylogenetic analysis, identifying the sequence behind the expression of certain colours. Although she is part of a University research team and has teaching duties within her department, the equipment and financing needed for her doctoral research is entirely financed by a Norwegian chemical company wishing to expand its pigments business in the long term. Ilona identifies thirty different sequences on GenBank, which were all uploaded in the scope of the Beatlemania European research project in 2017. Contacting the researchers that have conducted the prior research, Ilona obtains additional information related to the sequences, which have been retrieved from beetles that were acquired by researchers in Brazilian national territory in 2016. They forward her the complete dossier, including permits for collection, access registration information and the contractual terms they have signed and registered with SisGen before the shipment of the samples.

- *Would the beetles and associated genetic sequences be considered Brazilian genetic heritage?*
- *Does Ilona need to submit an access registration on SisGen for her doctoral research? What would she need to do (procedurally) and at which moment? Who would submit the forms and take on responsibility?*

- *What could Brazilian authorities do to monitor compliance of (1) Ilona & (2) the Beatlemania researchers with the Brazilian ABS Rules?*
- *Would the database have any role to play in this scenario? What about EU ABS authorities?*
- *What if the sponsoring chemical company develops a pigment based on Ilona's research?*

In 2017, Ilona isolates and identifies the properties of luciferase, which is the enzyme that gives one of the beetles its bioluminescent character. She sends this enzyme to Wěi the same year, another researcher working in China on the development of easy and cheap adenosine triphosphate (ATP) assay kits that Ilona herself uses in her own research. He does not receive any information on the origin of the luciferase from Ilona. Wěi uses the identified luciferase to develop a new kit for microbial detection, without relying on its bioluminescence, and obtains a patent for it in China, in the United States and in Brazil in 2018. The kit, which is commercialised in these countries by Wěi's start-up established in Beijing the year after, becomes an essential tool to companies active in the pharmaceutical, clinical and in food and beverage fields.

- *Would the luciferase be considered Brazilian genetic heritage?*
- *What would be the status of the ATP kits under Brazilian ABS Rules?*
- *Has Ilona complied with Brazilian ABS Rules? Would she have any obligation under the EU Regulation 511/2014?*
- *What would Wěi's obligations be under the Brazilian ABS Rules?*
- *What could Brazil do to ensure that both Ilona & Wěi comply with its national ABS Rules?*
- *Which authorities could have a role to play to ensure compliance with Brazilian ABS Rules in this scenario?*



2. A TIMELY YERBA TREE OF LIFE

Klaus, a plant enthusiast and seed saver from Germany, is given some native yerba mate plants as a gift by local amateur botanists while in Brazil in 1991. He subsequently plants the seeds and grows successive generations of the plants in his garden in Europe for personal use. He regularly exchanges plant cuttings and seeds with other biodiversity enthusiasts. In 1999, he provides Matthias, a molecular biology researcher at the local university, with samples, indicating that he received the plants years ago from Brazil. The researcher sequences the plant's DNA to try to determine metabolic pathways and identify different factors and genes responsible for heat tolerance. He sends the sequence data and other information to researchers he collaborates with in two European institutes, in a Brazilian University and a freelance researcher from Argentina. Together they publish their findings in an open-access journal, including an analysis of the agro-ecological cultivation conditions that they believe to be responsible for enhanced heat tolerance, and highlighting the history of the samples. They deposit the sequence to GenBank in 2002, but without indicating any geographical origin.

- *Would Klaus have any obligations under Brazilian ABS Rules?*
- *Would the yerba mate studied by Matthias the researcher, be considered Brazilian genetic heritage? What about the associated information published in the journal article?*
- *Would the group of researchers have any obligations under Brazilian ABS Rules?*
- *What could Brazil do to ensure that Klaus and the group of researchers comply with its national ABS Rules?*
- *Which authorities would have a role to play to ensure compliance with Brazilian ABS Rules in this scenario?*

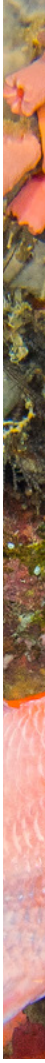
Having read Matthias' findings, François, a French plant breeder connects with Klaus and obtains some tree cuttings from him in 2003. He adds the specimen to his own private breeding pool of yerba mate, and after years of crossing and selection efforts, he stabilises a variety optimised for use as diet supplements for dairy cows to improve their productive and reproductive performance in 2013. The variety combines germplasm from Argentina, Bolivia, Uruguay, Paraguay, and the samples obtained through Klaus. As yerba

mate (ilex paraguariensis) is not a regulated species, its seeds can be marketed in the EU without prior variety registration. François therefore quickly contacts Guy, a seed multiplier who has contacts in the feed industry and specialised nurseries. The contract they sign states that the multiplication and marketing of seeds would be done exclusively by Guy's company, under supervision from François.

- *Would the yerba mate developed by François be considered as Brazilian genetic heritage?*
- *Would François have any obligations under Brazilian ABS Rules?*
- *What could Brazil do to ensure that François comply with its national ABS Rules?*
- *Which authorities would have a role to play to ensure compliance with Brazilian ABS Rules in this scenario?*

Leyla, a bright product developer for a Moroccan start-up company, takes an interest in Klaus' findings while doing a literature review in 2015. She downloads the sequence from Genbank and the journal article to start further enquiries about the commercial potential of yerba mate. After months of research, she identifies an enzyme that shows great promise to be used as an agent in washing powder. Together with her employer, they file a patent application at the European Patent Office in 2016, covering the enzyme and its inclusion in washing powder. Once the patent has been granted in 2017, they contact the Spanish biological household product company Ecologica to develop a product line using their enzyme. Manufacturing and marketing of the products starts in 2018, and covers the European Union and Morocco.

