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OPEN-ENDED WORKING GROUP
ON THE POST-2020 GLOBAL
BIODIVERSITY FRAMEWORK

Fifth meeting

Montreal, Canada, 3-5 December 2022

Agenda item 5

**RECOMMENDATION ADOPTED BY THE WORKING GROUP ON THE POST-2020 GLOBAL
BIODIVERSITY FRAMEWORK**

5/2. Digital sequence information on genetic resources

The Open-ended Working Group on the Post-2020 Global Biodiversity Framework,

Recommends that the Conference of the Parties at its fifteenth meeting adopt a decision taking into account the following:

[The Conference of the Parties,

Recalling that the Convention on Biological Diversity and the Nagoya Protocol and other access and benefit-sharing instruments provide the legal framework for access to genetic resources and the fair and equitable sharing of the benefits arising from their utilization,

Recalling decision 14/20,

Noting the outcomes of the science- and policy-based process on digital sequence information on genetic resources established in decision 14/20,¹

Noting also the Informal Co-Chairs' Advisory Group on digital sequence information on genetic resources established by the Co-Chairs of the Open-Ended Working Group on the Post-2020 Global Biodiversity Framework and the Executive Secretary, and the work on digital sequence information on genetic resources undertaken by the Advisory Group, including consideration of policy options,²

Recognizing that digital sequence information on genetic resources is under consideration in other United Nations bodies and instruments and *desiring* to develop a solution on fair and equitable benefit-sharing from the use of digital sequence on genetic resources that may be adaptable to other fora and contribute to deliberations therein,

Acknowledging that greater generation of, access to, and use of digital sequence information on genetic resources supports research and innovation and contributes to achieving the three objectives of the Convention and sustainable development,

¹ CBD/DSI/AHTEG/2020/1/2; CBD/DSI/AHTEG/2020/1/3; CBD/DSI/AHTEG/2020/1/4; CBD/DSI/AHTEG/2020/1/5; Report of the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources, CBD/DSI/AHTEG/2020/1/7.

² CBD/WG2020/5/INF/1.

Recognizing the importance of digital sequence information on genetic resources for the post-2020 global biodiversity framework,

Welcoming the efforts of databases, including the International Nucleotide Sequence Database Collaboration, to encourage the tagging of records with information on the geographical origin,

Emphasizing the importance of capacity-building and development, technology transfer and technical and scientific cooperation to support access to, and generation, analysis and use of digital sequence information on genetic resources,

Recognizing that a solution on benefit-sharing from the use of digital sequence information on genetic resources may include innovative revenue generation measures,

Noting that the differences between public and private databases should be considered in the development of a solution on benefit-sharing from the use of digital sequence information on genetic resources,

1. *Agrees* that a solution for fair and equitable benefit-sharing on digital sequence information on genetic resources should, inter alia:

- (a) Be efficient, feasible and practical;
- (b) Generate more benefits, including both monetary and non-monetary, than costs;
- (c) Be effective;
- (d) Provide certainty and legal clarity for providers and users of digital sequence information on genetic resources;
- (e) Not hinder research and innovation;
- (f) Be consistent with open access to data;
- (g) Not be incompatible with international legal obligations;
- (h) Be mutually supportive of other access and benefit-sharing instruments;
- (i) Take into account the rights of indigenous peoples and local communities, including with respect to the traditional knowledge associated with genetic resources that they hold;

2. *Recognizes* that the monetary and non-monetary benefits arising from the use of digital sequence information on genetic resources should, in particular, be used to support conservation and sustainable use of biodiversity and inter alia benefit indigenous peoples and local communities;

3. *Agrees* that the approach set out in this decision to fair and equitable benefit-sharing from the use of digital sequence information on genetic resources does not affect existing rights and obligations under the Convention and the Nagoya Protocol, including, as applicable, those related to traditional knowledge and the rights of indigenous peoples and local communities, and is without prejudice to national access and benefit-sharing measures taken under the Convention and the Nagoya Protocol;

4. *Also agrees* that benefits arising from the use of digital sequence information on genetic resources shall be shared fairly and equitably;

5. *Considers* that the distinctive practices in the use of digital sequence information on genetic resources require a distinctive solution for benefit-sharing;

6. *Recognizes* that a purely bilateral approach to benefit-sharing from the use of digital sequence information on genetic resources is unlikely to meet the criteria identified in paragraph 1, and that a multilateral approach has the most potential to meet these criteria;

7. *Agrees* to develop a solution for the sharing of benefits arising from the use of digital sequence information on genetic resources;

8. *Acknowledges* the different understandings of the concept and scope of ‘digital sequence information’, and *agrees* on the continuing use of the term as a placeholder;

