Dialogues
EUROPEAN UNION · BRAZIL

European Union

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

Diálogo Brasil-UE sobre patrimônio genético in silico nas Legislações ABS

WORKSHOP REPORT

Brasilia, 10th – 12th December 2019

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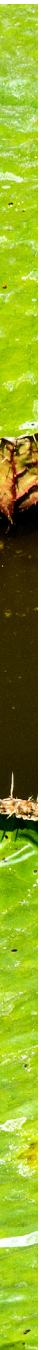

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OBJECTIVES

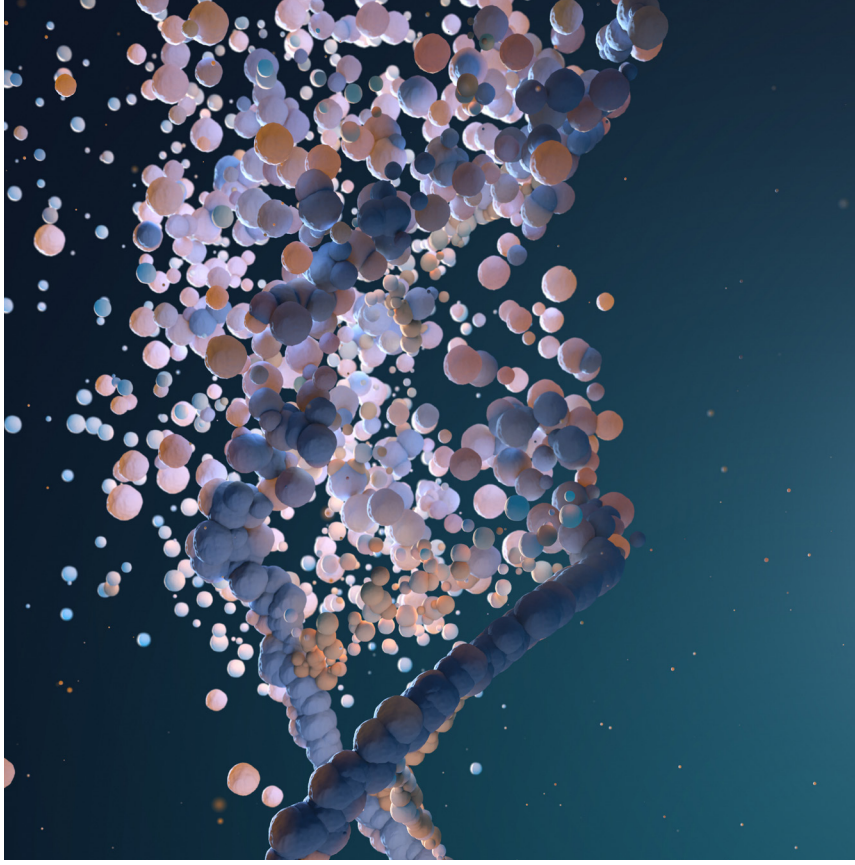
Held within the Sector Dialogue framework, which seeks to further develop mechanisms and tools to facilitate scientific and technological exchange and cooperation between Brazil and the European Union (''EU''), the workshop was convened as a means to better understand the scope of Brazilian Rules governing access and benefit-sharing (''ABS''), their relationship to those adopted at the level of the EU, but also their practical implications, strengths and shortcomings, with specific regards to the regulation of genetic heritage accessed from *in silico* sources.

The overall objective of the workshop held in Brasilia from the 10th to the 12th December was to stimulate scientific and technological exchange through the provision of information on procedures for access to Brazilian genetic heritage, most particularly from so-called *in silico* sources, and lift procedural uncertainties that remained with regards to the general functioning of Brazilian Rules. Held in Brasilia in the premises of the Brazilian Ministry of Science, Technology and Innovations (MCTI), the workshop gathered around 20 participants from both European and Brazilian public authorities and stakeholders, whether researchers, users or legal consultants.

Prior to the gathering, participants received a detailed *background paper*, which will also be made available online, and which analysed applicable Brazilian legislation and identified the open questions that were to be discussed during the workshop. This workshop report is a detailed account of the discussions that took place in Brasilia and is complemented by a final booklet that combines both documents and highlights the overall teachings of the project.

Through different presentations and group exercises, the workshop provided a good medium for discussion on the practical implications of the Brazilian ABS Rules in general, and more particularly its coverage of genetic heritage obtained through *in silico* sources (i.e. generated by or accessed from a computer medium), as prescribed in the Brazilian ABS Rules. Without discussing whether so-called Digital Sequence Information (''DSI'') should be or is within the scope of the (''Convention on Biological Diversity, (''CBD'') or its Nagoya Protocol, participants enhanced their understanding of the Brazilian ABS

Rules, their rationale, practical implications, advantages and limitations, along with their relation to ABS Compliance measures adopted in the EU and elsewhere. The presentations provided the background for immediate discussion, but also fed the two types of group interaction organized, first to debate the open questions identified in the background paper, which was distributed to participants beforehand, and secondly to resolve the different case studies prepared by the consultants. The detailed programme of the workshop can be found in Annex 1 of this workshop report, while all presentations made during the two days are found in Annex 2.



WORKSHOP ACTIVITIES

WORKSHOP PRESENTATIONS & DISCUSSIONS

On the first day, Tuesday 10th December, the workshop was formally opened by representatives of the delegation of the European Union (''EU'') to Brazil, the Brazilian Ministry of Foreign Affairs, the Brazilian Ministry of Environment and the Brazilian Ministry of Science, Technology, Innovations & Communications, who all highlighted the positive contribution of collaboration projects made possible by the Brazil-EU Diálogos framework. Following a short introduction to the programme and a tour de table of participants, the workshop kicked off in full gear through **legislative updates** given both by representatives of European Union and Brazilian public authorities, respectively by Mrs. **Alicja KOZLOWSKA,** representing the European Commission, and Mr. **Thiago ZEIDAN,** from the Genetic Heritage Management Council, Ministry of Environment, Brazil. Summarizing the general approach to access and benefit-sharing in the different legal orders at play, both presenters highlighted material definitions and procedural aspects in applicable legislation, with an emphasis on user compliance measures in the European Union, and the access registration process in Brazil.

Participants were then offered two presentations on the specific focus of the workshop, namely **Digital Sequence Information (''DSI'') in the international policy context & in the Brazilian ABS Rules**. An update on the history of the discussions regarding DSI at the CBD was given by Mrs. **Kristina TABOULCHANAS** (Secretariat of Convention on Biodiversity), who also highlighted the intersessional work carried out to prepare discussion that will be held during the next COP and COP-MOP in October 2020. The update was followed by a presentation by Mrs. **Leticia BRINA** (Genetic Heritage Management Council, Ministry of Environment, Brazil), who presented the roots of the notion of *''in silico''* genetic heritage in the Brazilian ABS Rules, with an emphasis on the regulation of access to genetic information in Brazil, whatever the source of such information, and how access to such heritage was regulated and implemented in the daily practice of the Council. Then was showed in detail how the user can inform the origin of the genetic heritage from *in silico* origin in SisGen registration process. According to SisGen records, out of the 51,162 access activities registered, 530 declared that the GH was obtained *in silico.* From these, 76 declared commercial intentions, through the

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

Thereafter, two presentations made the **case for multilateralism** in the regulation of access to genetic resources and the sharing of benefits deriving from their use. Mr. **Martin BRINK** (Wageningen University, the Netherlands) described the International Treaty on Plant Genetic Resources for Food and Agriculture, focusing on the latest discussions of the Treaty Governing Body in Rome in 2019 with regards to the enhancement of the multilateral system, especially on the lack of consensus between Parties on whether and, if so, how to integrate the issue of digital sequence information within the new standard contract (SMTA) that would be used for transactions of material included in the multilateral system. Giving very practical examples from the cosmetics industry, Mrs. **Francine FRANCO** (GSS Sustainability), made the case for a Global Multilateral Benefit-Sharing Mechanism for the development of products using multiple genetic resources in transboundary situations, which is a commonplace for cosmetic products.

