Keep talking while everything gets sequenced: Is global governance of Genetic Resources keeping pace with digitization?

Sylvain Aubry[a*], Pierre Walckiers[b], Christine Frison[c,d],

[a] Federal Office for Agriculture, Bern, Switzerland

[b] Law Faculty, University of Louvain, Louvain-la-Neuve, Belgium

[c] Government and Law Research Group, University of Antwerp, Antwerp, Belgium

[d] Law Faculty, University of Liège, Liège, Belgium

*Correspondence: sylvain.aubry@blw.admin.ch 00 41 58 462 74 95

Abstract

The digitization of data originating from the genomic analysis of biological material was long considered a minor technical-scientific detail in the global negotiations over environmental governance. During the last decade, it has gradually become a key element of many, if not all negotiation fora dealing with genetic resources: terrestrial and marine biodiversity, agriculture, health and human genomics. Genomics is the cornerstone of modern biology and large DNA sequencing projects are expanding in the big data era. Meanwhile, no standardized governance solution emerged. In this paper, we take a snapshot of the various debates over Digital Sequence Information in all the international environmental fora dealing with biodiversity, global health, and genetic resources. We discuss the extent to which the increasing institutional and legal fragmentation, essentially dealing with very similar issues and with often distinct governance procedures, stakeholders or spatial scope, is shaping the future of the Access and Benefit Sharing regime complex. While equity has become a central element of multilateral environmental negotiations, we question the ability of an increasingly fragmented institutional regime to effectively tackle global challenges like the biodiversity crisis or the next pandemic.

Keywords Access and Benefit Sharing, Regime Complex, Digitalization, DSI, Genetic Resources

How to agree on an undefined term? The DSI conundrum

Digitization has been one of the major bottlenecks in the recent Access and Benefit Sharing (ABS) negotiations. Signals from various fora where governance mechanisms for genetic resources data - often referred to as Digital Sequence Information (DSI) - are negotiated, show very striking similarities, in particular on ways to share the benefits arising from their use and call for more coherence across reglementary silos (Aubry et al., 2022; Sett et al., 2024). Divergent paths and competing mechanisms can be observed in various international legal instruments governing genetic resources, whether through *lex specialis* instruments (for seeds and marine genetic resources) or for all genetic resources under the Convention on Biological Diversity (CBD) and its Nagoya Protocol. The CBD was created in 1992 to govern the conservation, sustainable use, fair and equitable benefit sharing mechanism of material genetic resources [CBD, Art. 1]. For a long time considered a technical detail, the idea gradually pervaded that biodiversity and genetic resources governance might be missing the point by only focusing on physical samples without considering the digital information extracted from their material shell (Laird et al., 2020; Aubry et al., 2022). Many observers and parties believed that the CBD and other associated treaties like the International Treaty of Plant Genetic Resources for Food and Agriculture (ITPGRFA) may become obsolete by missing an important fraction of the genetic resources' utilization (Aubry, 2019). Since 2016, all international treaties dealing with genetic resources have integrated DSI into their agendas without effectively proposing a clear or coordinated governance mechanism to this day and without influencing the development of major sequencing capacity in any way (CBD, 2016, Figure 1). The stakes over DSI touch various levels: DSI may be within or without the scope of these instruments and with or without any clear legal solution to regulate their access or the benefits deriving from their use. In any case, their utilization is an essential parameter for megadiverse countries, mostly providers of material and data, as well as for stakeholders from the Global North whose research and development pipelines vastly rely on open-source data (Scholz et al., 2021).

Interestingly, while prompting a lot of "hot air", the terminology related to omics data is still not stabilised. At least two acronyms are commonly used in various negotiation fora to refer to slightly overlapping concepts: Genetic Sequence Data (GSD) and Digital Sequence Information (DSI). GSD is defined in the Pandemic Influenza Preparedness Framework (hereafter PIP framework) as the "order of nucleotides found in a molecule of DNA or RNA" (PIP, Art. 4.2). So far, GSD is almost exclusively used in the context of the PIP framework, while transiently taken over in the Pandemic Treaty negotiation to be later replaced by "sequencing information" (Walckiers et al., 2024). Noteworthy, it is unclear whether focusing solely on GSD adequately addresses current practices of modern omics, like the growing importance of non-DNA-based data such as metabolomics or protein structures for biomedical applications or nutrition (Gonzalez-Covarrubias et al., 2022; Jarvis et al., 2024).