9. *Encourages* those depositing digital sequence information on genetic resources in databases to provide information on geographical origin and other relevant metadata, and to deposit more digital sequence information on genetic resources;

10. *Welcomes* section H of the post-2020 global biodiversity framework, the long-term strategic framework for capacity-building and development³ and the strengthening of technical and scientific cooperation in support of the post-2020 global biodiversity framework⁴ and *calls for* specific and targeted capacity-building and development, technology transfer and technical and scientific cooperation to support the access, use, generation and analysis of digital sequence information on genetic resources;

11. *Noting* the policy options set out in the annex to this decision, and taking into account the information in the note by the Executive Secretary on digital sequence information on genetic resources (CBD/WG2020/5/3), *decides*:

(a) To establish a fair, transparent, inclusive, participatory and time-bound process involving, inter alia, stakeholders and rights-holders, to further analyze, against the criteria identified in paragraphs 1 and 2 above, [a number of] the policy option[s] to identify a solution on benefit-sharing from the use of digital sequence information on genetic resources;

(b) To pilot or test a potential solution and assess it according to the criteria in paragraphs 1 and 2 above; and/or

(c) To establish a solution for benefit-sharing from the use of digital sequence information on genetic resources, with the understanding that the solution will be regularly reviewed, adapted and improved, with the following characteristics: [the solution is global; the solution is multilateral; ...];

12. *[placeholder for description of process to COP16].*

Annex

PROPOSED POLICY OPTIONS ON BENEFIT-SHARING FROM THE USE OF DIGITAL SEQUENCE INFORMATION ON GENETIC RESOURCES

A. Policy options contained in annex I to document CBD/WG2020/3/4/Add.1

Option 0: Status Quo

Under this option it is recognized that some Parties have adopted domestic measures that regulate access to and use of digital sequence information on genetic resources (DSI), however, there is still a divergence of views among Parties regarding benefit-sharing from the use of DSI.

Option 1: Digital sequence information on genetic resources fully integrated into domestic access and benefit-sharing measures

In this case, DSI is subject to each Party’s ABS legislation. It is the traditional bilateral approach to access and benefit-sharing (ABS). Access is regulated similarly to how genetic resources are accessed under the

³ Decision 15/--.

⁴ Decision 15/--.

Convention on Biological Diversity and the Nagoya Protocol, meaning that depending on the national legislation in place, access to DSI could be subject to prior informed consent (PIC) and mutually agreed terms (MAT) (i.e., essentially, GR = DSI). The utilization of DSI is to be regulated by MAT, as are benefit-sharing obligations, and MATs are negotiated for each DSI access. According to the study on ABS measures made available for the consideration of the AHTEG on DSI, some countries are already including DSI within the scope of their national ABS measures, and more are planning to do so in the near future.

Under this option, a tracking and tracing system would be required to not only determine the country of origin of each DSI record uploaded to the database but also how the DSI was being utilized and by whom so researchers could comply with that country's ABS obligations.

Option 2: Standard mutually agreed terms

This more general grouping of options enables benefit-sharing from the use of DSI, but it is decoupled from access to DSI (MAT but no PIC). Access is therefore not restricted, but benefit-sharing is determined by some type of standard MAT/license/standard multilateral transfer agreement/terms and conditions. The fact that the MAT is standardized implies that there is no need for individual negotiation of a contract for each DSI utilization, but one or a limited number of standard contracts. This alternative requires downstream monitoring of DSI use for implementation or enforcement, and monitoring. The difference between the two sub-options is the way that MATs are dealt with, one at the national level and the other at the international level.

Option 2.1: Standard mutually agreed terms/licence at the national level

In this scenario, each Party establishes a policy system with one or a limited number of standard MAT/licences in their domestic ABS legislation with which users need to comply. This system goes through each country's domestic legislation. Triggers can occur at commercialization, for example, and the benefits would be shared bilaterally. In a similar policy, benefit-sharing obligation is triggered when a patent is registered and starts after successful commercialization of a product developed using DSI. Researchers whose activity is subject to such national legislation must comply with the national system and trace the DSI back to the country of origin of the genetic resource. If a researcher uses multiple DSI from different countries, he/she is required to potentially comply with a number of MAT/licences, depending on which standard MAT/licence the country has decided upon for their DSI.

Option 2.2: Standard mutually agreed terms/licence at the international level

This option addresses benefit-sharing at the international level, as opposed to going through each country's national system as presented under option 2.1. One or more standard licences are agreed upon and adopted by Parties, in which the terms and conditions depend on the licence attached to the DSI. The benefits from the use of DSI are handled by an international system that redirects them to the country of origin of the genetic resource. This means that the researcher/user does not have to approach each country individually.