Formal presentations thereon focused on the **different uses of digital sequences information**. Mr. **Chris LYAL** (Natural History Museum, London, United Kingdom) presented the uses of such information in the field of taxonomy, highlighting the increasing value of nucleotide sequence data as a tool for identification of species, and emphasizing the difficulties of coping with the regulation of such data bilaterally in ABS regime, which would require a significant (and potentially unrealistic) adaptation of the workflow, while Mr. **Eduardo PAGANI** (LNBio/CNPEM), presented the use of digital sequence information within the work of the Brazilian National Centre of Research on Energy and Materials, the Sincotron Light Laboratory (Sirius), especially it projects on protein crystallography, and a successful example of benefit-sharing partnership that established a ''sustainable chain'' for accessing four biomes in Brazil. Mr. **Guilherme OLIVEIRA** presented the Brazilian Vale Institute of Technology's perspective on conducting, funding and providing support multidisciplinary studies on ecology, biodiversity, remote sensing, geology, hydrology, land reclamation, socioeconomic and genomics, using eDNA for environmental assessment and monitoring; genome sequencing and gene/protein/metabolite profiles of plants for pharmaceutical use.

Practical discussions continued based on formal presentations focusing on the **issue of traceability and provision of digital sequence information**. Mrs. **Amber H. SCHOLZ** (DSMZ, Germany), presented primary research results on the traceability of digital sequence information, its production and publication by scientists, the existing landscape

of databases, which remain highly connected, depending on the INSDC infrastructure, and completely open for all users, the types of information that can be found in this landscape, and the profile of the users of such databases. Mr. **Guy COCHRANE** (EMBL-EBI) built upon this presentation to present the particularities of the operation of the International Nucleotide Sequence Database Collaboration (INSDC), highlighting the values of open access, the comprehensiveness of the INSDC, its governance structure, its instruments for data exchange and tools that all rely on large sets of openly available data, the procedures for data submission, and the terms of use attached to such data, reflected in the Toronto Principles and the EBI Terms of Use. Mrs. **Bárbara SCHORCHIT** (Genecoin) presented the potential to use blockchain technology for Biodiversity in the ABS context, highlighting a pilot project using the Genecoin application to track biodiversity assets, audit supply chains through smart contracts and ensuring transparent benefit-sharing with possibilities of oversight from public authorities, and a longer-term vision of constructing a blockchain powered database.

GROUP DISCUSSIONS ON OPEN QUESTIONS FROM THE BACKGROUND PAPER: *"IN SILICO"* GENETIC HERITAGE AND ABS

Quite a sizeable number of open questions had been identified in the background paper with regards to the regulation of access to genetic heritage from *in silico* sources. These questions had been clustered into four topics: the notion of genetic heritage, the different triggers for the registration of genetic heritage access from *in silico* sources, the availability and transfer of ABS information in *in silico* sources, and issues related to compliance with Brazilian ABS Rules. Applying the 1-2-4 technique, which aims to foster collective intelligence by confronting representations in small groups, and ensure more active participation from everyone, every participant reflected on the questions first by themselves, then discussed them in groups of two, then in a group of four participants before confronting results and discussion points to the whole group. Participants were asked to answer the questions by drawing from the information provided by the background paper, the workshop presentations, and also their intuition, delving as a result deeper into the scope of Brazilian ABS Rules, their implementation and their practical implications.

On the **notion of genetic heritage,** participants agreed that the definition of the concept in the Brazilian ABS Rules was broad enough to include **all types of information**, their physical and digital counterparts, as long as such information related to plants, animals, microbial species and any other species, including substances originating from the metabolism of these living organisms. Nucleotide data, metabolites, and protein data would thus definitely be covered in the material scope of the Brazilian ABS Rules. The threshold to be applied to **associated data** proved trickier to assess, since such data would theoretically be included in scope, as long as that link with the organisms are maintained. Recognizing that such an approach would lead to a very great breadth of information to be included within the notion of genetic heritage, it was pointed out that accessing pure phenotypic data would not be sufficient on its own to lead to an access registration triggering event under Brazilian ABS Rules, without genetic data on or the physical samples of the organisms themselves.

Lively discussions arose on the threshold of "**development of distinctive characteristics**", which determines whether an organism or information should be considered genetic heritage, participants pointing out that some official publications (like the list of traditional and creole varieties that is compiled by the Brazilian Ministry of Agriculture) would be useful in the process of determining which organisms would fall under Brazilian sovereignty. Thorough comparative research, whether in publications or information listing the biodiversity that exists in the country, would be needed to determine contentious cases. In any case, participants highlighted that the same principles regarding the development of distinctiveness could be applied by other signatories to the CBD, which could consider that biodiversity found, used and developed on their sovereign territory, especially when it adapts to local conditions, would fall under their sovereign rights according to Article 2 of the CBD.

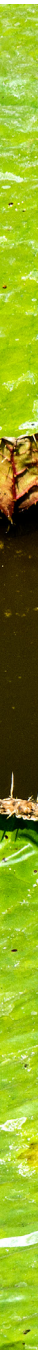
The issue of the Brazilian ABS Rules' material scope with regards to **microorganisms** was also debated at length, especially in the case of an isolation from a Brazilian citizen travelling in France for example, or of viruses moving around the globe and going through different variations, leading to the development of a vaccine. The existence of a thematic chamber within CGen on the proposed definition of distinctive characteristics was considered as a helpful mediating solution for some of the issues raised.

With regards to the **geographical and temporal scope** of the Brazilian ABS Rules, participants agreed that under Brazilian legislation specimens and information found in

overseas collections were to be considered as Brazilian genetic heritage, even if linked to plants collected in the 18th century, as long as access (research) activities are carried out after 30th June 2000, although some participants argued that a reasonable limit should be envisaged for acquisitions dating back over centuries.

Another question related to the distinction between **an intermediate and finished product,** which has considerable impacts on existing benefit-sharing obligations, since these only exist for the latter case. Although two well-defined thresholds exist in the Brazilian ABS Rules to determine whether Brazilian genetic heritage is the ''value-adding'' element to the finished product, i.e. because it contributes to the functional characteristics and the marketing appeal of such a product, some participants noted that such distinction could prove challenging when faced with products based on multiple components. Discussions also arose about the difficulties to determine which procedure to follow when a single product is marketed as a final product for a specific value chain, without knowing whether, how, and when it would or could lead to the development of another final product. Using the example of cocoa butter sold in pharmacy in a ''business to consumer'' value chain, but also sold to food processing businesses for use in chocolate manufacturing in a ''business to business'' chain, a potential solution that arose was that the user would need to distinguish between the two cases, ensuring the notification of a final product in the ''business to consumer'' value chain, and maintaining the access registration for the ''business to business'' value chain.

With regards to the **access registration triggers for genetic heritage obtained from *in silico* sources**, participants all agreed that the **consultation, upload or download** of genetic information itself would not lead to an access registration under Brazilian ABS Rules. They also concluded that given all legislative elements, including the specific technical guidance, and also institutional practice, performing a search in a database, even when comparative in nature, through the use of BLAST tools for instance, would not necessitate registration, unless it leads to the publication of research results, the development of an intermediate or final product, or the grant of intellectual property rights, Even if basic research activities, such as taxonomy or epidemiology, relying on genetic heritage information found in digital format would are agreed to fall within the definition of ''access'' under Brazilian ABS Rules, they would not warrant an access registration unless they generated the specific triggering events for such registration.



