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**ON PLANT GENETIC RESOURCES
FOR FOOD AND AGRICULTURE**

Item 6 of the Provisional Agenda

**INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES
FOR FOOD AND AGRICULTURE**

**FIRST MEETING OF THE SCIENTIFIC ADVISORY COMMITTEE ON THE GLOBAL
INFORMATION SYSTEM OF ARTICLE 17 OF THE TREATY**

Rome, Italy, 24 – 25 November 2016

**THE GLOBAL INFORMATION SYSTEM AND GENOMIC INFORMATION:
TRANSPARENCY OF RIGHTS AND OBLIGATIONS**

Background study paper n. 10

by

*Daniele Manzella**

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“Governance no longer relates to germplasm itself, but to the digital information about germplasm.”

Shakeel Bhatti, former Secretary of the International Treaty, in his report to the Sixth Session of the Governing Body.

“There has been no agreement at the international level that the definition of genetic resources in the Nagoya Protocol includes sequenced data.”

Government of the United Kingdom, Department for Environment Food & Rural Affairs (March 2015). Consultation on implementing the Nagoya Protocol, A summary of responses and the government reply. Page 10.

1. Background

The work of the Treaty on plant genetic resources and genomics has been progressing since 2013, when the Secretariat commissioned a study on mainstreaming agricultural research through genomics.¹ The study, which was complemented by a survey on existing plant genomics programmes, signaled the opportunities of the genomic revolution for conservation and use of germplasm. Sequence data result from the process of determining the sequence of nucleotides in the genome of an organism. It includes reference genome sequences, which are high-quality assemblies of the genomes of one or more individuals of a species, used as a base line or reference for high-throughput re-sequencing and analysis of genetic variation; and sequencing of any part or all of the genome of individuals of a species with the goal of identifying genetic variation. Through genomics research technologies that apply biomolecular analysis, the value of genomic information increase.² The role that genomic information is expected to play, spans from conservation and pre-breeding to breeding. Mapping the genetic variation of a crop onto the geographic landscape allows for prioritized collection. Genomic information allows for pedigrees and relatedness of germplasm in collections to be analysed, thus leading to informed genebank management.³ Genomic information guides selection for phenotypic evaluations for pre-breeding and development of introgression lines. Genomic information enables targeted breeding through advanced genotype and phenotype data analysis, to target agronomically significant genes by establishing causality between a particular trait and one or several loci in the genome and by providing molecular markers to detect trait inheritance. Having established that a given gene controls a given target trait, the breeder can select the gene directly, which is faster, less expensive and more reliable than the traditional approach of measuring the target trait. Genomic information also allow to decouple the haplotypes from the particular individual or variety that is analysed.⁴ The study also flagged current challenges to data aggregation and sharing and advocated for a global framework to facilitate such aggregation and sharing. Although Article 17 of the Treaty, which establishes the Global Information System (GLIS), was certainly not motivated by technological developments on genomics at the time of its negotiation - the study points out - the value of data aggregation and sharing that the text of Article 17 reflects, suits well the practical needs of the plant sector.⁵

In the period between the Fifth and Sixth Sessions of the Governing Body, an expert group on the GLIS, informed by the study and other documentation developed by the Secretariat on data links and institutional and legal setting for the system operation, started elaborating a vision for the system and a programme of

* Without prejudice to the disclaimer made, the author would like to thank Ruri Sackville Hamilton, Francisco Lopez, Dan Leskien and Kent Nnadozie for the comments made to previous drafts of this paper.

¹ Wartmann, N. (2014). *Plant Genetic Resources and Genomics: Mainstreaming Agricultural Research Through Genomics*, Background Study no. 5, FAO, Rome.

² Nussbeck S.Y., M. Rabone, E.E. Benson, G. Droege, J. Mackenzie-Dodds, R.T. Lawlor (2016). “Life in Data – Outcome of a Multidisciplinary, Interactive Biobanking Conference Session on Sample Data”, *Biopreservation and Biobanking*, 14(1):56-64.

³ Wartmann, above n. 1, “Genotyping of collections promises a new level of quality and genetic integrity control. Molecular markers and sequence data can effectively be used for accession identification during acquisition, regeneration and multiplication, elimination of duplicates, clarification of taxonomic relationships, and the stratification of collections according to genetic relationships and gene pools.”. At 25.

⁴ Id. at 49

⁵ Id. at 8-9.

work to implement priority actions. In elaborating the draft vision, the group advised on the opportunity to link the GLIS with the genomics information domain, and the underlying research and user communities, in order to improve information associated with available germplasm.⁶

At its Sixth Session, the Governing Body endorsed a holistic vision of the GLIS, centered on:

- access to, exchange of information, which will materialize in a web-based platform with use-oriented entry points to information, and in standards and tools for interoperability;
- collaborations for the effective use of such information, through communication, capacity development and technology transfer;
- transparency of rights and obligations related to accessing, sharing and using information associated with germplasm.⁷

Although genomic information is not expressly referred to in the vision, it features in the programme of work that accompanies the vision, among the data sets that the GLIS assembles along the germplasm value addition chain (thus, in line with the previous advice of the expert group).⁸

As stated in the vision, clarifying rights and obligations related to accessing, sharing and using information, is instrumental to the practical exercise of those rights and obligations within the System.⁹ This paper is a first contribution to this area of work in the GLIS.

The Secretariat has commissioned this paper to focus on genomics information, in the light of the importance previously attributed to such category, in order to explore whether and how access and benefit-sharing (ABS) frameworks may influence the overall policy direction of the GLIS and, more specifically, impact on the ability of the GLIS to gather and make available genomic information. In line with the request by the Secretariat, the analysis in this paper is limited to the ABS regimes, thus the Treaty and the Convention on Biological Diversity (CBD) and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to the Convention on Biological Diversity (Protocol), their possible interpretations and national implementation. This paper deals neither with the protection of confidential information nor with copyright nor database protections. These and other forms of legal protection of information may bring forward legal limitations to gathering, keeping and making available information through the GLIS. They also constitute an essential determinant of information flows and policy decisions on data sharing in research collaborations.¹⁰

This paper situates itself amidst a number of recent developments within and outside of the Treaty.

Within the Treaty, implementation of the 6-year programme of work (PoW) for the GLIS that the Governing Body approved together with the GLIS vision has begun. The issue of ABS-based restrictions to genomic data production, availability and use of genomic information may impact several areas of the PoW. A component of the PoW, which the Secretariat prioritizes, is to implement Permanent Unique Identifiers, in the form of Digital Object Identifiers (DOI), that connect information associated to individual samples of germplasm by the initial provider and recipient, and by subsequent recipients through further analyses and

⁶ FAO (2015). Report of the First meeting of the Expert Consultation on the Global Information System on Plant Genetic Resources for Food and Agriculture. IT/COGIS-1/15/Report. Available at <http://www.fao.org/3/a-be664e.pdf>.

⁷ FAO (2015). Report of the Sixth Session of the Governing Body, Resolution 3/2015. IT/GB-6/15/Report. Available at <http://www.fao.org/3/a-mo938e.pdf>.

⁸ Id. at Annex 2.

⁹ Id. at Annex 1.

¹⁰ The GLIS-SAC may wish to explore both these aspects in the future. See Lawson, C. (2015) "Information, intellectual property and the global information system for plant genetic resources for food and agriculture", *Australian Intellectual Property Journal*, 26(1): 27–38. For examples from the human health sector of the IPR determinants of a data sharing framework, Chokshi, D.A., Parker, M., Kwiatkowski, D.P. (2006) "Data sharing and intellectual property in a genomic epidemiology network: policies for large-scale research collaboration", *Bulletin of the World Health Organization*, May 2006, 84(5). Foster, M. W., & Sharp, R. R. (2007) "Share and share alike: deciding how to distribute the scientific and social benefits of genomic data" in *Nature Reviews Genetics*, 8(8), 633–639.

evaluations. DOIs can be assigned to extracted DNA in order to identify it separately from the source germplasm sample and connect the relationship of linked data sets, including genomic information, to the source germplasm.¹¹ This linkage system may have ABS implications. Another component of the PoW that the Secretariat intends to facilitate, is the identification of legal barriers preventing data sharing, and possible incentives for users to contribute data to the GLIS. In the past, the Secretariat has explored the possibility of supporting sequencing facilities for germplasm resulting from projects of the Benefit-Sharing Fund, to address farmers' needs and priorities on advanced characterization of plant germplasm.¹² Furthermore, DivSeek - an initiative to bridge the information requirements of gene bank curators, plant breeders and upstream biological researchers to facilitate the use of plant genetic variation, that the Secretariat has co-facilitated - aims in the future to define standards regarding the acquisition, storage, retrieval and analysis of, among others, genotypic data related to plant germplasm.¹³