By contrast, the DSI acronym is used mostly under the remits of the CBD and other ABS instruments, with a scope still to be determined. While many studies, publications, debates, workshops and informal discussions have been produced for almost a decade, there is no formally agreed definition of DSI. The

absence of a definition, while leading to some legal uncertainty, also provided some constructive ambiguity in the latest CBD negotiation rounds that led to the onset of a possible multilateral solution (CBD, 2022). A range of possible definitions have been proposed for DSI: *stricto sensu*, includes DNA and RNA (being then equivalent to GSD) but *lato sensu* can range to proteins, metabolites or even other phenotypic, structural, meta-data and traditional knowledge (CBD/DSI/AHTEG/2020/1/3, 2020).
Using a particular terminology may have very concrete impacts on the scope, obligations and mechanically on the effectivity of these instruments (Walckiers et al., 2024). Taking a step back, beyond the terminology itself, the decisions related to GSD/DSI taken in any of the ABS-related instruments could have dramatic consequences on the others.

Digital data from genetic resources accumulate independently of their governance

Generation of and access to data derived from genetic resources is central to contemporary research and development, and biodiversity research is no exception (Figure 1). For example, one of the biggest genetic data repositories, NCBI Genbank, is hosting 19,6 trillion nucleotides[1] by mid-2024 and its size roughly doubles yearly (Sayers et al., 2023). The potential values and interests of genetic digital information for the bioeconomy have been discussed since the nineties (Pistorius and Wijk, 1999). However, the first formal consideration of digital data as a discrete agenda item in the framework of the Convention for Biodiversity only emerged twenty years later, at the 13th Conference of Parties of the CBD (CBD, 2016). It "recogniz[es] the importance of digital sequence information on genetic resources for the three objectives of the Convention" (CBD, 2018). This cross-cutting issue over digital governance of genetic resources has crystalized many frustrations concerning a partially malfunctioning ABS framework.

Emerging new governance of DSI at the Convention for Biodiversity

After a decade of discussions, landmarks and decisions have been taken in various fora. In 2022, decision 15/9 of the 15th COP/CBD opened up the first avenue towards a multilateral solution. It was followed by decision 16/2 of the 16th COP in 2024 to set up the building blocks of a multilateral mechanism governing digital information CBD (CBD, 2024, 2022). This complex decision gathers key features like a dedicated fund (the "Cali Fund for the Fair and Equitable Sharing of Benefits from the Use of Digital Sequence Information") and opens the path to various possible governance options that the subsidiary body may explore. Interestingly, it targets big companies from specific sectors (enclosure 1, 16/2) and sets a precise (while non-binding) rate of payments. While new elements of governance can be taken for granted, major weaknesses remain: first, the formally non-legally binding nature of the COP decision is further undermined by the use of loosely binding obligations and language; second, the lack of understanding of the fluidity and speed of DSI practices (typically, the lack of practicability of a

[1] Nucleotides are units of DNA, also expressed in base pairs.

dedicated database to CBD-related DSI). While the discussions in other fora on DSI are acknowledged in the preambular of the decision, it is hardly possible to foresee any practical solution emerging for other instruments to deal with this emerging new multilateral system. Indeed, systemic thinking seems largely absent from the discussions. Major institutional and political limitations impair cross-sectorial dialogue (Aubry et al., 2022). Nonetheless, a slow but significant learning process across instruments and secretariats has been gradually observed. Many efforts remain to be made to reach a common understanding, or as mentioned above, a stable terminology over the DSI issues. There are also obvious political interests not to engage outside everyone's very own ABS backyard: an overarching solution encompassing several instruments might potentially reduce the power of each specific secretariat, governing body at the UN level or ministry at the national level (Koskenniemi, 2011, p. 338). This institutional powerplay has been very well described in the evaluation of regime complexes (Eilstrup-Sangiovanni and Westerwinter, 2022) but has dramatic consequences on the overall efficiency and accountability of the global governance of biodiversity. For example, debates over the possibility (and the process towards) the recognition of the forthcoming Pandemic Treaty as a specialized instrument as in article 4 of the Nagoya Protocol to the CBD are very illustrative (CBD, 2011; Rourke and Eccleston-Turner, 2021). The combined lack of understanding and clearness on both sides is representative of the gap between regulatory silos that is also observable in the DSI negotiations. But regardless of the pace of the negotiations, scientists keep piling up exponential amounts of data.