It was however unclear whether the **obligation for foreign researchers or users** to enter into a cooperation with a Brazilian partner would be required before said triggers. As the SisGen registration of access relates to the entire activity that lead to the triggering events, and not to every single point of the research process itself, the access triggers would seem to also apply to the obligation for foreigners to have a Brazilian partner. However, additional guidance and clarity from CGen and/or its Sectoral Chambers would be needed on the articulation of these two obligations (i.e. association with a Brazilian national at point of access in the sense of research, and registration of this access activity at a specific trigger points) not to hamper the generation and publication of knowledge on Brazilian biodiversity.

Discussions also focused on whether the **transfer** of *in silico* genetic heritage information would trigger an access registration. As such, the action is not listed as a triggering event, so would not require an access registration, as confirmed by CGen Technical Guidance no.8, but it was highlighted that a possible review of the guidance could warrant a mandatory inclusion of ABS-related information and obligations at the moment of transfer, which was pointed as potentially problematic since a lot of data transfer is not operated manually, but rather automatically and programmatically, and at quite a large scale.

When confronted to the thorny issue of **accessing multiple sequences from different origins, the same sequence from multiple origins, or "highly conserved sequences"** related to universal biological functions for instance, all participants largely agreed that bilateral ABS regimes showed their limits in dealing with such cases, and that discussions at the international level regarding digital sequence information would be important to bring workable solutions for users and public authorities.

Delving into the issue of **ABS information regarding *in silico* genetic heritage sources**, participants explored different mechanisms that would raise the availability and transfer of such information. Although **ABS disclaimers** in databases were mentioned as a possible path forward, they also present considerable setbacks in that they immediately create avoidance practices, data interoperability (especially since the Internationally Recognised Certificate of Compliance is not transferrable into Information Technology infrastructures because of its written format and lack of coding), as well as accuracy problems. It was highlighted that any **parallel system** that would be developed for ABS would need to take into account technical inter-operability issues vis-à-vis nucleotide

sequence databases for example, like in the case of oceanographic data which is linked up to the database system, but stands outside of the bio-informatics realm.

Notwithstanding the final practical solution that could be developed at the end of the day, all participants emphasized the fundamental need for targeted trainings, in order to **raise awareness-levels** of both uploaders and downloaders of *in silico* genetic heritage information, such as trainings on minimum information that ought to be uploaded (with possible involvement of grant donors and funders). When it came to discussing the **consequences of accessing and using incomplete data**, debates highlighted different aspects, from the mechanisms that could be developed at international level when it is impossible to grant or obtain prior informed consent, to the fact that the Brazilian ABS rules were built on a relationship of trust between regulators and users, which therefore includes risk management considerations.

During discussions on the open questions regarding **compliance** with Brazilian ABS Rules, **contractual terms** were cited as the most efficient tool, while the minimum requirements adopted by CGen for MTA's (which are also valid for the Shipment Invoice in case of long-term institutional MTA's) were cited as providing a welcome backbone to such terms. Participants also highlighted the central role of the Brazilian Patent Authority, IMPI, as a checkpoint for the **declaration of origin**, and also discussed the weight of the statutory empowerment that allows CGen to ask for information to any authority involved in product authorization procedures in Brazil. Several examples and practices were cited with regards to **tracking and tracing the use** of genetic heritage information by users, such as the GiZ project in India, the Peruvian practice to research worldwide the patents that would infringe their national ABS laws, and the practice of the Global Catalogue of Microorganisms from the World Federation of Culture Collection (WFCC). Participants also debated the utility of developing different systems at national level, either as a temporary systems developed until a better structured one is settled at international level, if it is indeed settled, or whether one should rather view them as stand-alone mechanisms to ensure better compliance with national ABS legislation.

SCENARIOS

Three working groups were created to work through the three different scenarios included in the background paper to explore the operation and practical implementation of the Brazilian legal framework. Each group, composed of representatives from all stakeholder groups, examined how users, regulators and other stakeholders would or could deal with the situations at hand, seeking mutually agreed approaches to resolve issues. Participants were given a list of questions to be answered and asked to design alternative responses or list open questions if they could not agree on a common solution.

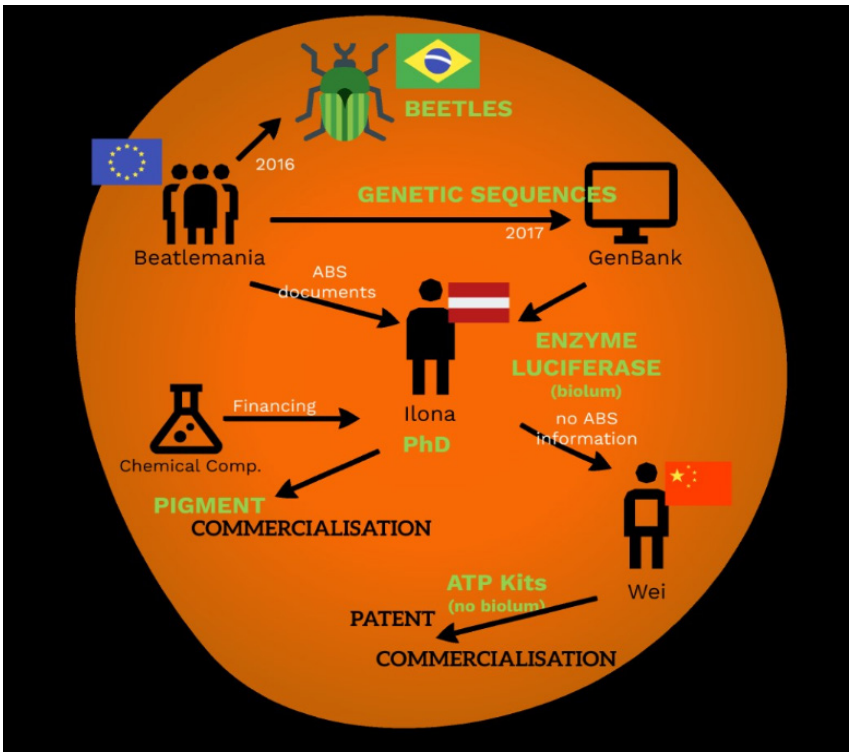
Scenario 1: a perfect day

THE SCENARIO

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.

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.



QUESTIONS

- *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?*
- *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?*

DISCUSSIONS

All participants agreed that the beetles, associated genetic sequences, as well as the luciferase enzyme (whether the researcher developed it from a strain or from sequence information), would be considered Brazilian genetic heritage. As a result, access registration would be required at the time of publication of scientific articles or the researchers' doctoral dissertation, with a Brazilian partner, who should carry out the registration procedure. A possible automatic partnership with MCTIC or MMA for carrying out registration procedures for foreign researchers was highlighted as a positive development for early career researchers without direct connections to Brazilian research partners. A potential problematic situation was highlighted, whereby the initial research team would refuse to transfer the doctoral researcher all the access documents. A possible intervention from CGen was discussed, as the institution could be a source from which researchers could get hold of (non-confidential aspects) of access registration dossiers in such cases.

With regards to the status of products developed on the basis of Brazilian genetic heritage, participants were at first divided as to whether the sponsoring chemical

company's pigment or the ATP kits should be considered intermediate or finished products under Brazilian ABS Rules. Consensus did nonetheless emerge to consider the pigment as an intermediate product, as the full commercial product development chain was not finished with a single pigment, therefore solely triggering an access registration, without benefit-sharing obligations. Even if the ATP kits have been patented as a product, participants agreed that they should also viewed as intermediate products under Brazilian ABS Rules, since they will be used in the development of another product by the pharmaceutical industry, which would need to enter into a benefit-sharing agreement if both formal conditions are met (i.e. when Brazilian genetic heritage's added value to the finished product is crucial for the existence of the product's functional characteristics or its marketing appeal). The commercialisation of the pigment by the chemical company would thus only need to be registered as an intermediate product to CGen, building upon the existing dossier started by the researcher. Another access registration trigger point would be the grant of a patent for the luciferase and linked ATP kits by the Chinese entity, as well as these kits' commercialisation, without however leading to the negotiation of a specific benefit-sharing agreement.