The biodiversity research sector is concerned about the possible reach of the Protocol to genomic sequences. Whether “ABS paperwork” is mandatory in case of development and use of sequence data remains an open question.¹⁴ Some scientists and ABS practitioners consider that the Protocol imposes restrictions on global data production, use and sharing.¹⁵ In April 2016, the CBD’s Subsidiary Body on Science, Technology and Technological Advice (SBSTTA) reviewed the recommendations of previously convened an *Ad Hoc* Technical Expert Group (AHTEG) on Synthetic Biology, which discussed ABS for digital sequence data, with contrasting views as to the opportunity to further advance consideration of the topic.¹⁶ The decision as to whether further intergovernmental work will deal with digital sequence data in the context of Protocol implementation, may be taken next December at the 13th Conference to the Parties but, given the high attention by many developing countries on the ABS implications of technological changes in sequencing (and gene synthesis), it seems unlikely that the issue will fade away from the agenda.¹⁷

Within the CGIAR, the Research Programs and Platforms for the period 2017-2022 feature three platforms, on big data, genebanks, and excellence in breeding.¹⁸ The big data platform aims to draw data, including genomics data, in open mode for unified and linked discoverability, including through the CGIAR Open Access and Data Management Policy.¹⁹ The genebank platform is intended to facilitate the targeted use and

¹¹ An object associated with a DOI name is described unambiguously by metadata. The DOI system is designed to facilitate access to multiple data sources. Specifically, DOI names can model relationships between objects and can also support the identification of individual attributes or groups of attributes of the object that need to be identified separately. Through a minimum set of relation operators, DOIs could be used to record the transformations of germplasm during its transfers. FAO (2015). Technical Options to Facilitate the Establishment of Data Links in the Field of Plant Genetic Resources for Food and Agriculture. IT/COGIS-1/15/3. Available at <http://www.fao.org/3/a-be643e.pdf>

¹² FAO (2015). Implementation of the Programme of Work on Sustainable Use of Plant Genetic Resources for Food and Agriculture. IT/GB-6/15/12. Available at <http://www.fao.org/3/a-mo314e.pdf>. At paragraph 25.

¹³ DivSeek (2016). *Frequently Asked Questions about DivSeek*. Available at <http://www.divseek.org/faqs/>.

¹⁴ Cressey, D. (2014). “Biopiracy ban stirs red-tape fears”, *Nature*, 514:14. Available at http://www.nature.com/polopoly_fs/1.16028!/menu/main/topColumns/topLeftColumn/pdf/514014a.pdf. At the time of negotiations of the Protocol, the CBD Secretariat had commissioned a study that reviewed the implications of using genomic and related data in public and private repositories on the monitoring and tracking of genetic resources. Garrity G.M., L.M. Thompson, D.W. Ussery, N. Paskin, D. Baker, P. Desmeth, D.E. Schindel and P.S. Ong (2009) *Studies on Monitoring and Tracking Genetic resources*. UNEP/CBD/WG-ABS/7/INF/2. Available at <https://www.cbd.int/doc/meetings/abs/abswg-07/information/abswg-07-inf-02-en.pdf>

¹⁵ Holt, W.V. (2015) *Implications of the Nagoya Protocol for animal genetic resources exploitation and collections*, International Embryo Technology Society. Available at http://www.iets.org/iets/Implications_of_the_Nagoya_Protocol.pdf

¹⁶ UNEP (2016). Recommendation adopted by the Subsidiary Body on Scientific, Technical and Technological Advice, XX/8. Synthetic biology, UNEP/CBD/SBSTA/REC/XX/8, 2 May 2016. Available at <https://www.cbd.int/doc/recommendations/sbstta-20/sbstta-20-rec-08-en.doc>

¹⁷ Hammond, E. (2016). *Synthetic biology debate ahead of biodiversity treaty’s top meeting*, Third World Network. Available at <http://www.twn.my/title2/susagri/2016/sa501.htm>.

¹⁸ At the date of this paper, the platforms are at the stage of full proposals submitted for review and funding.

¹⁹ CIAT and IFPRI (2016) *CGIAR Big data coordination platform. Proposal to the CGIAR Fund Council, 31 March, 2016*. International Center for Tropical Agriculture (CIAT), Cali, and International Food Policy Research Institute (IFPRI), Washington DC. Available at

exploitation of the collections by enriching the data associated with them, in particular the tools and data resulting from the large-scale genotyping (and phenotyping) initiatives.²⁰ The excellence in breeding platform aims to accelerate genetic gains of plant breeding programs including by genotyping and sequencing tools and services. Once these three platforms draw sequence data from plant germplasm in the genebank collections, including germplasm within the purview of the Treaty, and process, organize, interpret and combine those data with other data sets to render them more useful to research and breeding, the ABS regulatory framework may have an impact on their operation.²¹

The paper is organized as follows. In the next section, we will try to examine the legal status of genomic information within the Treaty and the Protocol. In the subsequent section, we will try to understand if and how the startup activities of the GLIS can account for ABS policy and legal factors. In the final section, the paper will delineate a policy exploratory trajectory to advance GLIS implementation.

Quick-read summary

ABS stakeholders are considering the applicability of ABS to digital sequence data.

The issue may be relevant to several components of the GLIS vision and programme of work, and to some of the operations of international genebanks in the framework of the Treaty.

2. Does the international ABS framework regulate access to genomic information?

The Treaty, the CBD and the Protocol constitute the current international ABS framework. How do these instruments regulate genomic information, per se and/or as a sub-category of information associated to genetic resources? Not surprisingly, the term “genomic” or “genotypic” does not appear in the texts of the agreements.²² Hence, genomic data may be one subset to be subsumed under the broader category of “information”.²³

2.1 The International Treaty

<http://library.cgiar.org/bitstream/handle/10947/4450/2.%20Big%20Data%20platform%20CGIAR%20Resubmission.pdf?sequence=1>.

CGIAR (2013) *Open Access and Data Management Policy*. Approved by the CGIAR Consortium Board, October 2 2013. Available at <http://library.cgiar.org/bitstream/handle/10947/2875/CGIAR%20OA%20Policy%20-%20October%202%202013%20-%20Approved%20by%20Consortium%20Board.pdf?sequence=4>. According to the policy, data (and any relevant data collection and analysis tools) shall, subject to any additional donor requirements, be deposited in a suitable repository and made open access as soon as possible. The policy requires that existing and future databases be made open access (section 4.2.4).

²⁰ CROP TRUST and CGIAR (2016). *Genebank Platform, Proposal 30 July 2016*, Global Crop Diversity Trust (CROP TRUST), Bonn, and Consultative Group on International Agricultural Research (CGIAR), Montpellier. Available at <http://library.cgiar.org/bitstream/handle/10947/4308/2->

[Genebanks%20Platform%20Full%20Proposal.pdf?sequence=1](http://library.cgiar.org/bitstream/handle/10947/4308/2-Genebanks%20Platform%20Full%20Proposal.pdf?sequence=1). In the proposal, it is recognized that “CGIAR’s acquisition, development and dissemination of both genetic resources and data are directly affected by international agreements”. Id. at 10.

²¹ CGIAR (2016). *Excellence in Breeding Tools and services that create synergies and accelerate genetic gains of breeding programs targeting the developing world*, Montpellier. Available at

<http://library.cgiar.org/bitstream/handle/10947/4449/Excellence%20in%20Breeding%20-%20Full%20proposal%202017-2022.pdf?sequence=1>

²² The two terms slightly differ. A genomic sequence measures the genetic constitution of an individual within a species or group. The genotype implies measuring how an individual differs within a species or group, typically with regard to a particular gene of interest and, for polyploids, the combination of alleles.

²³ In biological research, “information” and “data” may differ. “Data” is a building block that, once organized and processed (e.g. through context and structure), is turned into “information”. van den Berg R. A., H. CJ Hoefsloot, J. A. Westerhuis, A. K. Smilde, M. van der Werf (2006). “Centering, scaling and transformation: improving the biological information content of metabolomics data” in *BMC Genomics* 7:142. For the purpose of this paper, the two terms are used interchangeably, without any prejudice to further policy and legal analysis that may distinguish the applicability of norms and standards to “data” (e.g. raw sequence data) or to “information” (e.g. processed sequence data).

Article 17 of the Treaty establishes that the Contracting Parties shall facilitate the exchange of information from all publicly available sources, relevant to the conservation and sustainable use of biological diversity, taking into account the special needs of developing countries. Such exchange of information shall include the results of technical, scientific and socio-economic research.

In the part dealing with ABS, the Treaty contains references to information associated with germplasm that is available in the Multilateral System. In terms of Article 13.2 the exchange of information is one form of benefit-sharing. Specifically, sub-paragraph (a) provides that Contracting Parties make available to other Contracting Parties through the GLIS, information encompassing, *inter alia*, the results of technical research, to include the characterisation, regeneration, evaluation and utilization of the germplasm in the Multilateral System. Such information shall be made available when non-confidential and subject to any applicable laws and national capacities.