When the DSI question diffuses away to the global health discussions

As mentioned above briefly, one of the most rapidly evolving discussion concerning data governance may be taking place within the formal negotiations on a new international legally binding instrument dedicated to pandemic prevention and response (World Health Organization, 2023). Since 2021, an intergovernmental negotiating body was established by the WHO's Member States to draft a convention, agreement, or any other international instruments on pandemic prevention and response, formally referred to as the "WHO CA+" or the "Pandemic Treaty." Major driving principles are leading the negotiations, like including the "One Health" approach, aiming for a cross-sectorial approach to health, agri-food, environmental, human, and animal issues (Walckiers et al., 2024). Some of the discussions also aimed at defining the modalities of inception of a new pathogen Access and Benefit Sharing System possibly fitting into a pandemic context, in terms of speed, efficiency of access, fairness and equity (Article 12, WHO INB, 2024). The degree of multilateralism to be integrated into a new Access and Benefit-Sharing mechanism remains to be determined. Debates and positions are comparable to the DSI debates under the CBD bodies (INB, WHO, 2024). In both cases, most parties advocate for norms of solidarity, fairness, transparency, inclusiveness, and equity as a means to address the shortcomings of their governance. For example, COVID-19 international response, both in terms of strain, data sharing or vaccine distribution mostly happened outside any legal oversight (Rourke, 2024). Even before considering their digitization, the governance of pathogenic genetic resources is fragmented between

the Nagoya Protocol (Art. 8), the PIP framework and the forthcoming Pandemic Treaty. So far and in most cases, the pathogen genetic resources belong to the pool of genetic resources under the national sovereignty of their country of origin and access is regulated on a bilateral basis (Huvos et al., 2020). Noteworthy, there is a thin line from a genomic point of view, between human pathogen genetic resources and human-derived genomic data that sometimes leads to certain confusion, while it is commonly admitted at the institutional and legal level that human-derived data are excluded from the scope of the CBD (Lawson et al., 2018). Human genomic research standards have improved dramatically in the last decades, but whether and how data governance might include more equity, particularly regarding modalities of benefit sharing, is increasingly discussed (Mc Cartney et al., 2024). Calls for equity and open access were part of the early discussion on the Human Genome project some thirty years ago (Sulston and Ferry, 2002). It might therefore be surprising that discussions over human data governance are emerging again. We may interpret that as yet another reverberation of the DSI debate that started first in the biodiversity circles.

Overall, the credibility of the global ABS framework is still being tested. The Pandemic Treaty negotiations that almost stumbled down in May 2024 are not occurring in an institutional vacuum: they evolved in busy regulatory environments at the crossroads between biodiversity, scientific data and global health governance regimes. The ways a new Pandemic Treaty might interact with the current ABS framework, particularly how it deals with genomic data, will have consequences on other sectors, particularly for the conservation of biodiversity and maybe even human genomics.

Fragmentation and Incantatory mutual supportiveness

Despite repeated calls for consistency and supportiveness between ABS treaties, agreements and conventions (Sett et al., 2024), there is an increasing fragmentation of the genetic resource's governance: leading to an increasingly complexification of the overarching regime complex (Figure 2, Oberthür and Pożarowska, 2013). For example, independently of the final scope of the forthcoming Pandemic Treaty, the genetic resources from pandemic pathogens regulated through this new instrument will mostly originate from the genepool of the CBD and its Nagoya protocol (Figure 2). This significant subtraction (terrestrial biodiversity *minus* pandemic pathogens), or more precisely this additional layer of regulatory complexity on a subset of genetic resources is a symptom of the increasing trimming forces applied to the ABS framework. We attempt to represent these forces in two dimensions:

The first stream tends to multiply sector-specific instruments with scopes answering a specific subset of stakeholders' concerns (Horizontally in Figure 2). This is not a new process, *ad hoc* solutions are formally acknowledged in Article 4 of the Nagoya Protocol, but it may weaken the visibility and efficiency of the ABS framework generally. In this context, we can even question the relevance of creating new sector-specific instruments if they are to share the same underlying principles as the pre-existing instrument (Oberthür and Pożarowska, 2013).