Participants agreed that the compliance monitoring possibilities of Brazilian authorities were limited, especially if the patenting and commercialisation were to be done outside of Brazilian territory. While Brazilian authorities could be involved in resource-heavy checks of publications, or launch civil litigation procedures abroad based on the application of private international law principles and national civil law, some participants highlighted that awareness raising activities carried out by EU ABS authorities (on their own accord and without a legal obligation to do so) could potentially have beneficial side-effects to ensure better knowledge of Brazilian ABS Rules by European users. However, it was clear that the EU ABS compliance rules would not enter into play, even though Ilona acted in violation of Brazilian ABS Rules by not passing down the information to the researcher downstream, not only because Brazil is not a party to the Nagoya Protocol, but also because Ilona did not extract luciferase from physical specimens of the beetle but only derived it from data downloaded from a database; *in silico* access alone is not covered by the EU ABS Regulation. Participants remained more divided on the role that could possibly be played by the database involved in this specific case (providing the genetic sequence to the initial early career researcher); between those who considered that GenBank should provide information on a mandatory country tag, and/or provide link to articles and publications, and those who considered the database outside of ABS information chains.

Scenario 2: A yerba tree of life

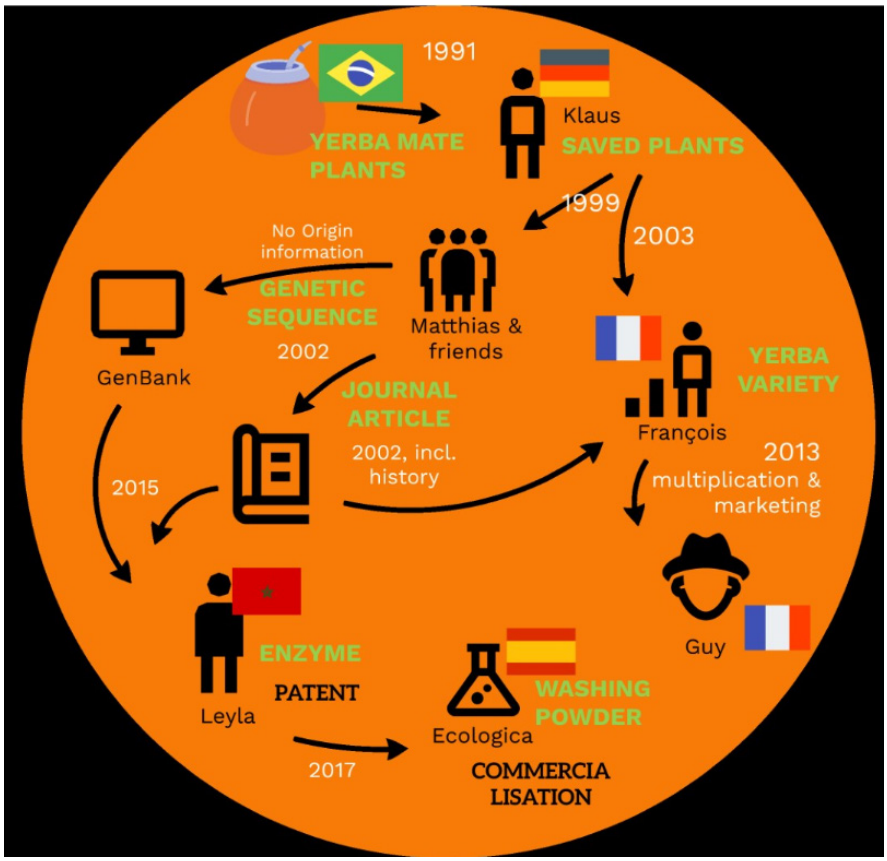
THE SCENARIO

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.

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.

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.



QUESTIONS

- *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?*
- *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?*
- *Would information have used 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?*

DISCUSSIONS

The temporal elements of the case study proved tricky because of the combined elements that required knowledge of formerly applicable Brazilian ABS Provisional Measures, but they showed the significant benefits of the new ABS Rules in terms of practicality and user certainty.

With regards to determining which information and products would be considered genetic heritage and fall under Brazilian ABS Rules, all participants agreed that, although the specific plants brought by the seed saver could potentially be considered Brazilian genetic

heritage if they had indeed developed their distinctive properties in Brazil, he would not have any obligation under the Rules since he was only using them for planting, an action not covered in the notion of ''access'' in old and new Brazilian ABS Rules. In the case of the plants used by the researcher, since the yerba mate had been cultivated in Germany for a considerable length of time, some participants argued that they should not fall under the rules, since it would very well be considered to have become a foreign genetic resource. However, some participants argued that the plants would have been considered as Brazilian genetic heritage held *ex situ* according to dominant Brazilian institutional practice, and thus fall under Brazilian ABS Rules. Other participants argued that, the seed saver's plants could not be considered Brazilian *ex situ* material, but rather part of his private collection, and that a specific CGen Resolution would be needed in order to determine the exact threshold to be applied to consider the plants as genetic heritage, as well as the exact scope of subsequent users' obligations under the Brazilian ABS Rules. All groups did settle on the fact that Brazilian authorities would consider the yerba mate plants' as Brazilian genetic heritage due to the exotic and non-established nature of *Ilex paraguariensis* on the European continent, even if such viewpoint would not necessarily be shared by other national ABS authorities. With regards to the plants developed by the breeder, even if breeding activities had been undertaken, they were also considered to potentially be viewed as Brazilian genetic heritage, with the caveat that the Brazilian plants would need to have contributed significantly to the development of the plant variety, as an element adding value to the final product (either its functional characteristics or final marketing appeal). Participants unanimously agreed that the information used by the enzyme developer following the download of a sequence linked to the researchers' publication on the yerba mate plants developed by the seed saver would be considered as genetic heritage by Brazil, maintaining the assumptions made above on the qualification of the seed savers' plants found in Germany as Brazilian genetic heritage.

With regards to the procedural obligations of the different actors involved in the scenarios, participants were clear on the need for researchers to regularize access according to the new Brazilian ABS Rules, and unanimously highlighted the added value brought by the SisGen system, which considerably eased the navigation of the Brazilian ABS Rules, providing procedural clarity for users compared to previously applicable measures. Participants all agreed that the plant variety would be considered a finished product/reproductive material under Brazilian ABS Rules (and thus trigger benefit-

sharing obligations), while the enzyme developed by the product developer would be an intermediate product, triggering therefore solely an access registration from the Brazilian partner she would associate with before the patent application.

Once again, compliance and monitoring options highlighted by participants mostly relied on soft measures like best practices, awareness-raising, education and training activities, but also existing new provisions with regards to the declaration of origin in different product and patent applications under the new Brazilian ABS Rules. Furthermore, participants cited the different legal measures that could be useful in the Brazilian legal order, like the prevention of product commercialization, or the refusal to grant national patents, emphasizing once again Brazilian authorities' limited judicial options for uses outside of Brazilian territory, especially in the absence of Nagoya Protocol ratification. However, due to the contentious legal qualification of the yerba mate grown in Germany, which may not be considered as Brazilian genetic heritage by EU ABS authorities, and also due to the fact that access to nucleotide data from a database would neither trigger due diligence obligations for users, nor a control by EU ABS authorities, EU ABS Compliance measures would not provide much assistance, even in the event of a Nagoya Protocol ratification from Brazil.