This option offers the possibility to integrate the licences in the DSI database itself, and the terms and conditions are communicated to the user upon access (for example, obligations for commercial and non-commercial uses of a particular DSI). Another possibility is the integration of the terms and conditions or licences in the intellectual property system (for example, when seeking intellectual property protection, on the basis of a disclosure requirement on the use of DSI). In this option, benefits consist of pre-negotiated fixed royalties on the successful commercialization of a product.

A collaboration with journals, patent offices, databases, or any other point along the value chain of DSI should help enforce the reporting back to the DSI provider. In this case, the user is responsible for complying with the licence terms and conditions, and a downstream utilization tracking/monitoring mechanism will ensure the enforcement of these ABS measures.

Option 3: No prior informed consent, No mutually agreed terms

This general grouping of options involves a payment or contribution to go into a multilateral fund. It avoids the need for tracing the origin of the genetic resource from which the DSI was extracted, or the need to monitor the downstream utilization of the product or service derived from DSI. This option includes various possible forms of payments and contributions, with one sub-option being linked to the DSI itself, and the other being separate from the information itself.

Option 3.1: Payment for access to digital sequence information on genetic resources

Here, the principle of a payment for access to the sequences itself is central and can be set up in several ways:

One way is to collaborate with databases to help introduce a membership fee/subscription to access DSI. This fee can be determined following pre-negotiated criteria, such as, but not limited to research application, sector of research, revenue, or a flat rate annual fee.

Another way is to introduce a very small payment for access to individual DSI in the database. An account is created, and each sequence download results in a pre-determined fee being charged to the account.

Finally, a different arrangement is to provide free access to the sequence data itself, including some minimal data around it, such as species name, but introduce a fee to be paid on the associated data resulting from the analysis and processing of the data, such as protein function or gene association, as this associated data is estimated to be valuable for research and development. The BioSample database currently links sequence data with other data associated with the sequence itself, or the genetic resource from which it comes. In this policy sub-option, a collaboration with the BioSample database would lead to a charge for access.

Option 3.2: Other payments and contributions

Several ways in which payments and contributions can be established to be paid into a multilateral fund for benefit-sharing from the use of DSI have been proposed in the literature, all stemming from agreements with external entities. One proposal includes payment for a DSI-related service, such as storage, processing, expertise, and analysis of the sequences, offered in return for a payment.

Another proposal imposes a levy on products or services associated with DSI. One example is the imposition of a micro-levy on laboratory equipment linked with the production of DSI, while another is on the cloud-computing space rented for the purpose of sequence storage and/or processing.

Yet another proposal revolves around biodiversity bonds, as experiences from other fields, such as payments for the use of wildlife images, or climate change green bonds could be used to inform options for DSI. Another option involves a marketing programme whereby a label or badge is used on products to boost their sale and convey an idea around biodiversity conservation, while the companies selling these products would redirect a negotiated percentage of benefits to a multilateral fund. Finally, voluntary contributions could fuel a multilateral fund and come from the private sector, database users, countries, private donors, subnational governments, or observers, etc.

Option 4: Enhanced technical and scientific capacity and cooperation.

Under this option, systematic and mandated technical and scientific cooperation and capacity development related to DSI are promoted. Enhanced capacity support for developing countries will democratize the access and use of DSI, making it more equitable so that each country has improved/expanded capacity and opportunity to generate, access and use DSI to its full potential. This could take the form of research collaborations, training, knowledge platforms, technology transfer, technology co-development, database satellites, database infrastructure, and more. This option is almost always presented in combination with other policy options.

Option 5: No benefit-sharing from digital sequence information on genetic resources

This option entails that the international community decides that no explicit benefit-sharing is necessary from the use of DSI from genetic resources and, thus, no additional mechanisms are proposed for benefit-sharing to be implemented.

Option 6: 1 per cent levy on retail sales of genetic resources

Under this option, a multilateral fund would be established and financed through a 1 per cent levy on all retail sales of goods in developed countries arising from the utilization of genetic resources in cases where the bilateral PIC and MAT system is not implementable or practicable. Funds would be distributed through a competitive project-based approach for conservation and sustainable use by indigenous peoples and local communities and others, guided by scientists and governed by the multilateral governing body.]