The second stream has been triggered by the digitization of genetic resources (Vertically in Figure 2). The many issues underlying the digitization of genetic resources, like the speed and scale of sequencing and the impossibility of holding a bilateral approach to benefit sharing, have not been sufficiently addressed (Laird et al., 2020; Aubry et al., 2022). Despite several "mutually supportive" provisions, the COP CBD decision 16/2 being no exception, the further the regime complex develops, the less likely a unique, inter-sectorial and multilateral solution will emerge. While all ABS instruments dealing with genetic resources share the same principles, mutual supportiveness across instruments remains largely incantatory (Aykut et al., 2021). Deep in a context of fragmentation, complexity, and institutional concurrencies in international law, particularly within genetic resource governance, we suggest a more holistic approach to the different instruments, where care must be taken across various negotiations and fora to mitigate these tensions (Aubry et al., 2022).

Conclusions and outlook

What has been long considered a techno-scientific detail, the digitization of data extracted from genetic resources pointed out a core weakness of the ABS framework architecture. This siloed approach to environmental and health governance can also be explained by the context of public international law: its general principles, practices, or rules of interpretation. For example, the Vienna Convention clearly states that "any relevant rules of international law applicable in the relations between the parties" shall be taken into consideration when interpreting a treaty (Art. 31.3(c), Vienna Convention, 1969). Following the principle *pacta tertiis nec nocent nec prosunt*, an obligation in international law applies only to the parties who have consented to it. Therefore, the interpretation of a treaty can mobilize the content of other treaties only if it is accepted by all parties (Gardiner, 2015, p. 311; McLachlan, 2005, p. 314). Yet, despite the frequent overlaps in the ABS regime complex, there are significant differences between the contracting parties to the various instruments (Supplementary Figure 1). This discrepancy between contracting parties, signatories and third parties to various instruments dealing with similar goals demonstrates a lack of systematicity. It fragments international law and tends to complexify the negotiations and the implementation of the treaty's provisions. In particular, globalized objects like omics data repositories that mostly navigate independently of formal legal constraints increase this complexity. Trying to integrate the digitization of modern scientific practice as a parallel track that largely evolved outside any legal construction has eventually revealed the permanence of the inequities the ABS framework is supposed to address. Most of these instruments deal with various elements of biodiversity, sometimes with some overlap, but generally share a commitment to bring equity within the global governance of DSI (Halewood et al., 2023).

In the meantime, care should be taken not to "tokenise" the DSI issue too far. While the issues over equity remain central, slowing negotiations for years might eventually be counterproductive to the objectives of the conventions, particularly the imperatives of biodiversity conservation (Armstrong, 2024). Indeed, twenty-five years of open-access science produced enormous amounts of data. There

might be enough data available that is openly accessible not to prime for a quick solution to share any benefits that could be extracted from their use. Even if no viable running policy has yet emerged from this first decade of discussion, with the notable exception of the newly adopted BBNJ, where national sovereignty issues are less contentious, the DSI debate has undoubtedly reconciled a lot of the bioscience performed in isolation with many other previously unconcerned societal actors. The tremendous work from parties, scientists and civil society that tirelessly tried to bring science and policy to communicate effectively must be acknowledged. Collectively pursuing the progress initiated at the two latest CBD COPs will be essential.

A stable, ethically sound and politically viable legal environment considering newly adapted ABS modalities is necessary for the ABS framework's stability and to guarantee that environmental and public health challenges can be addressed. Multiple calls for reflexivity, new normative frameworks and transdisciplinarity across the various ABS instruments appear to systematically collide with some inertia, institutional competing interests and ever-growing legal complexity. This may ultimately question the capacity of these institutional arrangements, the regime they constitute and their underlying norms to tackle urgent global challenges.