These Treaty provisions apply to State Contracting Parties. There are other provisions regarding the sharing of information through the GLIS, which apply to individual Providers and Recipients of germplasm in the Multilateral System. They are specified in the text of the Standard Material Transfer Agreement (SMTA). Facilitated access under the ABS system of the Treaty applies to all “passport data” and “any other associated available non-confidential descriptive information” that the Provider is to make available together with the germplasm.²⁴ Passport data are essentially information that identifies the material for exchange. Typically, passport data specify the date and place of collection and may also include additional information related to the original location of the material. The FAO/Bioversity Multi-Crop Passport Descriptors are the international standard of reference for passport data.²⁵ Descriptive information may be taken to include characterization and evaluation data, which may also derive from genomic information. The SMTA also provides for Recipient’s obligations in relation to information. If the material is “conserved”, the obligation is to pass the information received from the Provider in case a third party requests access to the material under the Multilateral System, i.e. through the SMTA.²⁶ If further “research and development” are conducted - and nothing in the SMTA prevents the Recipient from conducting such research and development by extracting information, including genomic information, from the germplasm - the obligation on the Recipient is to make available through the GLIS “all non-confidential information” resulting from such research and development.²⁷ The SMTA provisions do not define the boundaries of confidentiality. International agreements define the legal protection of confidentiality through minimum standards.²⁸

Both the Treaty and the SMTA contain general references to the GLIS in relation to the sharing of germplasm-associated information but the provisions do not clarify how the GLIS collects and under what conditions it makes that germplasm-associated information available, both in terms of practical mechanisms and of legal requirements for access and use. Indeed, the Treaty foresees that the operation of the GLIS may be limited by the legal protection of confidential information and by other forms of legal protection that applicable law may create for descriptive information.

Under Article 17 of the Treaty - the scope of which is not confined to Annex 1 crops - Contracting Parties make a general commitment to build the GLIS in order to facilitate access to information. However, the specific conditions of such facilitated access are not set forth. The reference to “existing information systems” in Article 17 does not add any concrete regulatory element for access to information. It would simply make the GLIS reliant on the access and use conditions of such “existing information systems”.

In addition to the above, it shall also be observed that, in the text of the Treaty and the SMTA, information per se (e.g. genomic information in a database), as an autonomous object of access (for research, breeding or training for food and agriculture), is not regulated. The provisions deal with information that is associated to

²⁴ FAO (2006). Standard Material Transfer Agreement. Available at <http://www.fao.org/3/a-bc083e.pdf>. See Article 5b).

²⁵ Alercia, A., Diulgheroff, S., Mackay, M. (2015) *FAO/Bioversity Multi-Crop Passport Descriptors V.2.1 [MCPD V.2.1]*, Food and Agriculture Organization of the United Nations (FAO), Rome; Bioversity International, Rome. Available at <http://www.bioversityinternational.org/e-library/publications/detail/faobioversity-multi-crop-passport-descriptors-v21-mcpd-v21/>

²⁶ SMTA, above n. 24, Article 6.3.

²⁷ Id. Article 6.9.

²⁸ Art. 39.2 of the TRIPS Agreement provides remedies against the disclosure, acquisition and use, without consent, of information that is: secret; of commercial value; for which reasonable steps are taken to keep it secret.

the transfer of a physical sample of germplasm between a Provider and a Recipient and they do so without any indication as to the conditions of access and further transfer, or use. They are also silent on the possible triggers and types of benefit-sharing obligations for information generated by research and development of such germplasm that is accessed and used by third parties.

Looking beyond legal reading and into the wider policy evolution of the Treaty, there is growing recognition by Treaty stakeholders that “plant genetic resources”, i.e. genetic material of plant origin with actual or potential value for food and agriculture containing “functional units of heredity”, are subject to new characterization techniques in genomics that translate both the function and the physical unit into digital data sets.²⁹ However, beyond such a general recognition, the ability to introduce normative standards for genetic information, for those data sets, is limited by the fact neither the Treaty nor the SMTA as they stand, regulate genomic information if accessed and used as such and not in conjunction with the germplasm, the genetic resource. Even by considering that the generation of data and the processing, presentation, interpretation and analysis of such data qualifies as “research” for food and agriculture – one of the purposes of access that are covered by the Multilateral System –, which may well be the case especially if comparative and functional genomics techniques are applied to extract and evaluate the genomic data, the only ensuing obligation is to make available the information through the GLIS “to the Multilateral System” – arguably, to others who may want to access it - when the information is not deemed “confidential” under any applicable law. Under what standards of facilitated access and under what fair and equitable benefit-sharing conditions for their utilization, it is specified neither in the SMTA nor in another normative standard.³⁰ Evidently, all these considerations would apply to any type of information generated by Recipients of plant germplasm in the Multilateral System, not just genomic information. Information could well consist of geographical, environmental, phenotypic data.

One possible construction of the provisions in the Treaty and the SMTA could be that, as the current regulatory setting in the Treaty allows Recipients to generate information while carrying out research on germplasm in the Multilateral System and to exploit the knowledge so acquired, any third party willing to conduct research and breeding for food and agriculture would equally not be prevented by the Treaty or the SMTA from getting access to, and from using the information made available through the GLIS.

Open access to information is indeed the standard policy of CGIAR international genebanks. Pursuant to their agreements with the Governing Body under Article 15 of the Treaty, CGIAR genebanks make collections and associated descriptive information - typically passport data - under their management, publicly available. In conformity with the CGIAR Open Access and Data Management Policy, all CGIAR genebanks commit to making their data and databases publicly available and searchable, as part of the strategy to promote more effective use.³¹ Genesys provides a common portal for open access to information

²⁹ FAO (2016). Report of the Secretary. IT/GB-6/15/05. Available at <http://www.fao.org/3/a-bb303e.pdf>. This reasoning is corroborated by the observation that data sets may indeed represent functions. For instance, transcriptomics is the study of gene expression from sequencing technology and through annotation of a genome. The transcriptome identifies regions in the genome that exerts a function and is the first step of the “expression” of genomes towards phenotypes. See Wartman, above n. 1, at 31-34.

³⁰ Literature cites examples of MTAs on genomic information, which clearly define data per se as the object of transfer. A model MTA by Syngenta for requestors working with commercial institutions on rice DNA sequence information, defined “material” as “the annotated draft assembled rice genome sequence described in [name of the publication] and the medium on which it is provided”. The MTA also covered modifications (e.g. multiple sequence alignments and/or gene predictions) and unmodified derivatives (“substances or data created by the recipient which contain/incorporate the material and includes without being limiting replicated forms of the material and all cells, tissues, plants and seed containing/incorporating any part of the material”). The MTA is cited in, Lightbourne M. (2009). *Food security, biological diversity and intellectual property rights*, Ashgate, Farnham. At 259-260.

³¹ The CGIAR Open Access and Data Management Policy state that best efforts shall be used by the CGIAR Centers to make all information products, which include data and databases, “subject always to the legal rights and legitimate interests of stakeholders and third parties” (section 4.1.1). CGIAR (2014). *CGIAR Open Access and Data Management Policy*, Montpellier. Available at <http://library.cgiar.org/bitstream/handle/10947/2875/CGIAR%20OA%20Policy%20-%20October%20202013%20-%20Approved%20by%20Consortium%20Board.pdf?sequence=4>. The Implementation Guidelines identify five main types of data related to agricultural research: (1) socio-economic; (2) spatial; (3) genetic; (4) genomic; and (5) germplasm. CGIAR (2015) *CGIAR Open Access & Data Management*

on all CGIAR accessions. It assembles data from international and national genebanks into a searchable public database and operates under an agreement with each data provider, which states that providers should only provide data that can be made publicly available.³² In the future, the CGIAR genebank Platform will obtain and manage available evaluation and genotyping datasets so to link them to genebank databases. Some CGIAR Centers will initiate efforts to develop mechanisms and approaches for associating additional information, which may presumably include genomic information, with existing accession passport data.³³

Quick-read summary

Genomic information, as one possible category of information resulting from research on germplasm in the Multilateral System, may be made available to the Multilateral System through the GLIS, by Recipients of germplasm, subject to the protection of confidentiality.

The Treaty does not provide for standards of access to and utilization of information in the GLIS.

2.2 The CBD and the Protocol

In terms of Article 15(2) of the CBD, State Parties shall endeavour to create conditions to facilitate access to “genetic resources”, on mutually agreed terms and subject to prior informed consent, for environmentally sound uses, and not to impose restrictions that run counter to the objectives of the CBD. The Protocol has specified the CBD provisions on prior informed consent and mutually agreed terms, and has added obligations on compliance. To analyse if and how the Protocol deals with genomic information, it is necessary to examine the provisions on substantive and temporal scope, and those on “utilization” and “derivatives” of genetic resources.