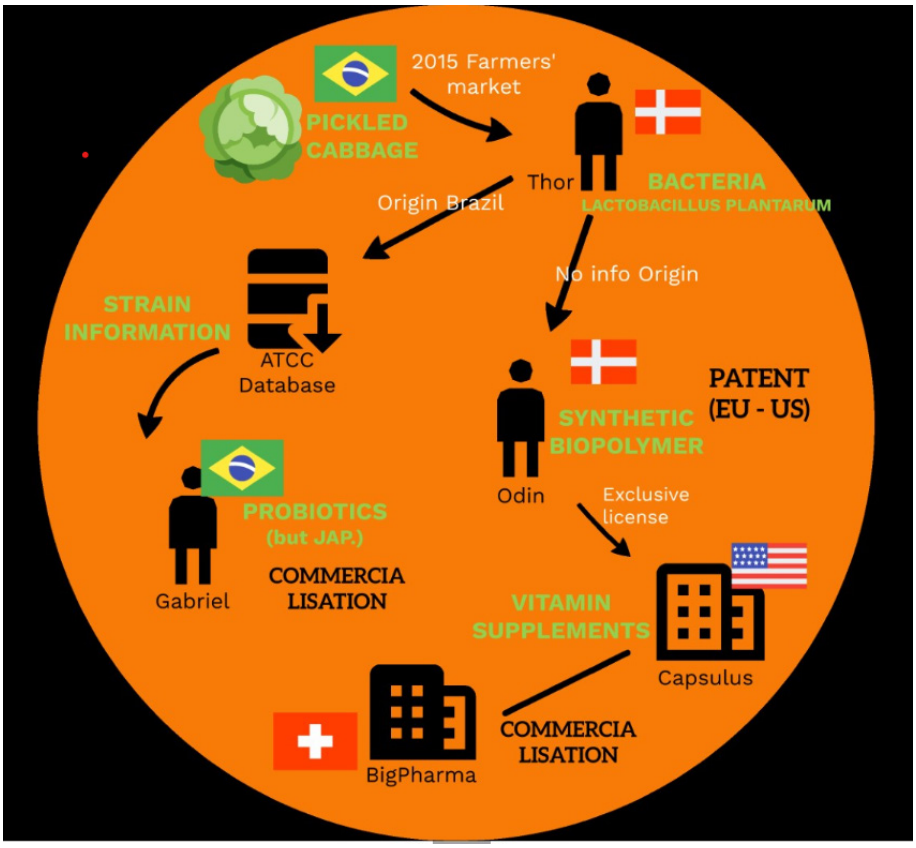
Scenario 3: A strain reaction

THE SCENARIO

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 commercialize the capsules worldwide, including in Brazil in 2019.

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 commercialize his probiotics in Brazil and neighbouring countries.



QUESTIONS

- *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?*
- *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?*

DISCUSSIONS

Long discussions arose when participants were trying to determine whether the bacteria would be considered Brazilian genetic heritage or not, debating whether it was the place of isolation or the origin of the specific bacteria that took precedent in the assessment. Indeed, the Brazilian ABS Decree reverses the burden of proof when it comes to microorganisms, stating that they will not be considered as genetic heritage if it is proven that they have been isolated from substrates not from Brazilian national territory, which could have very well been the case in this scenario, as the bacteria could have developed in Denmark, or elsewhere outside of Brazil. However, as the

researcher considered the bacteria to be Brazilian genetic heritage, his assumption was followed throughout the resolution of the scenario. Since the bacteria itself was genetic heritage, the related sequence information was also to be considered as such, while the polymer would be an intermediate product, although the proportion of the bacteria's contribution remained unknown. The capsules developed as a result of the integration of the polymer was regarded as a final product by participants, since its self-disintegrating character came from Brazilian genetic heritage. However, in the case of the strain developed based on the same sequence as the Brazilian bacteria but from Japanese origin, participants were clear that the Brazilian ABS Rules would not apply, even if all the strains, theoretically the Brazilian ones, were used in the research and development process.

With regards to the procedural obligations of different actors involved, participants considered that the initial researcher, who actually did not engage in any formal triggering events, but uploaded a sequence to a database, would be advisable to make an access registration with a Brazilian partner, especially if the upload immediately precedes a publication of research results. As the subsequent synthetic biology researcher applied for patent protection on the polymer he develops for biomedical applications, his obligations to register (through a Brazilian partner) for access and intermediate product development were clearer. Discussions arose as the responsibilities of the niche pharmaceutical company that negotiated the exclusive license on the one hand, and the company sub-contracted to actually engage in the commercialisation of the final vitamin supplements developed at the end of the value chain. Participants agreed that the responsibility to engage with Brazilian ABS authorities to notify the development of a final product, and thus sign a benefit-sharing agreement would lie not with the entity commercialising the product as such, but with the exclusive license holder. Both patent and food and drug authorities were designated as essential in ensuring transparency and control over such value chains, when the products are commercialised in Brazil. Once again, the very small margin of manoeuvre of national authorities, from both Brazil and user countries, was highlighted, especially in cases of obvious avoidance of sequence information with attached ABS obligations against those without such attachment.

In all scenarios, quite heated discussions arose when it came to consider the information and products at hand as genetic heritage, with arguably the most contentious case being the status of a microorganism isolated in Denmark but from a jar of pickled cabbage bought in a market in Brazil, and the yerba mate plants cultivated in Germany by a seed saver. The extension of the status of genetic heritage under the Brazilian law to information found in the digital realm was unanimously understood by participants, although its limits were exemplified faced by missing ABS information and obvious avoidance. In parallel to the intricacies of the notion of genetic heritage itself, distinguishing between an intermediate and a final product was not always smooth sailing, even with the criteria provided by Brazilian ABS Rules, which lead to different interpretation as the notion of ''final consumer'' which is central in the definition of a finished product was viewed as either solely directed to ''business to consumer'' value chains, or potentially also applying to ''business to business'' chains if the product would not be further transformed or just be integrated in its final form into a value chain.

The procedures themselves for registration of access and notification of final products were well understood by workshop participants, partly on account of the notion of ''trigger points'' that was developed throughout the background paper and expanded during the workshop, although some issues still remained open with regards to the temporal articulation of access registration obligations and the association with Brazilian partners for foreign entities. Discussions on the implementation of trigger points for access to genetic heritage from *in* silico sources helped form a clear understanding of the fact that the consultation, upload and download of such information would clearly not require an access registration, while the transfer of such genetic heritage information was identified as a more controversial issue where legislative interpretation changes were being discussed at CGen, even though transfers of genetic heritage information obtained from *in silico* sources or *in silico* format would not trigger access registration according to currently applicable technical guidance. All scenarios unequivocally highlighted the limited options with regards to monitoring and ensuring compliance with Brazilian ABS Rules outside of their own jurisdiction, a consideration with great importance when looking at the potential uses of genetic heritage information obtained from *in silico* sources.

CONCLUSIONS & RESULTS

During the three days, participants had the extensive opportunity to discuss the types of information that fall under the Brazilian notion of *in silico* genetic heritage, and how such information moves around the globe, and how it is used in different sectors.

The governance structures surrounding the Brazilian ABS Rules were cited as a unique opportunity to bring clarity to users of genetic heritage, interpreting the Rules in a rapidly changing technological context. For instance, additional sectoral guidance was requested by participants for the articulation of obligations for foreign researchers engaged in activities considered as ''access'' before the different official registration trigger points, as well as for the distinction between intermediate and finished product in different sectors, building on the work already done by CGen and the Sectoral and Technical Chambers. It was however also noted that the same flexible governance structure also leads to a considerable scattering of useful (and sometimes crucial) information on the scope and implementation of Brazilian ABS Rules, making it very difficult to navigate for users, especially foreign ones. In this respect, it was concluded that English translation of CGen's Resolutions and Technical Orientations would be important.