Contributors

SA, PW and CF conceptualized and wrote the paper.

Declaration of interests

We declare no competing interests.

Ethical approval

Not applicable

Funding statement

Christine Frison, is supported by the ERC-Starting Grant n° 101117449 DecoLawBiodiv project, and Pierre Walckiers under the Belgian National Funds for Scientific Research (F.R.S-FNRS) grant n°40011887 (ASP- FNRS).

Acknowledgments

The views and opinions expressed in this article are those of the authors and do not necessarily reflect the official policies or positions of their affiliated institutions.

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Figures

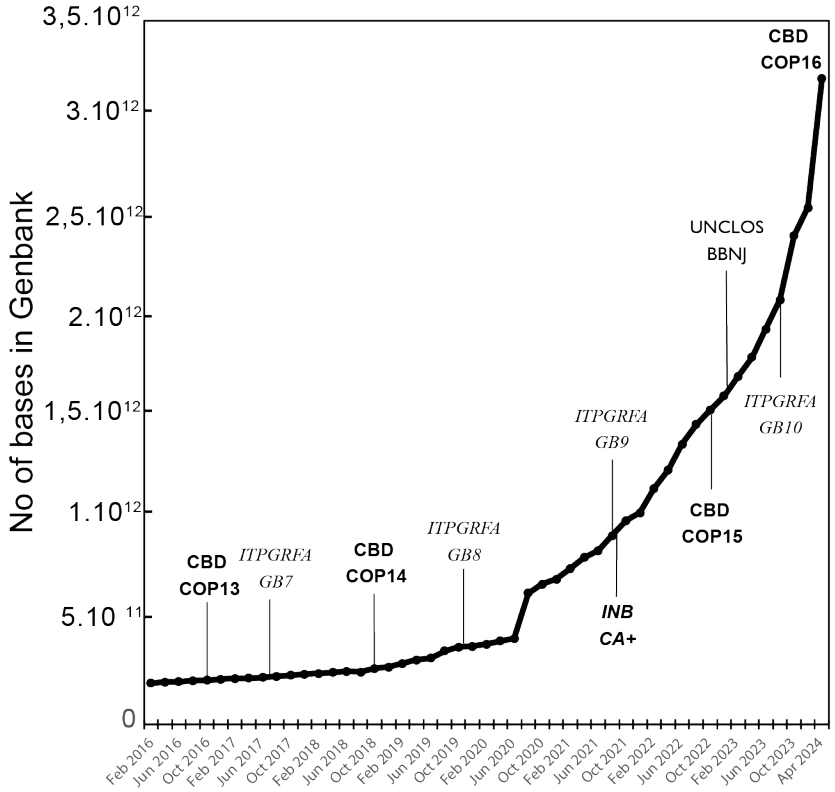


Figure 1. Accumulation of nucleotides (bases) in NCBI Genbank since the beginning of the DSI discussions in four ABS fora: the Conference Of Parties of the Convention for Biological Diversity (CBD COP, the Governing Body Meeting of the International Treaty for Plant Genetic Resources and Agriculture (ITPGRFA GB), the Intergovernmental Negotiation Body mandated by the World Health Organization for negotiating a Convention, Agreement, or any other international instrument on pandemic prevention, preparedness and response (INB CA+) and the High Seas Treaty under the United Nations Convention on the Law of the Sea ruling the Biodiversity Beyond National Jurisdiction (UNCLOS BBNJ). Noteworthy, while UNCLOS BBNJ is adopted, all other processes are ongoing. Since 2016, approximately $2{,}9.10^{12}$ nucleotides have been sequenced and stored in NBCI Genbank. Data: https://www.ncbi.nlm.nih.gov/genbank/statistics/