With regard to substantive scope, the CBD and the Protocol define “genetic resources” to mean “genetic material of actual or potential value.” Genetic material, in turn, means any material that contains “functional units of heredity.” The literal meaning of those provisions does not seem to reach out to intangibles and as such would delimit the scope of the Protocol to tangible genetic resources.³⁴ This is the interpretation that some State Parties are following, e.g. in the consultation process for national ratification of the Protocol and such an interpretation is also followed by some practitioners.³⁵ In this context, ABS, as set forth in the CBD and the Protocol, would not apply to the access to digital information about a genetic resource, in our case genomic information. Interpretations, however, are not uniform as to whether information is within the scope of regulation. Some Parties and stakeholders advocate for a dynamic, progressive understanding of the term “genetic resources” that would encompass digital information, as the object of access or utilization.³⁶ The so called *in silico* resources – it is claimed - when accessed and/or transferred separately from the physical material, could lead to by-passing benefit-sharing obligations if those obligations are linked exclusively to the physical material, and make the whole ABS system irrelevant to modern genomic research. The transfer of data resulting from genetic sequencing should be considered as transfer of genetic resources for ABS

Implementation Guidelines. Montpellier. At 13. Available at <https://docs.google.com/file/d/0B9CkhNNcAYs2T0tpemhlYjVkwTA/edit?pli=1>.

³² CROP TRUST and CGIAR above n. 20, at 18.

³³ *Id.* at 18.

³⁴ A different issue is whether the term “genetic resources” extend to cover a coding sequence or a DNA sequence that regulates gene expression. Bagley, M.A., A.K. Rai (2013). *The Nagoya Protocol and synthetic biology research: a look at the potential impacts*, Wilson Center, Washington, DC. Available at http://scholarship.law.duke.edu/faculty_scholarship/3230.

³⁵ Crawley, F. (2015). *The Nagoya Protocol: what it is and what it means for your business*. Available at http://www.ukbioscienceforum.org/IP_hot_topics_-_The_Nagoya_Protocol_-_Fiona_Crawley_Asymptote.pdf

³⁶ Hammond, E. (2016). *Digital genebankers plan to ignore UN request on the impact of genomics and synthetic biology on access and benefit sharing*, Third World Network, A preliminary Report, 4 April. Available at http://www.twn.my/announcement/digital_genebanks_final_uslet.pdf. The author invites governments to immediately move to regulate access and benefit sharing for sequence data and related information and recognizes that “The emerging gap in the application of access and benefit sharing rules between physical and digital access to genetic resources must be closed. Whereas physical access to genetic resources increasingly occurs under signed ABS agreements, electronic access to genetic resources is comparatively unregulated.”. At 4-5.

purposes.³⁷ In order to construct an extension of the object of access or utilization to intangibles for realizing benefit-sharing, the term “genetic resources” is read in conjunction with the term “utilization”.

With the purpose of achieving greater certainty as to access requirements and user compliance, the Protocol has indeed introduced the definition of “utilization” of genetic resources. It means “to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology”, i.e. “any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use”. The term “biotechnology” could be interpreted as referring to technology that uses a physical, material, resource. Hence, it would not allow for the equation between a genetic resource and genetic information and would not cover the application of technology to the informational element of the biological systems, living organisms or derivatives. However, the broad definition of “utilization” in relation to research and development on the genetic composition, could entail that the generation or analysis of genomic data qualifies as research on, hence utilization of, the genetic resource. In other words, genetic resources would be utilized not only when *in situ* or *ex situ* conditions but also through the medium of data exchanges or databases.³⁸

Expanding this legal construct of the Protocol, once utilization occurs, further questions arise in two contexts: the trigger of benefit-sharing; and the “derivatives”.

It is heavily debated whether the trigger of benefit-sharing in the Protocol is at the time of access, transfer of the resource across a geographical border, or at the time of utilization, of an object that may already have been accessed. In other words, the term “access” – which is not defined in the Protocol – can be understood as the physical acquisition of genetic resources in a territory, a country, or as its utilization in innovation processes, including biotechnology.³⁹ As literature has analysed, the issue carries heavy systemic implications for the entire ABS infrastructure.⁴⁰ Expert draft comments on the EU Regulation No. 511/2104 have considered qualifying research based on sequence data available in the public domain as utilization of genetic resources.⁴¹

In practice, even assuming that genomic information constitute a self-standing object of access, an interpretation of the trigger of benefit-sharing being the act of access, would raise the further difficulty of ascertaining when data cross a border, when they are transferred. Those who advocate for the containment of ABS to physical access to genetic resources, with the exclusion of any attribution of ownership over data, also doubt that States will be able to control data through attributions of ownership.⁴²

“Derivative” means a naturally occurring biochemical compound resulting from the genetic expression or

³⁷ Hammond above n. 17. See in particular the reported statements made by Namibia, Bolivia and China at the SBSTTA meeting of 25 April. A review of different positions and predictions expressed in literature is in, Reichman J.H., P.F. Uhlir, T. Dedeurwaerdere (2016). *Governing digitally integrated genetic resources, data and literature*, Cambridge University Press, Cambridge. At 146-149.

³⁸ This interpretation has recently been stated in the context of a joint EU-UNEP-CARICOM project. See CARICOM Secretariat, “The Nagoya Protocol on Access and Benefit-Sharing”. Available at http://www.abs-initiative.info/fileadmin/media/ABS_Simply_explained/Nagoya_Protocol/CARICOM_Secretariat_Nagoya_Protocol_Fact_Sheet.pdf. For an analysis of the drivers and motivations of extensive interpretations of ABS in relation to information, see Winter, G. “Knowledge commons, intellectual property and the ABS regime”, in Kamau E.G. and G. Winter (eds) (2013). *Common pools of genetic resources: equity and innovation in international biodiversity law*, Routledge, New York. At 285-302.

³⁹ F. Rabitz (2015). “Biopiracy after the Nagoya Protocol: problem structure, design and implementation challenges” in *Bras. Political Sci. Rev.*, 9 (2): 30-53.

⁴⁰ Von Braun J., D. Brack (2013). “Access or utilization – who will pull the ABS trigger?” in *Bioresources* 7:3, 25 July. Available at <http://www.ictsd.org/bridges-news/biores/news/access-or-utilisation-%E2%80%93-who-will-pull-the-abs-trigger>

⁴¹ European Commission, Register of Commission Expert Groups (2015). “Guidance on the EU Regulation implementing the Nagoya Protocol – Guidance on the scope of application and core obligations” Draft. Available at <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailDoc&id=20818&no=3>. At 8.

⁴² The Chartered Institute of Patent Attorneys (2014). “European Regulation to Enforce the Nagoya Protocol”. Available at <http://www.cipa.org.uk/policy-and-news/consultation-responses/historical-consultation-responses-and-position-papers/european-regulation-to-enforce-the-nagoya-protocol/>.

metabolism of biological or genetic resources, even if it does not contain functional units of heredity. Derivatives are not explicitly included in the scope of the Protocol. The term just appears in the definition of “biotechnology”. It is not clear whether the Protocol’s obligations, including on user compliance, should extend to derivatives or be limited to genetic resources. On the one hand, any use of genetic resources, even if comprising just a fragment of the object of access, and even if remote from the point where the original genetic resource has been modified, would activate ABS obligations. Some products of genomic research, for instance a biological product developed on the basis of an isolated gene sequence, may qualify as a derivative. On the other hand, if benefit-sharing is bound to the time of access, the utilization of derivatives would not be relevant. Although the Protocol’s definition of “derivatives” still refers to an object in its material or tangible form, it should be borne in mind that, at a certain point in time during the Protocol negotiations, precisely in 2008, collections of data related to genetic resources were brought into the ABS via a possible definition of the term “derivative”, which was suggested to include “information or knowledge derived from genetic materials on general or a specific gene sequence in particular”.⁴³ Even if the actual value of the proposition is limited when interpreting the text of the Protocol, it is nevertheless a significant antecedent of positions, views of certain countries that combine the interpretation of access, utilization, and derivatives to broaden the scope of the Protocol to intangibles, genomic information included. This position may resurface, as we will examine below, in national legislation and may influence, as we will also present further below, “best practices” of data generators and holders.

Quick-read summary

The subject matter that the Protocol regulates, i.e. “genetic resources”, does not expressly refer to intangibles.

Interpretations relying on the need not to defy the general objective of benefit-sharing and on the concept of “utilization” in the Protocol, are nevertheless being advanced, which would result in broadening the application of the Protocol to intangibles, genomic information included.