The workshop also made it quite clear that the Brazilian ABS procedures relied on a relatively uneventful and impeccable chain of information flow, which could very easily be challenged by practical sectoral realities. This led participants to the conclusion that the Brazilian ABS system greatly relied on trust and users' willingness to participate, stressing the necessity for awareness-raising, education and training with regards to ABS issues in different sectors in general, and to Brazilian ABS Rules in particular. With regards to compliance in general, although numerous entities would potentially be directly involved in the Brazilian legal fora, it became clear during the workshop that their reach significantly diminished when faced with uses of Brazilian genetic heritage outside of national territorial borders, without any return back to Brazil for commercialisation or patent application, a risk which was quite high in the context of *in silico* genetic heritage. The ratification of the Nagoya Protocol would in various cases allow Brazilian authorities

to partially rely on user compliance measures adopted in different legal orders, and notably the comprehensive EU ABS compliance measures, provided nonetheless that the organisms are considered as Brazilian genetic heritage by EU national authorities (and not a country's own sovereign resource like the contentious case of the yerba mate plants cultivated for a long time in Germany, or the microorganism isolated in Denmark but from a jar bought in Brazil), and provided that the research based on the information obtained from *in silico* sources is combined with research on the material genetic resources themselves.

With specific regards to *in silico* genetic heritage, the workshop clarified the different trigger points for access registration, illustrating the practical implications of applicable CGen resolutions and technical guidance which allow for facilitated conditions for research, as the download of genetic sequence data, and the operation of a BLAST search without publication of data was confirmed to be outside of access registration obligations under Brazilian ABS Rules. However, for the Brazilian ABS Rules to truly be operational, there is a clear need to explore feasible and practical tools to improve ABS functionality of the different *in silico* sources of genetic heritage information, as well as a clear need to develop trainings on the concept of ABS itself for data users, which are different than physical resource users, who are getting accustomed to principles. It was also clear from the workshop that any tool developed in these directions would need to take into account the customary practices of scientists who both upload and use the data, and the scientific developments that are epitomized by the exponential growth in the number of sequences that can be part of a single research question, and that can be downloaded speedily.

ANNEX 1: WORKSHOP PROGRAMME

DAY 1: TUESDAY 10TH DECEMBER 2019

Session 1: 9:30-10:30
Opening: Representatives of Delbra (UE), DG ENV (UE), MCTI, MMA, MRE, ME
Introduction to Program and Workplan
Tour de Table (presentation of participants)

Session 2: 10:30-12:00
Legislative updates from Brazil & the European Union
Presentations by European Union and Brazil participants: update in the Implementation status and issues on the EU and Brazil Regulations

- Alicja KOZLOWSKA, European Commission: ''State of Play of ABS Rules in the European Union: an update''
- Thiago ZAIDAN, CGEN, Ministry of Environment, Brazil, ''State of Play of ABS Rules in Brazil: an update''

Questions & Answers

Session 3A: 13:30-14:30
Digital Sequence Information (DSI) in the international policy context & in the Brazilian Law

- Secretariat of the Convention on Biological Diversity, ''History and Update on CDB discussions on DSI''

Questions & Answers

Session 3B: 14:30-15:30
Digital Sequence Information (DSI) in the international policy context & in the Brazilian Law

- Leticia, Ministry of Environment, Brazil ''Brazilian legal framework applied to genetic heritage *in silico*''

Questions & Answers

Session 4: 15:30 – 16:00

Background paper presentation

Presentation of the background paper & open questions (Fulya BATUR & Paulo HOLANDA)

Questions & Answers

Session 5A: 16:30 – 18:30

***In Silico* Genetic Heritage and ABS**

- 'DSI' and the International Treaty on Plant Genetic Resources for Food and Agriculture – Martin BRINK, Wageningen University, NL
- "Global Multilateral Benefit-Sharing Mechanism from multiple access from genetic resources" - Francine FRANCO, GSS
- "Taxonomy & Digital Sequence Information"- Chris LYAL, Natural History Museum, London
- "Use of Natural Products Information in Drug Discovery" – Eduardo PAGANI. LNBio/ CNPEM

Questions & Answers

DAY 2: WEDNESDAY 11TH DECEMBER 2019

Session 5B: 08:30 – 10:00

***In silico* genetic heritage and ABS**

- "Conducting, funding and providing support to biodiversity research. A perspective from Vale/ITV" – Guilherme OLIVEIRA, Vale Institute of Technology
- Tracking and Tracing DSI – Amber H. SCHOLZ, DSMZ, Germany
- "Blockchain for Biodiversity in the ABS context" – Bárbara SCHORCHIT, Genecoin
- Operation of the International Nucleotide Sequence Database Collaboration (INSDC) - Guy Cochrane, EMBL-EBI

Questions & Answers

Session 6A: 10:00 – 12:00

Discussion: *in silico* genetic heritage and ABS

Drawing from the presentations made the previous day, participants will discuss the questions raised in the previous session in more detail. To that end, without discussing

whether DSI should be or is within the scope of the CBD or the Nagoya Protocol, the participants will discuss the open questions from the background paper through the 1-2-4 technique. Compilation of answers by the consultants.

Session 7A: 13:30 – 16:00
Scenarios (World café)
Small workgroups meet to work through different scenarios and case studies included in the background paper to explore the operation and practical implementation of the Brazilian legal framework. Each group, composed of representatives from all stakeholder groups, will work on two scenarios. Through practical scenario analysis, participants will examine how researchers and regulators would deal with real situations that might arise, seeking mutually-agreed approaches to resolve issues. Participants will be asked to design alternative responses, and list open questions if they cannot agree on a common solution. A rapporteur will be elected by each group to report back to the whole group.

Session 7B: 16:30 -18:00
Scenario-based Group Work (continued)

DAY 3: THURSDAY 12TH DECEMBER 2019

Session 8: 8:30-10:30
Group work results presentations to plenary & discussions
Presentations of solutions developed & questions raised in each group, all participants will discuss identified open questions, address misunderstandings and areas of confusion in both Brazil and the EU.

Session 9: 10:30-11:30
Conclusions & Closing remarks
Summary of discussion & scenario group work results, open questions and the way forward.

Session 10: 11:30-12:00
Closing Session

ANNEX 2: WORKSHOP PRESENTATIONS

ABOUT THE AUTHORS

Alicja KOZLOWSKA is Policy officer at the European Commission, Directorate General Environment, Multilateral Environmental Cooperation unit. She took up office as Policy Office responsible for the Nagoya Protocol and the EU ABS Regulation in March 2014. Her scope of responsibilities include representation of the European Union in international discussions related to the Nagoya Protocol on access to genetic resource and fair and equitable sharing of benefits arising from their utilisation, and development and implementation of EU policy and legislation related to the Nagoya Protocol, as well as institutional support to the international and multilateral work under the Convention on Biological Diversity. Prior to taking the office as a Policy Officer in the Multilateral Environmental Cooperation unit she was a case handler, responsible for many years for infringement cases against Poland as well as promoting compliance with the EU environmental legislation in this country.

Thiago ZAIDAN is an Environmental Analyst, a team member of the Department of Support to the Management of Genetic Heritage Council of the Secretariat of Biodiversity of the Ministry of Environment (DCGen/SBio /MMA), a department that exercises the functions of Executive Secretariat of CGen.

Kristina TABOULCHANAS is Program Management Officer with the Nagoya Protocol Unit at the Secretariat of the United Nations Convention for Biological Diversity.

Leticia PIANCASTELLI SIQUEIRA BRINA is an Environmental Analyst, a team member of the Department of Support to the Management of Genetic Heritage Council of the Secretariat of Biodiversity of the Ministry of Environment (DCGen/SBio /MMA), a department that exercises the functions of Executive Secretariat of CGen.

Fulya BATUR holds a general law degree and a PhD from the Université Catholique de Louvain, as well as a Master in Laws in international environmental law from University College London. She is a consultant, facilitator and trainer versed in all policy topics related to the conservation and sustainable use of biological diversity and more particularly genetic resources. She has over ten years of experience as a legal researcher and adult educator, having organized and animated numerous trainings and workshops for very different audiences, from the most general presentations to highly technical discussions amongst experts. Based in Brussels, she has over five years of experience in policy guidance, advocacy and communication, having drafted and disseminated technical and legal briefs on different policies impacting the movement and marketing of seeds and the conservation of agricultural biodiversity for Arche Noah, an Austrian seed savers' association.