- *Would information used by Leyla considered Brazilian genetic heritage?*
- *Would the enzyme be considered an intermediate or a finished product?*
- *What should Leyla do to comply with Brazilian ABS Rules in her situation and state of knowledge?*
- *What could Brazil do to ensure that both Leyla & Ecologica comply with its national ABS Rules?*
- *Which authorities would have a role to play to ensure compliance with Brazilian ABS Rules in this scenario?*



3. A STRAIN REACTION

Thor, a Danish researcher isolates the bacteria Lactobacillus plantarum from pickled cabbage bought in a farmers' market in Brazil in 2015, after sequencing it in Aarhus University through Illumina & Oxford Nanopore technologies two months later. He then uploads the sequence data to the ATCC genomes database, indicating the origin of bacteria as Brazil. He also passes the sequence information informally and directly via email to Odin, a former colleague, without mentioning where he got the bacteria from. Odin is now a researcher in a private biotechnology start-up active in synthetic biology in Denmark. He recreates the organism thanks to the information received and uses it in the development of a synthetic biopolymer to be used in biomedical applications, especially in drug delivery. The start-up applies for two patents, first on the biopolymer itself, and secondly on its integration into an efficient drug delivery system via a self-disintegrating capsule, in the European Union and the United States in 2018. Capsulus, a niche pharmaceutical company based in the United States, negotiates an exclusive license for both patents to manufacture capsules of vitamin supplements for toddlers. However, it uses the infrastructure, network and name recognition of BigPharma, based in Switzerland, to commercialise the capsules worldwide, including in Brazil in 2019.

- *Would the bacteria, its sequence information, the polymer and the capsules be considered Brazilian genetic heritage?*
- *What would be the obligations of Thor, Odin, the start-up, Capsulus and BigPharma under Brazilian ABS Rules?*
- *Would a SisGen registration of access be required? By whom and when?*
- *Would a finished product notification be required at SisGen? By whom?*
- *What could Brazil do to ensure that these actors comply with its national ABS Rules?*
- *Which authorities would have a role to play to ensure compliance with Brazilian ABS Rules in this scenario?*

In 2015, Gabriel, a researcher in a private Brazilian company, downloads the sequence information from the ATCC database, together with all associated information, including its country of origin. At the same time, he downloads fifty Lactobacillus plantarum sequences, and notices that another strain has the same sequence as the Brazilian strain but originating from Japan. Next to this strain, he identifies three other strains useful for

the development of probiotics: two of them with no origin information, and one isolated in Indonesia. He buys and combines all the strains to develop his product, using the strain originating from Japan rather than the one from Brazil. In 2018, his company is ready to commercialise his probiotics in Brazil and neighbouring countries.

- *Would the strain used by Gabriel be considered Brazilian genetic heritage?*
- *What would be Gabriel's obligations under Brazilian ABS Rules? What would be the threshold to require a finished product notification?*
- *What could Brazil do to ensure he complies with Brazilian national ABS Rules?*
- *Which authorities would have a role to play to ensure compliance with Brazilian ABS Rules in this scenario?*

ANNEXES

ANNEX 1: Brazilian Law 13.123

ANNEX 2: Brazilian Decree 8772

ANNEX 3: CGen Resolution no. 12, of 18th September 2018 (model MTA)

ANNEX 4: CGen Resolution no.13 of 18th September 2018 (in silico)

ANNEX 5: Brazil's submission to the CBD DSI Consultation, 2019

ANNEX 6: Workshop Programme "at a glance"

PRELIMINARY WORKSHOP PROGRAMME

BRASIL-EU DIALOGUE ON *IN SILICO* GENETIC HERITAGE IN ABS LEGISLATIONS
DIÁLOGO BRASIL-UE SOBRE PATRIMÔNIO GENÉTICO IN SILICO NAS LEGISLAÇÕES ABS
BRASILIA, 2019

Date:
December 10-12, 2019

Location:
CONCEA Meetings Room, Ministry of Science, Technology & Innovations (MCTI), South Police Sector - SPO, Quadra 3, Área 5, Bloco E. CEP 70610-200 / Brasília- DF, Brazil. Phone: +55 (61) 3411-5000

Purpose:
The overall objective is to stimulate scientific and technological exchange between Brazil and the EU through providing information on procedures for access, management of ABS agreements, and provision of supporting tools, aiming to increase interest and investment in knowledge and legal exploitation of Brazil's Biological Diversity, contributing to its conservation and sustainable use. Workshop participants will look at practical implications of access to genetic heritage, focusing on the information of genetic origin acquired from databases. They will identify open issues, especially with regards to access to genetic heritage found in silico. The workshop aims to explore potential solutions and develop tools to enhance the understanding of Brazilian ABS Rules & the EU ABS compliance system.

DAY 1: TUESDAY 10TH DECEMBER 2019 | 09:00 – 18:00

Session 1	Opening Session Introduction to Program & Workplan Tour de Table (presentation of participants)
Session 2	Legislative Updates from Brazil & the European Union
Session 3	Digital Sequence Information (DSI) in the International Policy Context & in the Brazilian Law
Session 4	Background Paper Presentation
Session 5	In silico Genetic Heritage and ABS

DAY 2: WEDNESDAY 11TH DECEMBER 2019 | 08:30 – 18:00

Session 6A	In silico Genetic Heritage and ABS
Session 6B	In silico Genetic Heritage and ABS
Session 7A	Scenarios-based Workgroups
Session 7B	Scenarios-based Workgroups
Session 8	Workgroups Results Presentations to Plenary & Discussion

DAY 3: THURSDAY 12TH DECEMBER 2019 | 08:30 – 12:30

Session 9	Workgroups Results Presentations to Plenary & Discussion
Session 10	Conclusions & Closing Remarks
Session 11	Closing Session

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