2.3 National legislation and mutually agreed terms (MATs)

From legal and practical standpoints, the extraction, utilization of and access to genomic information are not explicitly regulated in the two international agreements. Both treaties are of uncertain application to the handling of information in general, including genomic information, separately from the genetic material. The obligations in relation to the access and utilization of genomic information are not definite, and the consequences for individuals extracting and using genomic information from germplasm are equally uncertain. This does not mean, however, that genomics science to identify DNA sequences that improve traits and the research to improve knowledge of DNA sequences (including not only sequences that code for proteins but also sequences that have other functions) will continue utilizing significant quantities of genomic data developed from tangible genetic material in an unregulated, ABS-unencumbered space. On the contrary, national control may be asserted in the near future, regardless of how international ABS agreements are advanced in the respective intergovernmental decision-making bodies. National ABS legislation and mutually agreed terms in material transfer agreements are, and arguably will become, more relevant.⁴⁴ Over time, especially once State parties to the Protocol enact new national ABS legislation and bilateral ABS agreements are concluded accordingly, this body of norms, articulated in a complex web via “rights” or contract, may indeed establish genomic information governance, with the result that the various open access policies may be tempered with disclosure limitations stemming from such normative governance

⁴³ UNEP (2008). Report of the Group of Technical and Legal Experts on Concepts, Terms, Working Definitions and Sectoral Approaches. UNEP/CBD/WG-ABS/7/2. Available at <https://www.cbd.int/doc/meetings/abs/absgtle-01/official/absgtle-01-abswg-07-02-en.doc>

⁴⁴ Schindel D.E., T. Bubela, J. Rosenthal, D. Castle, P. du Plessis, R. Bywe, PMCW (2015). “The New Age of the Nagoya Protocol”, in *Nature Conservation* 12:43-56. Available at <http://natureconservation.pensoft.net/articles.php?id=5412>

and the connected enforcement apparatus to sanction the unauthorized publishing or transfer of genomic information.

Before the Protocol, there are precedents of definitions of genetic resources in regional and national legislation that encompass information. The Brazilian Provisional Act of 2001 (No. 2,186_16, Title II, Art.7) defines genetic heritage broadly as “information of genetic origin, contained in samples of all or part of a plant, fungal, microbial or animal species, in the form of molecules or substances originating in the metabolism of these living beings, and in extracts obtained from *in situ* conditions, including domesticated or in *ex situ* conditions, collected from national territory in *in situ* sources, in the continental shelf or in the exclusive economic zone”.⁴⁵ The Andean Community Commission’s Common Regime on Access to Genetic Resources, adopted in 1996, includes a reference to genetic information. It defines genetic resources as “all biological material that contains genetic information of value or of real or potential use”.⁵²

It is foreseeable that, with respect to digital genetic information per se (i.e. utilised and transferred separately from the genetic material), determining origin and claiming control will remain burdensome.⁴⁶ In the aftermath of the Protocol’s entry into force, countries considering themselves as provider countries may assert that digital information, even if it does not fall within the scope of the CBD and the Protocol (“genetic resources”) and may not be subject to access control, can be regulated through the concept of “utilization” of genetic resources, in order to impose requirements for accessing and utilizing such information, for instance in access permits or MATs that define the allowed utilization and handling of research and development results.⁴⁷

One example illustrates the current level of attention to the role that national legislation and MATs will play in regard of genomic information. In the process of implementation of the Protocol and the EU Regulation on ABS, a document containing the UK government response to questions raised by various interest groups, points out to the possibility that the use of published sequence data, from material accessed after the entry into force of the Protocol, may be subject to regulation by ABS legislation in the provider country. The document alerts to the possible application of the Protocol (presumably, the user compliance measures) to cases where the use of genomic information derived from sequenced genetic resources, is addressed in MATs, hence in the private law of contract. Users are accordingly invited to introduce the best practice of seeking PIC and MATs for the use of genomic information where this is set out in the ABS legislation of the provider country.⁴⁸

In sum, questions regarding the application of the Protocol to intangibles, to genetic information (i.e. information or knowledge derived from genetic materials in general or a specific genetic sequence in particular) and the derivative products do not have a univocal answer. Certain State Parties have advocated, and will arguably continue to do so, for the inclusion of genomic information into the ABS regulatory setting, via intergovernmental processes and decisions and, it can be predicted, in their own national legislation and the resulting bilateral MATs that may cover the use or publication of sequence data, derived from an accessed genetic resource.

As the temporal scope of Protocol’s obligations remains debated, there will continue to be legal uncertainty regarding acts of utilization of genetic resources, including through the medium of genomic information.

⁴⁵ An analysis of the Provisional Act is in, J. Santilli (2012.) *Agrobiodiversity and the Law – Regulating Genetic Resources, Food Security and Cultural Diversity*, Earthscan, New York. At 173-183.

⁵² Sarmiento L.R. “Research on genetic resources in Latin America and the Caribbean – Perspectives for facilitated access” countries” in Kamau E.G., G. Winter, P.T. Stoll (eds) 2015. *Research and Development on Genetic Resources: Public Domain Approaches in Implementing the Nagoya Protocol*, Routledge, New York, 132-150. At 135.

⁴⁶ Winter G., above n. 38, at 296. In recent literature, the concept of States trying to assert control over information resulting from genetic resources, is critically compared with the interest by private holders in asserting such a control via IPRs. Roa, C., R.S. Hamilton, P. Wenzl, W. Powell (2016). “Plant genetic resources: needs, rights, and opportunities”, *Trends in Plant Science* 21(8): 633-636.

⁴⁷ Bagley M.A, A.K. Rai, above n. 34, at 8

⁴⁸ Department for Environment Food & Rural Affairs, “Consultation on implementing the Nagoya Protocol, A summary of responses and the government reply”, March 2015. Available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/415474/nagoya-consult-sum-resp.pdf. At 10.

Working with genetic information in research and development will have to consider the additional variable of the possible reach of ABS domain into intangible genetic information or derivative products. The issues are under debate at the intergovernmental level and, arguably, time will elapse before a general direction, if any, will emerge. What might occur is that individual countries will not wait for consensual positions to develop in the inter-governmental process. As they retain the full ability to establish the conditions of utilization in national legislation, they will find their own answers to the issues in their domestic processes.

It is beyond the scope of this paper to assess how effective attempts to control information through ABS legislation might be. Considering how implementation of ABS for the physical object is hampered by complex administrative procedures and insufficient institutional capacity, the task of regulating genetic resource information may prove particularly challenging. It is equally not within reach for this paper to discuss whether the limited ability to govern genomic data represents one component of larger conceptual flaws of the ABS regulatory framework in relation to the definition of “genetic resources”, as one eminent author has recently suggested, advocating for a redefinition of the genetic resources, the gene, as natural information and for a consequent paradigm shift of the whole ABS system towards bounded openness, distancing itself from the mantra of national sovereignty and its corollaries of PIC and MAT.⁴⁹ The issue of most practical relevance, as we will examine next, is whether the prospect of a regulatory setting resulting from PIC and MATs on the extraction and utilization of information from genetic resources, enshrined in national ABS legislation, induces as best practice of repositories of information extracted from genetic resources, hence genomics included, to inform future users about any rights and obligations attached to the genetic resources from which the information is extracted, and/or to the information itself, and their further utilization.⁵⁰

Quick-read summary

National legislation and mutually agreed terms may regulate the utilization of genomic information derived from genetic resources.

Users of such information should be informed of its regulatory status. Genomic researchers may have to inquire into the origin of tangible genetic material and ensure that such material was accessed in compliance with the domestic law of a provider country, as applicable.

2.4 Coping strategies

How are stakeholders in genomic information from the research sector reacting to the Protocol’s normative setting, within and outside of the plant community? That ABS constitutes an organizational framework essentially driven by political factors, exogenous to the values of scientific research, is a perception that certainly predates the Protocol and the Treaty as well. With the Protocol in place, the fate of public availability of genomic information associated with holdings of genetic material is perceived as particularly uncertain. Scientists in various sectors of biological sciences are assessing whether they will continue to be able to extract, analyse and publish genetic information from genetic samples, specimens. They are aware of possible legal implications of depositing sequence data in public repositories, and recognize that ABS regulated in provider and user countries may qualify as one restriction to the use of that information.⁵¹

⁴⁹ Ruiz Muller M. (2015). *Genetic resources as natural information: implications for the Convention on Biological Diversity and Nagoya Protocol*, Routledge, New York.

⁵⁰ Global Genome Biodiversity Network (2015). *Best practice for access and benefit-sharing*. Revised in June 2015. Available at [https://ggi.si.edu/sites/default/files/resources/GGBN%20Guidance%20 Best Practice June 2015-Final.pdf](https://ggi.si.edu/sites/default/files/resources/GGBN%20Guidance%20Best%20Practice%20June%202015-Final.pdf). At 6-7.