Paulo HOLANDA works as a consultant at Bioquallis in Brazil, developing and implementing strategies for biological resources management for public and private organizations from the sectors of health, agriculture, environment and industry. He has participated in national and international initiatives in standardization and conformity assessment in the fields of biotechnology and biodiversity, promoting productive links between R&D institutions, government and stakeholders.

Martin BRINK has been working at the Centre for Genetic Resources, the Netherlands (CGN) since 2012. His work focuses on genetic resources policies, especially on Access and Benefit-Sharing (ABS) principles and practices. He is the National Focal Point on ABS for the Netherlands and is currently involved in the development of guidance on the Regulation implementing the Nagoya Protocol in the European Union. He also advises the Netherlands government on issues related to genetic resources, e.g. in the framework of the Convention on Biological Diversity (CBD), the Nagoya Protocol, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and the FAO Commission on Genetic Resources for Food and Agriculture (CGRFA). He is active, as a coordinator and a teacher, in training courses on genetic resources management and policies.

Francine FRANCO is a consultant at ABIHPEC and a managing partner at GSS Sustentabilidade e Bioinovação, a consulting company with great performance with CGen and on topics related to the ABS system in Brazil and worldwide. GSS also has a highly qualified technical and legal team. ABIHPEC, the Brazilian Association of the Personal Hygiene, Perfumery and Cosmetics Industry, with over 20 years of activity, supports actions focused on the progress of the industry, through fronts that promote internationalization, innovation, sustainability, regulation and the sectoral projection of Personal Hygiene, Perfumery and Cosmetics companies. ABIHPEC has a seat at CGen in the role of Advisor to the National Confederation of Industry – CNI, representing the sector and actively acting in the construction of a safe regulatory framework for all involved.

Christopher H.C. LYAL worked as a taxonomist at the Natural History Museum in London for more than 45 years and is now a Scientific Associate of the Museum. He has published extensively on insects, on the relationship of taxonomy to conservation and sustainable use of biodiversity, and on aspects of Access and Benefit-Sharing (ABS). He has also advised museums on collection facilities, and on means of collection and research compliance with ABS legislation. In addition to his taxonomic expertise he has worked for the Secretariat of the Convention on Biological Diversity, and a deep understanding of the Nagoya Protocol, both from policy and implementation points of view. He has instrumental in developing the best practices adopted by the Consortium of European Taxonomy Facilities and those of the Global Genome Biodiversity Network. He was chair of the Informal Advisory Committee to the CBD's ABS Clearing House from its inception to 2018, and was recently co-chair of the CBD second AHTEG on Digital Sequence Information.

Eduardo PAGANI is a medical doctor specialized in pre-clinical and clinical drug development, currently working on drug repositioning against COVID-19 and current member of the ANVISA Technical Chamber of Herbal Medicine. Graduated in Medicine (São Paulo State University- USP), specialized in Pharmaceutical Medicine (São Paulo Federal University- UNIFESP), master's degree in Molecular Biology (UNIFESP), doctorate in Science (USP) and training in Clinical Research (Schering-Plough Research Institute-USA). Former positions: medical manager at Cristalia and Schering-Plough pharmaceutical industries; drug development manager at the National Biosciences Laboratory at LNBio/

CNPEM; president of the Brazilian Medical Association of Herbal Medicine, member of Brazilian Chamber on Ethics in Animal Experimentation – CONCEA.

Guilherme OLIVEIRA is a Senior Researcher at the Vale Institute of Technology in Belém, Brazil. The Institute is a non-profit research institution that conducts multidisciplinary research focused in the northern mineral province of Carajás, Pará State in Brazil. Dr. Oliveira's main research interests are in Amazonian biodiversity, from microorganisms to plants and invertebrates.

Amber HARTMAN SCHOLZ is Scientific Deputy to the Director at the Leibniz Institute DSMZ, the German Collection for Microorganisms and Cell Cultures. She headed the team that led to the DSMZ becoming the first Registered Collection under the Nagoya Protocol in the European Union, demonstrating the collection's voluntary and stringent compliance with EU Regulation 511/2014. She was also the lead author on the *Combined Study on Digital Sequence Information in Public and Private Databases and Traceability* submitted in January 2020 the Parties to the Convention on Biological Diversity, which was organized under the auspices of the Global Genome Biodiversity Network. Amber is currently leading a German-funded project on DSI open access policy options and is deeply engaged in DSI, CBD, and Nagoya Protocol issues. Her broader work at the DSMZ focuses on internationalization, strategic development, and science policy. Dr. Scholz has broad experience in science and policy through her work in the United States at the White House Office of Science and Technology Policy (OSTP) as Executive Director to the President's Council of Advisors on Science and Technology from, the National Cancer Institute as a Policy Advisor, and as a Science Fellow to the California State Senate Environmental Quality Committee. She received her PhD in Biology with a focus on the human intestinal microbiome and bioinformatics methods development in 2009 from the Johns Hopkins University.

Bárbara SCHORCHIT is the co-founder & CEO of Genecoin - Blockchain for Biodiversity and UNEP's Young Champions of Earth finalist (2019). Awarded entrepreneur by Draper University *in Silico*n Valley (2019) and Shell Livewire Brazil (2018), she joined Google Launchpad Global Accelerator Bootcamp (2018), UC Berkeley's Lean Startup Launchpad

(2017) and graduated in Chemical Engineering at the Federal University of Rio de Janeiro (2019). She founded Genecoin to leverage blockchain technology for the compliance of ABS regulations by all stakeholders."

Guy COCHRANE is the head of the European Nucleotide Archive (ENA) in the European Bioinformatics Institute of the European Molecular Biology Laboratory (EMBL-EBI). The ENA provides a comprehensive repository for public nucleotide sequence data, attracting users from a multitude of research disciplines and serving as underlying data infrastructure for numerous bioinformatics services. Under Dr Cochrane, the team has launched important new services, including the Sequence Read Archive for raw data from next generation sequencing platforms and the CRAMtools sequence data compression platform. In addition to the leadership of a team of biological curators, bioinformaticians and software engineers, he contributes editorial work to a number of journals and meetings and has been involved in standardisation activities in many areas of bioinformatics. He received his PhD in cancer cell and molecular biology from the University of East Anglia in 1999 and carried out post-doctoral work in the molecular biology of photoreception at Cambridge University prior to joining EMBL-EBI.

PRESENTATIONS

Alicja KOZLOWSKA, European Commission: "State of Play of ABS Rules in the European Union: an update"

http://sectordialogues.org/documentos/noticias/adjuntos/70ab79_1.%20Kozlowska.pdf

Thiago ZAIDAN, CGEN, Ministry of Environment, Brazil, "State of Play of ABS Rules in Brazil: an update"

http://sectordialogues.org/documentos/noticias/adjuntos/88c69b_2.%20Zaidan.pdf

Secretariat of the Convention on Biological Diversity, "History and Update on CBD discussions on DSI"

http://sectordialogues.org/documentos/noticias/adjuntos/b3977c_3.%20CBD.pdf

Leticia BRINA, Ministry of Environment, Brazil "Brazilian legal framework applied to genetic heritage "

http://sectordialogues.org/documentos/noticias/adjuntos/8e499f_4.%20Brina.pdf

Fulya BATUR & Paulo HOLANDA, "Presentation of the background paper & open questions"

http://sectordialogues.org/documentos/noticias/adjuntos/49c8db_5.%20BATUR%20&%20HOLANDA.pdf