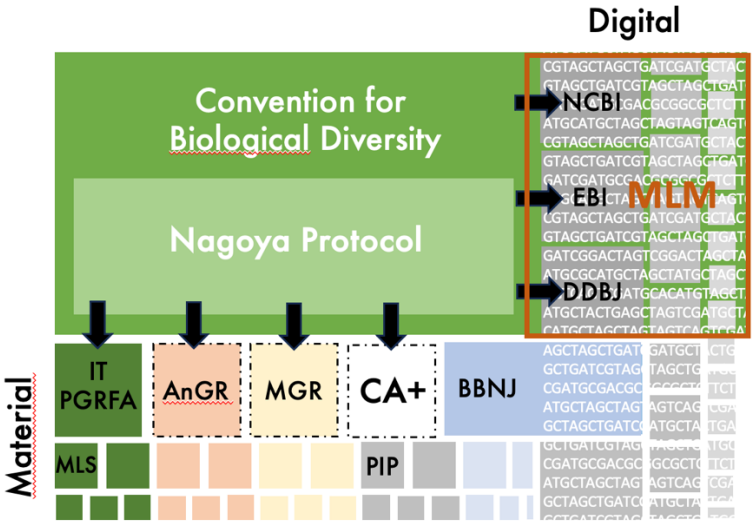
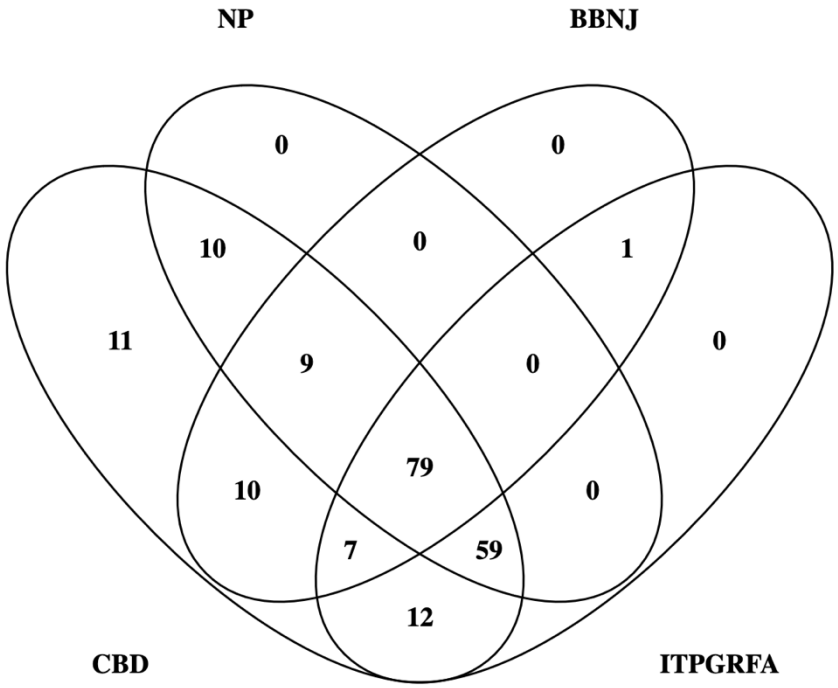


Figure 2. Trimming forces applied to the Convention for Biological Diversity and its Nagoya Protocol genepool. The multiplication of sub-sectorial instruments that extract specific subsets and try regulating them ad hoc (vertical arrows) and the split between material and digital resources. Some of the major databases are provided as an example: NCBI, National Center for Biotechnology Information, EBI, European Bioinformatics Institute and DDBJ, and DNA Data Bank of Japan. ITPGRFA, International Treaty for Plant Genetic Resources and Agriculture; MLS, Multilateral System; AnGR, Animal Genetic Resources; MGR, Microbial Genetic Resources; CA+, refers to the WHO CA+; PIP, Pandemic Influenza Preparedness Framework; BBNJ, Biodiversity Beyond National Jurisdiction; MLM, Multilateral Mechanism drafted in the CBD COP 16.

Supplementary Data



Supplementary Figure 1. The overlap between signatories of treaties dealing with genetic resources. CBD, Convention for Biological Diversity; NP, Nagoya Protocol; ITPGFRA, International Treaty for Plant Genetic Resources for Food and Agriculture; BBNJ, Biodiversity Beyond National Jurisdiction. All details about contracting parties are summarized in Supplementary Table 1.

Supplementary Table 1. Summary table of the data used for Supplementary Figure 1. Details over contracting parties and their respective status in the various treaties.