⁵¹ Neumann D., C.H.C. Lyal, J. Bodegard, C. Lohne, A. Casino, A. Nivart, C. Williams, P. Giere (2014). “Access and Benefit-Sharing – Global Implications for Biodiversity Research, Collections and Collection Management Arising from the Nagoya Protocol”, *SPNHC Connection*, September 2014, 40-42. Available at http://www.spnhc.org/media/assets/ABS-GlobalImplications_SPNHC-Sep2014Vol28.pdf. See also, “Report of the multi-stakeholder expert workshop for validating the IP model agreements for pre-competitive access”, Marine

After the entry into force of the Protocol, various research communities are asking themselves how to respond to the new legal environment without overburdening science, and molecular studies in particular. Coping strategies are taking two directions. One is more ambitious, and revolves around the idea of maintaining and augmenting a public good perspective for research. Another, more targeted, looks at upgrading information management practices.

Under the first perspective, genomic information is considered as an asset for upstream research. The microbial sector is leading this line of thinking and is trying to establish an updated, Protocol-wise global scientific research commons to incentivize the sharing of research assets. Recognizing how public availability of genomic data may be jeopardized by regulatory pathways asserting national sovereignty, the sector envisages a different role for external regulators of data vis-à-vis the regulation of materials. In the case of digital commons, characterized by a modular architecture and with actors driven by non-market incentives, the regulatory regime should be grounded on soft law arrangements such as codes of conducts and community norms in order to leave the control of research assets in the hands of the researchers and reduce transaction costs.⁵² Interestingly, in order to construct a collaborative, social production model of information and shareable goods, scientific communities are invited to exploit two opportunities that the Protocol offers: a simplified ABS regime for non-commercial research; the menu of non-monetary benefit-sharing options.⁵³

Concerning the second, less ambitious perspective, information management practitioners recognize that ABS is affecting the generation, analysis and publication of genomic data for biodiversity research.⁵⁴ What is observable is that the practice of linking molecular data with records of processes carried out, samples utilized and mutually agreed terms with regard to those samples, is consolidating. The linkage of samples of animal germplasm, for instance, to their MATs applies both to internal (i.e. within the same organizations) and external transfers and extends to linking the sample data (i.e. the equivalent of genebank accession passport data) with sequences.⁵⁵ The post-Protocol ABS era is changing the rules-in-use and raising the level of due diligence for the documentation and management of biological samples, associated data and research data, genomic data included. By way of illustration, researchers are warned to carefully consider GenBank sequence uploads “if the original PIC and MAT do not permit publication of DNA sequence data”. A lack of documentation of PIC and MAT is a point of concern and genetic analysis is discouraged “as it may be illegal utilization of genetic resources without PIC and MAT of the country in which samples have originally

Microbial Biodiversity, Bioinformatics and Biotechnology Deliverable No 8.5: Multi-stakeholder expert workshop, Dec. 2014. Available at www.microb3.eu/work-packages/public-deliverables.

⁵² Dedeurwaerdere T, P. Melindi-Ghidi, A. Broggiato (2016). “Global scientific research commons under the Nagoya Protocol: towards a collaborative economy model for the sharing of basic research assets”, *Environmental Science & Policy* 55:1, 1-10. Available at <http://www.sciencedirect.com/science/article/pii/S1462901115300605>.

⁵³ The qualification of non-commercial has two possible articulations: one that considers as non-commercial utilization all research in the exploratory phase, that does not involve the sale of a genetic resource, its components or derivatives and whose research results remain the public domain; another that privileges all activities at the stage of basic research, without any monetary benefit for profit or personal gain. Under the second option, any distribution not for the purpose of basic research (e.g. for developing a subsequent application) would amount to a change in intent. Under this option, the utilization of genomic data, even if deposited in a public database, would add to the qualification of the activities as beyond basic research. See, Dedeurwaerdere T., A. Broggiato, S. Louafi, E. Welch, F. Batur (2012). “Governing Global Scientific Research Commons under the Nagoya Protocol” in Morgera E., M. Buck, E. Tsioumani (eds) (2013). *The Nagoya Protocol in Perspective: Implications for International Law*, Martinus Nijhoff. Available at https://www.researchgate.net/publication/236035006_Governing_Global_Scientific_Research_commons_under_the_Nagoya_Protocol. At 21. FAO also seems to be responsive to some of the motivations that animate the initiative of the microbial sector. FAO is promoting an initiative by the food safety sector, still in an embryonic phase. Learning from the experience that the Secretariat of the Treaty has acquired by serving a system of facilitated access to germplasm for research, FAO intends to promote discussions towards having clear understanding of the implications of the Protocol, as well as available applications of genome sequencing technology in the food safety sector at the global level. FAO (2016). *Applications of Whole Genome Sequencing in food safety management*, Technical Background Paper, Rome. Available at <http://www.fao.org/documents/card/en/c/61e44b34-b328-4239-b59c-a9e926e327b4/>. See the programme and content of a side event organized for the 25th Session of the Committee on Agriculture, 26 - 30 September 2016, available at <http://www.fao.org/coag/side-events/side-event-9/en/>.

⁵⁴ Neumann D., C.H.C. Lyal, J. Bodegard, C. Lohne, A. Casino, A. Nivart, C. Williams, P. Giere, above n. 51.

⁵⁵ Holt W.V., above n. 16.

been collected”.⁵⁶

An example comes from the Global Genomic Biodiversity Network (GGBN), which is a large-scale international network of genomic tissue sample collections with the mission to globally aggregate biodiversity biobank data. GGBN establishes standards for genomic data sharing and publishing. As published sequence data were found to often lack information on the underlying physical sample, GGBN has revised its best practice for access and benefit-sharing in June 2015, with the intent to make the revision consistent with Article 20 of the Protocol, which encourages the development of voluntary codes of conduct, guidelines and best practices. In order to comply with ABS regulations and function effectively, GGBN is encouraging all its affiliate institutions to manage data associated with collections in a way that allows for the tracking of, among other data sets, sequence information to the original sample and to retain all relevant records and legal information covering genetic resources – in practice, PIC and MAT in the provider country.

ABS is also finding its way into genomic data management through protocols for publishing metadata associated with the sequence data.⁵⁷ The European Consortium of Taxonomic Facilities (CETAF) calls for upgrading data management and curation systems in order to store and make available ABS legal documentation and at the same time to track the deposit of sequence data in databases (for instance in GenBank) to the use of the physical material.⁵⁸ Through this upgrading of data management and curation standards, the link between the spirit, if not the letter, of ABS law and sequence data starts materializing.

Another example of this link comes from the terms of use of the Metagenomesonline database, a public database: “This genetic information downloaded from ... may be considered to be part of the genetic patrimony of [name of the country], the country from which the sample was obtained. Users of this information agree to: (1) acknowledge [name of the country] as the country of origin in any publications where the genetic information is presented and (2) contact the CBD Focal Point identified on the CBD website [URL] if they intend to use the genetic information for commercial purposes”.⁵⁹

Outside of the plant sector, the standards for high throughput sequencing, bioinformatics and computational genomics that the World Assembly of Delegates of the World Organization of Animal Health (OIE) approved in May 2016, require as data management practice to store sequence data in a manner in which there is a clear link to the metadata associated with the specimen, including information on the “ownership” of the animal sampled. Although this standard is not dictated in relation to ABS, it nevertheless concretizes a link between the data and the physical material.⁶⁰

The practice is still mixed, as shown by the fact that, for instance, the International Nucleotide Sequence Databases do not require information depositors to supply ABS information such as country of origin, or evidence of PIC and MAT. In GenBank, ‘source’ field do not refer to geographic source, and the optional field ‘origin’ refers to the sequence start in previous records.⁶¹

However, as noted in literature, data management quality has a significant impact on the quality of the research outputs and the missing link between genomic data and the physical material may represent a

⁵⁶ Neumann D., C.H.C. Lyal, J. Bodegard, C. Lohne, A. Casino, A. Nivart, C. Williams, P. Giere, above n. 51, at 42.

⁵⁷ Global Genome Biodiversity Network, above n. 50.

⁵⁸ CETAF (2014). *Code of Conduct and Best Practice for Access and Benefit-Sharing*, Oslo. Available at https://www.cbd.int/abs/doc/FINAL_CETAF_ABS_CoC021015.pdf

⁵⁹ This example is referenced in Bagley M. (n.d.). “Digital DNA: The Nagoya Protocol, Intellectual Property Treaties, and Synthetic Biology”. Available at http://www.synbioproject.org/site/assets/files/1393/bagley_wilson_center_digital_dna_2015_slides.pdf.

⁶⁰ OIE (2016). “Standards for High Throughput Sequencing, bioinformatics and computational genomics”, adopted by the World Assembly of delegates of the OIE in May 2016. Terrestrial Manual, Chapter 1.1.7. At 5.