Martin BRINK, Wageningen University, the Netherlands, "'DSI' and the International Treaty on Plant Genetic Resources for Food and Agriculture"

http://sectordialogues.org/documentos/noticias/adjuntos/103141_6.%20Brink.pdf

Francine FRANCO, GSS Sustainability Consulting, Brazil, "Global Multilateral Benefit-Sharing Mechanism from multiple access from genetic resources"

http://sectordialogues.org/documentos/noticias/adjuntos/002931_7.%20ABIHPEC.pdf

Chris LYAL, Natural History Museum, London, United Kingdom, "Taxonomy & Digital Sequence Information"

http://sectordialogues.org/documentos/noticias/adjuntos/d81ece_8.%20Lyal.pdf

Eduardo PAGANI. LNBio/CNPEM, Brazil, "Use of Natural Products Information in Drug Discovery"

http://sectordialogues.org/documentos/noticias/adjuntos/a1bb95_9.%20Pagani.pdf

Guilherme OLIVEIRA, Vale Institute of Technology, Brazil, "Conducting, funding and providing support to biodiversity research. A perspective from Vale/ITV"

PRESENTATION SUMMARY

The area is a hotspot for biodiversity and there is a need to reconcile industrial operations and biodiversity conservation. In addition to traditional biodiversity assessment, taxonomic descriptions and ecological studies, we have invested heavily in providing genetic data regarding the local flora and fauna. We have sequenced over 8,000 specimens to generate DNA barcodes. This includes the only ecosystem in the country with a complete barcode dataset, the altitude Amazonian fields known as Canga. In addition, the unknown cave fauna has been studied in the same manner. To obtain increased resolution on species we have also generated chloroplast and mitochondrial genomes for plants and animals, respectively. The genetic structure of populations is studies using deep genetic data generate with next generation sequencing techniques and several nuclear genomes are under production. Finally, environmental assessment and monitoring are being explored with the use of metagenomics and metabarcoding approaches, enabling a quick, objective and deep production of information on the environment. All of the data produced is published and populates public data repositories. The issues we face relate to managing all of the compliance needs for the SISGEN and SISBIO systems that need improvements to streamline and facilitate usage.

http://sectordialogues.org/documentos/noticias/adjuntos/7e9af4_10.%20OLIVEIRA.pdf

Amber H. SCHOLZ, DSMZ, Germany, "Who? What? Where? Public databases for nucleotide sequence data (NSD)"

PRESENTATION SUMMARY

To understand DSI, it is important to understand the databases and infrastructure where it is used and the nomenclature that scientists use. Scientists use the term "nucleotide sequence data" when referring to the ACGTs that make up the genetic code of DNA. DSI is not a term employed by scientists.

As a normal part of their work, scientists submit their sequence data to large international open-access databases. Why? Because the journals that they want to publish their

scientific results in require this. And often the funding agency that funds their research also requires this. Also, there is a cultural and ethical imperative because open access data allows for scientific integrity, transparency and reproducibility and reduces scientific fraud. Finally, and perhaps most importantly, it is not possible to ''read'' DNA – I don't know how to interpret ''ACGTACGTACT''. Instead, we begin the process of scientific interpretation by comparing new sequences to old ones. And the bigger and more comprehensive the dataset is the better we get at understanding new biodiversity, new meaning, new discovery. And all of this requires openness.

The scientific process is to first sequence the organism of interest (genetic resource), perform bioinformatics and ask scientific questions, submit the sequences to a database that is part of the International Nucleotide Sequence Data Collaboration (INSDC), receive a unique identifier (Accession Number, AN) from the INSDC, submit the manuscript along with the AN to the journal (they require the ANs before accepting the paper into the journal), and then to publish the paper. The NSD is then pulled into >1,700 downstream databases that re-process or re-analyse that NSD in different sub-specialties. The data is available for all and remains part of the permanent scientific record.

The INSDC infrastructure is a tight integration of 3 international databases (GenBank in the USA, ENA in the UK/EU, and DDBJ in Japan). It costs approximately 50 million USD annually to maintain and has been in operation for around 40 years. Use of the INSDC databases has always been free to users, requires no registration to use. Furthermore, NSD are free and unrestricted, and INSDC ''will not attach statements to records that restrict access to the data''.[1]

Through an analysis of nearly 1,800 databases published in the annual database journal Nucleic Acids Research, we determined that 99.9% of non-human NSD databases rely on the INSDC. This means that these databases receive their data directly from INSDC and that without the openness from the INSDC these databases and their users would not be able to function. The term of access of these databases is almost entirely open access without any restrictions. A very few databases indicate that open access if free to non-profit organizations but that commercial users require a license.

The biological contents of the database reflect the biological diversity of the planet with organisms from every type of life found there – viruses, bacteria and archaea, fungi, single-celled eukaryotes, plants, algae, and animals. There are considerable portions of the database where the original GR likely falls outside of the scope of the CBD – human NSD, model organism and synthetic NSD. This means that any future solution for DSI will need to consider this heterogeneity in the databases and recognize that a ''one size fits all solution'' will be challenging.

There are around 15 million users of INSDC and they live in every country in the world. Brazil had 165,505 users of GenBank (1 of the 3 INSDC databases) in 2018. Since the costs per user are around $4 per user, one could say that this represents a non-monetary benefit sharing from the US/EU/Japan of around $2.6 million USD (only for 2018) for only the GenBank usage. In terms of NSD contribution to the NSD, Brazil as the country of origin represents 2.3% of country-tagged sequences in the INSDC.

If we compare INSDC use vs. contribution it is interesting to note that some countries use much more than they contribute. One could also understand these countries as receiving significant non-monetary benefits from the infrastructure. Here, Brazil has a middle-upper ratio of use to contribution – ranking 73 out of 228 countries/regions. This means that on average Brazilian scientists ''use'' more than they ''contribute''. (Middle would be a country with a rank of 110 or so.)

In summary, the public NSD databases, and especially the INSDC, enable scientists to better understand life on this planet. A system of openness and transparency has enable a large network of databases that generate new knowledge and enable cooperation and integration across the life sciences.

http://sectordialogues.org/documentos/noticias/adjuntos/f1af25_11.%20Scholz.pdf

Bárbara SCHORCHIT, Genecoin, Brazil, "Blockchain for Biodiversity in the ABS context"

http://sectordialogues.org/documentos/noticias/adjuntos/5ba2dc_12.%20Genecoin.pdf

Guy Cochrane, ENA at EMBL-EBI, United Kingdom, "Operation of the International Nucleotide Sequence Database Collaboration (INSDC)"

PRESENTATION SUMMARY

New science builds on the science that comes before it. Publication of data in databases and narrative in the scientific literature are essential aspects that enable scientific progress. In the ever-increasingly data-rich life sciences, open data sharing has established itself as a central paradigm that enables all to benefit. As soon as they become available, openly shared nucleotide sequence data are rapidly picked by many tools, processes, secondary databases and curation routines in what can be thought of as a "machine" into which raw data flow and, ultimately, knowledge emerges. Without openly accessible data, the most basic - and essential functions, such as "BLAST" search, phylogenetic tree building and reference-based annotation, would be impossible for scientists around the world. The knowledge provided by the machine is the basis for sharable benefits and the machine itself - the manifestation of biological data science - provides an additional sharable benefit. The International Nucleotide Sequence Database Collaboration (INSDC; http://www.insdc.org/) was established in the early 1980s as an open platform for the sharing of sequence. Three partner institutions make up the collaboration to provide global coverage and free and simple access to all, imposing no restrictions or requirements on those that access the data. Working closely with the many scientific communities that it serves, with funders, policy makers and journal publishers, INSDC databases provide the scientific record around which those engaging in sequencing and the use of sequence gather. The data life cycle begins with submission and ends with curation and presentation in the INSDC databases, a cycle that brings validation, integration, standards compliance and the broadest possible reach. Not only are direct services available from INSDC databases for users to search and access data, data are directly and autonomously propagated to many connected "secondary" databases, such as the ELIXIR Core Data Resources. Operating at significant scale, INSDC databases receive new data once every 6 minutes and their providers' servers are accessed at great rate around the world.

http://sectordialogues.org/documentos/noticias/adjuntos/dbf7f7_13.%20Cochrane.pdf

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