B. Proposal for the establishment of a multilateral benefit-sharing mechanism

1. A multilateral benefit-sharing-mechanism may operate as follows:⁵

(a) Each developed country Party shall, in accordance with Articles 20 and 15.7 of the Convention, take legislative, administrative or policy measures, as appropriate, to ensure that 1 per cent of the retail price of all commercial income resulting from all utilization of genetic resources, traditional knowledge associated with genetic resources or digital sequence information on genetic resources is shared through the multilateral benefit-sharing mechanism to support the conservation and sustainable use of biological diversity, unless such benefits are otherwise being shared on mutually agreed terms established under the bilateral system;

(b) All monetary benefits shared under the multilateral benefit-sharing mechanism shall be deposited in a global biodiversity fund operated by the Global Environment Facility, as the financial mechanism of the Convention, or in the new Global Biodiversity Fund if one is created and this global fund shall also be open for voluntary contributions from all sources;

(c) The global biodiversity fund shall be used, in an open, competitive, project-based manner, to support on the ground activities aimed at the conservation of biological diversity and the sustainable use of its components, in line with the ecosystem-based approach, carried out by indigenous peoples, local communities and others, in pursuit of spending priorities identified from time to time by the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services through scientific assessments.

2. The Executive Secretary would be requested, in consultation with all Parties and the Global Environment Facility, to prepare options for national legislative, administrative or policy measures to implement a multilateral benefit-sharing system and to report to the Conference of the Parties at its sixteenth meeting.

C. Possible approaches for a hybrid solution on access and benefit-sharing arising out of the use of digital sequence information on genetic resources

- No Previous Informed Consent (PIC) would be required, just Mutually Agreed Terms (MAT) required when the triggering point for benefit-sharing is reached.

The sequences in the databases will remain public for access and without payments associated with their use for non-commercial purposes. This proposal does not intend to make significant changes to the ecosystem of public databases or to the dynamics of using DSI for research processes and development processes before the commercialization stage.

⁵ The inclusion of this suggested option is without prejudice to discussions at the Conference of the Parties and is not intended to indicate any preference among potential options/solutions.

- The triggering point for benefit-sharing will be the commercialization of a product developed from DSI or the obtention of a patent associated with DSI.
 - For the sharing of benefits, there would be four alternatives depending on the country of origin identified in the “country tag” of the passport data of the DSI, or if it is traditional knowledge involved:

*The country of origin must be understood as the country of origin of the genetic resource from which the DSI was obtained.

Bilateral:

a) When the DSI subject of development (single or multiple) has a single and known country of origin, the sharing of benefits must be negotiated directly with that country. In this case monetary and/or non-monetary benefits may be agreed, and this could be done according to its national provisions.

To avoid jurisdictional shopping, increase legal certainty for users and providers, and seeking for expedite negotiation processes, it is desired to establish and agree international standardized Mutually Agreed Terms (MAT) to be implemented individually by countries. However, those MAT should be flexible enough to give countries the possibility to adapt them to their national provisions, needs and interests.

b) In respect of and the recognition of the rights of indigenous peoples and local communities, when it is used traditional knowledge associated with genetic resources held in databases or any other digital media, whoever intends to make use of this information must obtain the respective “prior and informed consent”, “free, prior and informed consent” or “approval and involvement” (language agreed in decision XIII/18) and carry it out under mutually agreed terms negotiated with the Community. In this sense, the distribution of benefits would also negotiated and shared in a bilateral way directly with IPLCs; an approach similar to what its representatives have proposed in the negotiations.

Multilateral

c) When the DSI subject of development has more than one, but known, countries of origin, the sharing of benefits is handled through a multilateral mechanism that directs the benefits to the countries of origin.

d) When the DSI subject of development has no country of origin identified the sharing of benefits is also handled through a multilateral mechanism. However, in this case the benefits are used for global efforts for the conservation and sustainable use of biodiversity, mainly with developing countries and those with economies in transition.

- For both cases under the multilateral mechanism, internationally standardized mutually agreed terms must be used, i.e., the percentages and types of benefits to be distributed are homogeneous and agreed internationally.
- Despite it is more practical to share only monetary benefits through a multilateral mechanism. Taking as an example the provisions of Article 5 of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization and its Annex, through a multilateral mechanism there would be the possibility to share also non-monetary benefits, i.e., actions for capacity-building or to support efforts for biodiversity conservation.

Indeed, when the countries of origin are known it would be feasible to direct these actions to those countries. However, even when the origin of the DSI is not known, it would be desirable that the sharing of mechanisms is based on criteria different from competitiveness that allow the benefits to be directed towards the countries that needed it the most. For example, developing countries, the ones with economies in transition, countries facing environmental emergencies, etc.

- The multilateral component of the proposal is compatible with any other proposal of a multilateral benefit-sharing mechanism. However, even if some desired details of the operation of the

multilateral component are mentioned, those details are subject for further development, and they must be agreed at the international level in the context of the CBD negotiations.