⁶¹ Davis K, E. Fontes, L. Marinoni (2013). *Ex situ collections and the Nagoya Protocol: A briefing on the exchange of specimens between European and Brazilian ex situ collections, and the state of the art of relevant ABS practices*. Paper prepared for the International Workshop on “The role to be played by biological collections under the Nagoya Protocol”, Brasilia 18-20 June 2013. Available at http://sectordialogues.org/sites/default/files/acoes/documentos/background_paper.pdf. At 43-44.

weakness of information systems. In view of the impact of the Protocol on research, a more cohesive approach for how genomic data are tracked, exchanged and standardized across research communities is advocated for.⁶² Paradoxically, the plant sector, historically the main object of attention of ABS regulators, may be trailing behind in respect of best practices on genomic information. Even when operating in open access mode, scientific publications of plant genomic studies appear as incognizant of ABS. Typically, they indicate the germplasm collections from which accessions studied were drawn as well as, when applicable, the genetic stocks registered with new accession numbers, but do not supplement these data with information as to the legal requirements accompanying the use of accessions, which may entail restrictions or benefit-sharing obligations.⁶³ DivSeek may be proactive in moving the plant community towards an integration of germplasm-associated information management with genomic information standards. In the construction of its programme of work, centered on the development of a plant biodiversity informatics management system, DivSeek aims to take stock from a number of existing plant genomics project and assess what the current standards and protocols for metadata recording and data sharing are; how passport, accession and descriptive data, including genotypic, are used; and, most importantly, what protocols exist or are being developed for linking digital data with physical germplasm resources.⁶⁴

Quick-read summary

Research on genetic resources is adapting to the new ABS legal environment.

Regulatory pathways asserting national control of genomic information are eliciting a response by the research sector that incentivizes research commons.

Repositories of genomic information inform users about any rights and obligations attached to the genetic resources from which the information is extracted or attached to the information itself, and their further use.

3. The further development of GLIS

What does all of the above mean for the GLIS? After conducting a landscape analysis of the ABS regulatory framework applicable to genomic information, it is necessary to translate the analysis to the goals and objectives of the GLIS. Should the development of GLIS infrastructure take into account the evolution of ABS towards genomic information? What are the next steps to make GLIS responsive to the ABS legal environment? Should and if so how, the Treaty affirm its specialized regime of facilitated access and benefit-sharing in relation to genomic information and activate the GLIS for this purpose?

These are essential strategic questions that will need response in the course of development and operation of the system. They are not likely to find one definitive answer, though, in the immediate future. The GLIS is still in its inception phase and regulatory trends will also evolve. So will the overall relationship between the Treaty and the Protocol, between their governing bodies, expert groups and Secretariats, which may, or may not, be conducive to mutual supportiveness and repartitioning of work and tasks.

In the light of these and other possible variables, this paper focuses on the infrastructure of GLIS and its actual and possible practical functions in relation to genomic information, in order to determine the “freedom to operate” of the system, that is, its ability in the medium term to build the infrastructure and perform

⁶² Nussbeck S.Y., M. Rabone, E.E. Benson, G. Droege, J. Mackenzie-Dodds, R.T. Lawlor, above n. 2, at 56.

⁶³ See, for example McCouch S. R., M. H. Wright, C. W. Tung, L. G. Maron, K. L. McNally, M. Fitzgerald, N. Singh, G. DeClerck, F. Agosto-Perez, P. Korniliev, A. J. Greenberg, M. E. B. Naredo, S. M. Q. Mercado, S. E. Harrington, Y. Shi, D. A. Branchini, P. R. Kuser-Falcão, H. Leung, K. Ebana, M. Yano, G. Eizenga, A. McClung, J. Mezey (2016). “Open access resources for genome-wide association mapping in rice”, *Nature Communications* 7, February 2016.

⁶⁴ Slide presented at the Second DivSeek Partner Assembly of June 2016, in live broadcast. The full presentation is not available at the date of this publication. DivSeek may follow a meta data approach to make data sets interoperable. In the context of the CGIAR Open Access and Data Management Policy, a core metadata schema (CG Core) entities to present and share metadata in consistent ways across the network of CGIAR repositories is under development. The schema includes fields related to legal rights. CGIAR (2016) *2015 CGIAR Intellectual Assets Management Report*. Montpellier. At 9. Available at <http://library.cgiar.org/bitstream/handle/10947/4372/2015%20CGIAR%20IA%20Report.pdf?sequence=4>.

functions in the current ABS environment. This pragmatic approach should, however, not lose sight of, rather exploit, other longer-term, programmatic elements of the vision, where ABS will also be a relevant consideration.

3.1 The GLIS infrastructure

The GLIS infrastructure may be functional to multiple approaches to genomic information:

- Collecting and aggregating genomic data through a metadata infrastructure;
- Generating genomic data through sequencing facilities;
- Enabling access to and utilization of the above information.

With regard to the collection and aggregation of genomic data through metadata (e.g. metadata that describe a DOI name), it would be advisable to deploy this function in the context of research information produced by recipients of germplasm under the SMTA. In recognition of the scope of Article 17, which is all plant germplasm and not just germplasm under the purview of the Multilateral System, the design of the infrastructure can be open to all PGRFA (which, reportedly, would make it attractive to genomics and breeding communities). However, its initial function may prioritize information generated from plant germplasm within the purview of the Multilateral System. The Governing Body has recalled the interlinkages between the GLIS and the Multilateral System, as expressed in Article 13.2.a, in practice asking the GLIS to offer an infrastructure to share the non-confidential information produced by recipients of material under the SMTA. As germplasm transferred with the SMTA is under the purview of the Multilateral System and not subject to other ABS regimes, this would offer initial ABS viability in terms of access to and utilization of information associated with germplasm, including genomic information. Information may be aggregated both through the linking existing repositories (“existing information systems”) and through an autonomous data repository. Linking genomic information to metadata related to the source germplasm, including the SMTA through which the germplasm has been transferred, will become an indispensable measure both for associating repositories and for any new Treaty repository. The current initiative on DOIs seems to suit this purpose.

If the GLIS infrastructure in the future generates genomic data, for instance through sequencing facilities, it will equally be advisable to sequence accessions that are available under the Multilateral System. As for the legal status of the resulting information, it should however be borne in mind that GLIS is unlikely to assert ownership, possession or control of any data on its own right. Indeed, neither GLIS nor the Governing Body nor the Treaty Secretariat are legal entities and the two latter rely on the juridical personality of FAO.⁶⁵ This vacuum concerning the actual data provider would probably open the opportunity to establish a new commons regime within the Treaty, possibly anchored to international public domain, and applied to genomic and conceivably other germplasm-derived, information. On the other hand, producing genomic data through an international, GLIS-sponsored facility, in a legal environment that does not regulate access to and utilization of information per se, would bear the risk that claims of national control, anchored in various forms to the ABS line of thinking, may resurface within the Treaty.

Enabling access and use – two distinct issues, it is always worth remembering, as not everything that is publicly accessible on a database is available and usable without restrictions - to genomic information would be intrinsic to the construction of a functional GLIS. Indeed, the ambitious vision of the GLIS is to enable connecting data sets by registering to an access Portal: a) existing sources of germplasm (e.g. ex situ collections, in situ crop wild relatives, on- farm resources and other sources) and their relationship with the Multilateral System; b) information generated through characterization, evaluation, phenotyping and genotyping; and c) the further utilization of such information.⁶⁶ Through the issue of access to and use of

⁶⁵ An analogous consideration is made in, Group on Earth Observation (2011). “Legal Options for the Exchange of Data through the GEOSS Data-CORE”, Legal Interoperability Sub-Group, Data Sharing Task Force, draft October 2011. Available at https://www.earthobservations.org/documents/dsp/draft_white_paper_geoss_legal_interoperability_30_october_2011.pdf. At 3.

⁶⁶ FAO (2015), above n. 7, at Annex 2.

information extracted from germplasm, the concept of interoperability, which stakeholders in plant germplasm data normally interpret in its technical and semantic meaning, extends into legal interoperability, that is, the ability to give access to information that is legally usable. In the light of the above analysis of possible trends in ABS legislation and MATs, it is recommended to include ABS considerations into the analysis of legal interoperability.

Indeed, the concept applies well beyond ABS. It requires a legal analysis of information in the context of statutory law encompassing IP laws that protect the rights holder and restrict the user of data (e.g. copyright or database protection laws), as well as the limits to statutory IP law (e.g. limitations and exceptions and public domain status). The analysis would also need to combine the use of private law, e.g. in the form of waivers, licenses and contracts, for databases and other data compilations. As clarified in the introduction, this paper does not cover all the legal factors impinging on genomic data access and use.⁶⁷ For the limited scope of this paper, suffice it to note that the presumption that normally applies to data sets, including genomic data, in statutory law is that data providers will themselves take appropriate measures to restrict access and use of data which may be protected by national laws and policies, or regulated by contract. These national laws and policies may include ABS. MATs would also be relevant. Terms and conditions for access and use of genomic information, among various data sets, on an information portal would in principle be established by the provider of such information and the responsibility to monitor compliance with those terms and conditions, if and as necessary, would also be with the data provider.⁶⁸ When linking data sets in different repositories through metadata, the practice would be to refer users to restrictions that are imposed on accessing the individual websites and databases, which in turn may apply the said presumption and leave the legal control of data to data providers themselves.