- The proposal does not intend to impose traceability obligations for authorities. It is based on the information that users disclose when registering a product for commercialization or to obtain a patent.
- There is no need to trace back the information on the country of origin, or that this information is attached to the sequence at every step of the value chain. The information of the “country tag” is available at one click through the unique identifier of the DSI (i.e., the accession number, DOI or its equivalent) at any stage of the development and it must be provided by the user, not identified by the authorities.
- The proposal does not intend that users must disclose the origin of every single sequence when they register the product for commercialization or to obtain a patent. The way in which benefits should have been distributed could be identified by simple yes or no questions at the registration point, or, with future developments, by just providing the accession number(s) of the DSI. However, the easiest way for authorities to determine if the benefit-sharing obligations were met is to request the mutually agreed terms obtained by the user.
- The proposal is also based on the “good faith” principle of users. Even if for making it fully operational it could be thought that the proper identification of the origin of every single sequence would be needed, this won’t be technical and administrative feasible for any authority. The same currently happens for physical genetic resources. At the end, it mostly relies on users’ practices.

D. Proposal for how to address digital sequence information on genetic resources in the post-2020 global biodiversity framework

Recommends to the Conference of the Parties that digital sequence information on genetic resources be included in the post-2020 global biodiversity framework under goal C, target 13, target 13bis, target 15 and in the monitoring framework for the post-2020 global biodiversity framework. Further recommends that it be included in the decision adoption the global biodiversity framework with a clear subsequent interpretive agreement that utilization of genetic resources is equivalent to utilization of biodiversity, a decision to establish a global multilateral benefit-sharing mechanism and a call on all society to start contributing a 1 per cent of the retail price of all biodiversity products.

E. Proposal for a hybrid solution to promote access and benefit-sharing from digital sequence information on genetic resources

The ABS gap

The rapid evolution on research and utilization of genetic resources shows a clear tendency to resort almost entirely to genetic sequences in international data banks. As the collections in these banks grow, the research and industrial sectors become less dependent on physical samples of biodiversity, creating a gap between the letter of the Convention on Biological Diversity and the practice of the utilization of genetic resources.

The restriction of the third pillar of the Convention on Biological Diversity to only those situations in which there is a utilization of genetic matter will result in the extinction of the ABS regime. Hence, it is of utmost importance that the object of international discussions should not focus on the format of the genetic resource but in its core object: the genetic information being utilized, and more than that, the resulting outcomes from the use of genetic information.

Monitoring results of DSI use is easier and cheaper than controlling individual DSI access through databanks that are not under providers jurisdiction. Results of use will be sooner or later registered, published and/or explored (through Scientific publications, IPR and Products commercialization), and monitoring such utilization could be built from the already established instruments under the Convention

(Checkpoints, CAN, NFP, ABSCHM etc) and compliance would be achieved through the registration of results on an electronic platform, governed by parties, and managed by the Secretariat of the Convention, a “DSI clearing-house and compliance mechanism”.

The funding gap

Discussions on resource mobilization under the Convention on Biological Diversity are currently focused on mobilizing resources from all sources and innovative mechanisms, including from the private sector. There is a broad recognition that the interim financial mechanism does not currently cover the needs to implement the post-2020 global biodiversity framework under negotiation. Therefore, the possibility of implementing a fund under Article 10 of the Nagoya Protocol must be seriously considered. Even if the resources mobilized through ABS would not be substantial, comparing to other funds, all sources should be welcomed to support the implementation of the global biodiversity framework.

Filling the ABS and funding gaps – hybrid solution for DSI

A decision on DSI must follow the recommendation adopted by the Working Group at its third meeting, in which Parties recognize that a solution for fair and equitable benefit-sharing on digital sequence information on genetic resources should, inter alia:

- (a) Be efficient, feasible and practical;
- (b) Generate more benefits, including both monetary and non-monetary, than costs;
- (c) Be effective;
- (d) Provide certainty and legal clarity for providers and users of digital sequence information on genetic resources;
- (e) Not hinder research and innovation;
- (f) Be consistent with open access to data;
- (g) Not be incompatible with international legal obligations;
- (h) Be mutually supportive of other access and benefit-sharing instruments, namely, for instance the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRA);
- (i) Take into account the rights of indigenous peoples and local communities, including with respect to the traditional knowledge associated with genetic resources that they hold.” (recommendation WG2020-3/2, para.5)

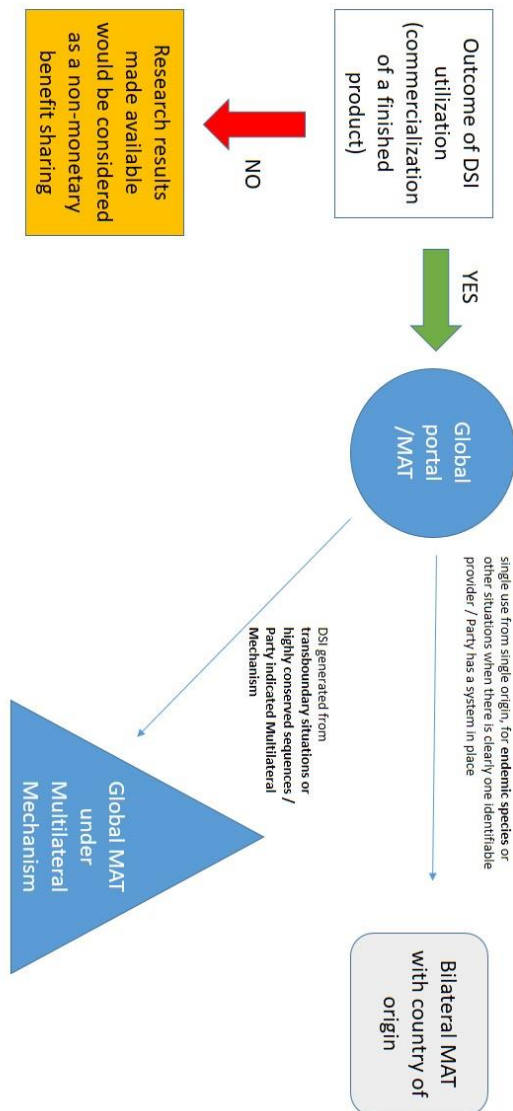
For such solution, Parties should change the focus from regulating processes/procedures, like controlling access, towards regulating results, publications, patents, cultivars, and marketable products and processes. This shift relieves the bureaucratic burden of research and development and focuses on the end of the chain, the economic exploitation of products and reproductive material.

Predictable rules will allow users to foresee their costs and obligations, in the short and long term, and will provide legal clarity to users and thus encourage the use of genetic resources. Legal measures that facilitate and foster research and development will generate more benefits, which can be channelled to biodiversity conservation and sustainable use, fulfilling the objectives of the international agreements on ABS.

Understanding that a hybrid solution offers flexibility to couple a multilateral system with national systems, a hybrid solution (mixing policy options 2.1, 2.2 and 3.1 from the Co-leads’ report on the work of the Informal Co-Chairs’ Advisory Group on digital sequence information on genetic resources since the fourth meeting of the Open-ended Working Group on the Post-2020 Global Biodiversity Framework, (CBD/WG2020/5/INF/1)) could be adopted with the following general understanding:

1. DSI falls under the purview of the Convention of Biological Diversity;

2. Open access, under terms and conditions, for research and development. Research results made available would be considered as a non-monetary benefit-sharing;
3. Requires monetary benefit-sharing from the economic exploitation of final products arose from the use of DSI;
4. The **trigger for benefit-sharing** is the registration of the **finished product** for commercialization and is calculated over the **net revenue** from sales (economic benefits are shared when they exist) – **predictability and legal certainty for researchers, users and business**;
5. **Hybrid system**, with a **single point of entry** (“**global portal**”), composed by **bilateral mechanisms** (national legislation compatible) and a **multilateral mechanism** (Nagoya compatible)
6. **Multilateral mechanism** (Nagoya compatible) – applies for DSI generated from **transboundary situations or highly conserved sequences**. No PIC, and no requirement of MAT when there are multiple sources, or the source is an open access public data base (**no mandatory tracking**);
7. In the case when multiple sequences or highly conserved sequences are used in the research phase, only the genetic information utilized in the **finished product** or **reproductive material** will trigger benefit sharing obligations. All the genetic information utilized in the research phase but not effectively used in the finished product or reproductive material are exempt from benefit-sharing obligations;
8. In the case of the multilateral mechanism, the manufacturer of a product should share benefits through a global multilateral benefit-sharing mechanism functioning under the Global MAT in a fixed percentage of the net revenue as agreed by Parties;
9. **Bilateral mechanisms** require MAT (without or with PIC, for instance when traditional knowledge is involved) – single use from single origin, for **endemic species** or other situations when there is clearly one identifiable provider;
10. For single uses or from a single origin, endemic species, or other situations when the origin is known, the producer should share benefits under bilateral negotiations such as under nationally established policy models or under the Global MAT, as per previously determined by the Party;
11. In the case of food and agriculture products – after registration to allow marketing, benefit-sharing is calculated over the **net revenue** from sales of **reproductive material** (seeds/seedlings/other forms of reproductive materials of **protected varieties** or semen/embryos of registered animal breeds), except for those under the SML of ITPGRA;
12. Benefit-sharing obligations are applicable while revenues are being obtained from the market;
13. Monitoring and compliance are less complex due to the single trigger point and single point of entry (“**global portal**”), well established rules and direct relation to net revenue.



The Brazilian experience with ABS and DSI

The Convention on Biological Diversity (CBD) explicitly recognized the authority of States to determine access to genetic resources as part of their sovereign rights over natural resources under their jurisdiction. Furthermore, it obliges all contracting parties to take legislative, administrative or policy measures, to share in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources.

For more than 20 years now, Brazil has put in place an ABS System which regulates the use of genetic information, even if disengaged from the physical sample since its first legal framework on ABS. Law No 13,123/2015 defines genetic heritage as the genetic information from plants, animals, and microbial species, or any other species, including substances originating from the metabolism of these living organisms. Therefore, Law 13123/2015 already includes in its scope the use of digital genetic information, and users are subject to the need for registration and, according to the case, sharing of benefits from economic exploitation of products or reproductive material arising from it, since the economic exploitation of a

finished product or reproductive material was established as the single point of incidence of benefit-sharing obligations.

A systemic reading of the CBD and the International Treaty on Plant Genetic Resources for Food and Agriculture (Plant Treaty) strongly influenced the elaboration of Law 13,123/2015 and its Decree No. 8,772/2016. The CBD defines “genetic material” as any material of plant, animal, microbial or other origin containing functional units of heredity.

According to the Oxford Dictionary, the word “material” can be defined as “information or ideas for use in creating a book or other work”. The definition of the word “matter” is “physical substance in general, as distinct from mind and spirit; (In physics) that occupies space and possesses rest mass, especially as distinct from energy”. The term “material” should not be confused with the term “matter”. The definition of the word “material” allows the interpretation of the term to include the set of information associated with the genetic resource, that is, the substrate information or working material. Restricting the meaning of the word “material” to the word “matter” jeopardizes the obligation to share benefits, the sovereignty of the countries parties over their genetic resources, and contradicts the CBD and the Plant Treaty.

Even if genetic information obtained digitally is to be considered as excluded from the concept of genetic material, a systemic interpretation of the CBD and the Nagoya Protocol leaves no doubt that the utilization of this information is subject to benefit sharing. 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 this obligation. Since there was “utilization” of a physical sample to access this type of information, its application and subsequent commercialization should be shared in a fair and equitable way, in line with Article 5 of the Nagoya Protocol and article 10 of the Plant Treaty.

The new ABS Legislation entered into force in November 2017, when the ABS electronic registration system “SisGen” started to operate. The National System for Genetic Heritage and Associated Traditional Knowledge Management (SisGen)⁶ is the electronic system maintained and operated by the Executive – Secretariat of CGEN, under the Ministry of Environment, it is the “one stop shop” for the registration of ABS activities. In general, there is no need for a prior authorization to start a research or development activity on Brazilian genetic heritage. The prior authorization was replaced by a registry made with the system, which is declaratory.

SisGen manages the registry of access to genetic heritage or associated traditional knowledge; Notifications of finished product or reproductive material and benefit-sharing agreements. Additionally, the SisGen issues the Certificates of lawful access, that, to be granted, the access (research and development activity) registration must be carried out previously to:

- I – the remittance of samples of genetic material;
- II – the application for any intellectual property rights;
- III – the commercialization of the intermediate product;
- IV – the disclosure of final or partial results in scientific or communication circles; or
- V – the notification of finished product or reproductive material developed because of the access.

Users are free to choose the best moment to do the registration as long it is before the above-mentioned triggering events. Moreover, since there is no need for a prior registration, if a given access activity does not have any results, any intellectual property right applications, products or processes developed, that access activity does not have to be registered. The main idea is to promote and facilitate access and to only demand information when a concrete result has been achieved, which is moment the user must declare what activities took place (i.e. research and technological development) and provide all the required information.

⁶ <https://sisgen.gov.br>

It is through the notification that users of the Genetic Heritage declare to comply with the requirements of the Law and indicates the preferred modality of benefit-sharing to meet their legal obligations. The modality is up to the User to decide and are “monetary”, through a payment to the National Fund, or “non-monetary”, with the user directly funding a conservation project or activity, in accordance with the National Benefit Sharing Programme created by the Law nº 13.123/2015. In the non-monetary modality, a Benefit-Sharing Agreement must be signed with the Ministry of Environment, foreseen all the activities that the user declare to execute as benefit-sharing.

The Notification of a Finished Product equals to the celebration of mutually agreed terms, in accordance with Article 15 of the Convention, since the user agrees with the terms and conditions required by the national legislation. Briefly explained, Users must adhere to the ABS Terms and conditions pre-set in Law/Decree. Users accept the predefined conditions by registering their ABS activities in an online system – the SisGen. Users adhere to the pre-set rules (ABS contract) by registering/notifying ABS activities through the SISGEN website.

A finished product is defined by Law as a Product which is apt to be used by the final consumer, whether it is an individual or legal entity. Moreover, the benefit-sharing obligations applies only to a finished Product, that must arise from access (research and technological development in the Brazilian Law), independently if it was produced in the country or abroad, and finally, the Genetic Heritage should be one of the main elements adding value to the product.

According to the Law, it does not matter who has conducted the access on DSI or who is selling the finished product, it is the manufacturer of the finished product that must meet the benefit-sharing obligation.

Out of the almost 68.300 registered access activities in the SisGen by now, 1.411 declared in silico origin, from which 336 declared commercial intention activities, through the registration of Technological Development activities arising from the utilization of digital sequence information/genetic information on Genetic Resources. The other 1.075 are equivalent to “access activities from commercial and non-commercial use of digital sequence information on genetic resources”.

The conclusion of the registration of a Research activity by the user equals to the obtaining of a non-commercial access permit. Thereto, the registration of a Technological Development activity by the user, which in the Law is considered as a “systematic work on genetic heritage carried out with the objectives of developing new materials, products or devices, or improving or developing new processes, for economic exploitation”, equals to the obtaining of a commercial access permit. Almost 800 Legal Persons (60% companies) and more than 25 thousand individuals concluded their registrations and are providing information on their research and development activities arising from genetic heritage (including from in silico origin) and ATK in the SisGen.

In order to provide concrete examples on the “benefit-sharing arrangements from commercial use of digital sequence information on genetic resources”, one could refer to a Technological Development activity registered in the SisGen, which proposes the use of bioinformatics to find pharmacological receptors (proteins), deposited in the Protein Data Bank PDB, of natural products from the Brazilian Biodiversity.

Nevertheless, since there is in general no prior authorization to use Genetic Heritage from Brazil, anyone using that proteins sequences would have to register their results or notify products only when there is a concrete result and before some triggering events, such as the publication of a Scientific Paper, a Patent Application, a By Product commercialization or a finished Product Notification.

In other words, Brazilian genetic heritage can be openly accessed, under terms and conditions, but the results and products of its utilization must be regularized by a registration or notification procedure, in the proper moment and according to each case. Its paramount for Brazil to foster research and development arising from its genetic diversity and, having in mind the evolution of the techniques available to do so, it is the national understanding that access, including through the utilization of genetic resources from an in-silico origin, must be facilitated to generate the benefits that will fund biodiversity conservation and sustainable use. Hence, to do so, the regulation should focus on results rather than procedures.

With the SisGen, the Brazilian ABS system evolved from a case-by-case prior authorization and MAT celebration, to focus on end-users for benefit-sharing, for monitoring of access outcomes, and for results and value chain regularization through an online registration system.

In summary, Brazil has adopted:

- A facilitated mechanism for access to genetic resources, with a change in the focus of regulation, previously focused on the control of access to genetic resources, now shifted towards control of the economic exploitation of products or reproductive materials arising from access;
- The development of an online declaratory registration system to trace, track and oversee access to genetic resources and associated traditional knowledge activities – SisGen;
- The registration is an obligation only in specific trigger points, such as shipment, request for intellectual property rights, publication of results and commercialization. Research and development activities that do not result in any of the above-mentioned activities are not demanded to register;
- Prior Informed Consent for access to traditional knowledge (TK) is mandatory and should be obtained directly with indigenous peoples and local communities (IPLCs);
- The single point of incidence of benefit-sharing obligations is the economic exploitation of a finished product or reproductive material: this is the link of the value chain with the highest value added, discharging any research and development activity. Therefore, economic benefits are to be shared when they do exist;
- The percentage of monetary benefit-sharing from products or reproductive material derived from the use of genetic resources is established as 1% of net revenues from the product or reproductive material sales. Hence, there is no speculation of values and no surprises for genetic resources users. It gives predictability and legal certainty to invest in Bio-based products arising from access;
- The clearly established point of incidence combined with a defined percentage of benefit-sharing to be valued under a specific concept such as “net revenue” make the monitoring of compliance feasible, since they are based on fiscal and accounting principles and rules;

Brazil also have positioned in favor of using the Global Multilateral Benefit-Sharing Mechanism to resolve issues of benefit-sharing relating to 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 origins.

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