For information that relate to Multilateral System germplasm, the foreseeable option in a future GLIS information portal or portals, would be not to impose any access or use conditions on the information per se (e.g. disjoint from germplasm), which would continue to be held or kept under the legal control of the provider of such information, i.e. the Recipient of germplasm under the SMTA.

This option would guarantee a neutral startup of the system. It would, however, be in some tension with the ambition of creating an information commons within the Treaty, as the provider of information would always retain the ability to restrict the utilization of the information. Another option would be to require the provider of information to share with the Multilateral System, through the GLIS, only information that he considers to be publicly accessible without restriction. It should also be recalled that one of the components of the GLIS vision is to promote the transparency of rights and obligations to be exercised within the GLIS. In this sense, a clarification of the legal status of source germplasm would bring added value to GLIS users. An initial step, as the data management practice of repositories suggests, is to facilitate the gathering and sharing of information on the source germplasm. It is thus advisable to ensure that, within the future GLIS infrastructure, there is a function that specifies the “SMTA status” of the original material and accompanies the management of all associated data sets. The DOI system that is being put in place would be a valid instrument to track DOI objects, including genomic data sets, to the original germplasm object, transferred with the SMTA.⁶⁹

The information systems of international genebanks, so far the largest repositories of plant germplasm, are a priority partner for the GLIS to promote the transparency of rights and obligations. There is growing recognition within the sector that a key upgrade in genebank infrastructure would be to connect information systems to technologies, such as high-throughput sequencing data, that add value to existing diversity in germplasm repositories and that can stimulate the demand for such diversity.⁷⁰ To date, those data have been

⁶⁷ Lawson C., above n. 10.

⁶⁸ Group on Earth Observation, above n. 65, at 21.

⁶⁹ In its Resolution on the GLIS, the Governing Body has acknowledged the need to facilitate the documentation and dissemination of PGRFA available in the Multilateral System and its associated information to facilitate research, plant breeding and training subject to applicable law. FAO (2015), above n. 8, Annex 2.

⁷⁰ The CGIAR genebanks offer tools and methods for exploring the collections: mini-cores at ICRISAT; Focused Identification of Germplasm Strategy (FIGS) subsets at ICARDA; a molecular atlas at CIMMYT; whole-genome

underused, because they have not been available to the genebanks and are not always tied to accessions.⁷¹ In an ABS-wise perspective, the task would then be not only to put in place the infrastructure in order to gather and mine the data collected by recipients and users of genebank accessions, but also to alert the further users of the information to the legal status of the source germplasm and, for germplasm that is not the Multilateral System, to ABS obligations they may incur into based on the applicable law regarding the source of the germplasm or the use of the information.

Quick-read summary

The GLIS infrastructure should reflect the scope of Article 17 but initially prioritize information extracted from germplasm that is in the Multilateral System.

DOIs are a useful tool to link information extracted from germplasm in the Multilateral System to the SMTA status of the original material.

Recipients of germplasm with the SMTA who make available, through the GLIS, non-confidential information, including genomic information, resulting from research, should retain the legal control of such information.

Any future comprehensive analysis of legal interoperability for the GLIS infrastructure should include ABS.

3.2 The GLIS vision

For an effective exercise of rights and responsibilities within the GLIS, it appears essential to synchronize the system over time with legal developments on two fronts: new national legislation on ABS; the policy evolution of both the Treaty and the Protocol. Regarding the former, we have examined how ABS legislation may regulate the transfer and use of genomic information through multiple legal concepts: the definition of genetic resources; the definition of utilization; the definition of derivatives. It is premature to anticipate what strategy national regulators will adopt if they wish to include information into the realm of ABS, for instance whether they will decouple the two objects of regulation. The GLIS should set up an observatory to monitor these possible legislative developments and inform its users.

Regarding the Treaty and the Protocol, it is worth remembering that Article 4 of the Protocol asserts that although it is the instrument for implementing the ABS provisions of the CBD, it does not apply to Parties of other specialized international agreements with ABS provisions that are consistent with the objectives of the CBD and the Protocol in respect of the specific genetic resource and the purpose covered by the specialized instrument. It is commonly understood that, under such provisions, the access to and utilizations of germplasm covered by the Multilateral System of the Treaty are excluded from the Protocol. However, the relevance of such exclusion is ambiguous in relation to a subject matter, genomic information, that at present is expressly regulated neither in the Protocol nor the Treaty.

In the future, both instruments may incubate policy evolutions in parallel, and many are the paths that such evolution may follow (e.g. synergy, cooperation, conflict).⁷² Arguably, the capacity of the two instruments to expand their policy influence, respectively in the direction of national control and multilaterally facilitated access and utilization, to digital resources, genomic information included, will be more than an exercise of legal interpretation and constructivism. It may turn, as literature suggests, into an exercise of grand bargaining by transnational governance.⁷³ Such bargaining is likely to rely on facilitating mechanisms for non-monetary benefit-sharing in order to preserve wide accessibility of genomic information. If the GLIS evolves in this direction, a measure of realism is necessary in order to kick off the discussion of such a bargain. The starting point to construct such a bargain is that, in the part dealing with information, the Treaty

sequence data for thousands of accessions at IRRI. CROP TRUST and CGIAR, above n. 20, at 12. McCouch et al., above n. 63.

⁷¹ CROP TRUST AND CGIAR, id., at 48.

⁷² Richerzhagen C. (2014). "The Nagoya Protocol: Fragmentation or Consolidation?", *Resources* 2014:3, 135-151. Available at www.mdpi.com/2079-9276/3/1/135/pdf

⁷³ Reichman J.H. et al., above n. 37, at 32.

is not an operational instrument, rather a framework treaty that does not prescribe. Not dissimilar from the CBD and, arguably, the Protocol as well, it evolves through the decisions of its assembly, the Governing Body. So far, these decisions have indeed been quite enabling in relation to the GLIS and it is advisable to activate them in a combined fashion in order to start up the system in an inclusive manner and gradually extend its areas of operation. This is why, in implementing the GLIS vision, it is advisable to pursue not only the transparency of rights and obligations but also incentives to collaboration for the effective utilization of information, through capacity development and technology transfer.

It is clear from the preparatory work and the resulting vision of the GLIS that the ambition is to make the system more than the sums of its parts. While the different information systems on which it is based remain owned and operated by the respective participating organizations, and so may the data in those systems, including genomic data, the GLIS stakeholders can leverage each other through GLIS in order to make data more accessible, understandable and exchangeable for processing into useful products to disseminate. The policy and legal approaches that are necessary to implement the GLIS vision should be complemented by a wider paradigm shift, that does not only focus on building linkages among data systems and assess freedom to operate on the information and among the systems, but also embeds those data and systems with a strategic and cooperative framework for stakeholders to co-design and co-develop technologies and capacity to make use of the information.⁷⁴ On this front, the call by the Governing Body is clear and should be integrated into the deployment of GLIS functions.⁷⁵

This strategy would not only be functional to GLIS acceptability and absorption capacity. Indeed, it would also be a way to develop responses to the current legal uncertainty in respect of ABS. Legal uncertainty can be tackled through a multi-pronged strategy that combines the development of information management practices with cooperation based, bottom up, on information sharing practices that would enable the practical use of information in a setting where reciprocity is achieved not only through unencumbered access and usability of information but also through capacity development and technology transfer.

The existence of a formal governance structure is an important advantage that the Treaty should value. Outside of the plant sectors, many authors have advocated an international policy framework of reference to orientate and incentivize collective action.⁷⁶ Stakeholders in plant germplasm are lucky to have one in their sector, and may work within the structure of the Treaty to promote more legal certainty through information management practices while, at the same time, activate the so called non-monetary benefit-sharing mechanisms (capacity development, technology transfer) within the GLIS. Research communities outside of the plant sector are already devising common pool approaches, looking at knowledge commons, taking advantages of the flexibility that the current ABS framework offers, for instance on non-commercial research and voluntary best practices, and reinforcing, securing such commons through concrete measures of non-monetary benefit-sharing.⁷⁷ The GLIS could be instrumental to launching similar, and even more ambitious efforts, utilizing multiple elements of the GLIS vision that is in place.

Quick read summary

The GLIS should set up an observatory to monitor possible ABS legislative developments on digitalized information and inform its users.

For the GLIS to establish a policy profile that positively influences accessibility and usability of information, it is advisable to activate the capacity development and technology transfer elements of its vision and programme of work.

⁷⁴ FAO (2014). Improving Interoperability of PGRFA Data within the Global Information System. IT/COGIS-1/15/4. Available at <http://www.fao.org/3/a-be652e.pdf>.

⁷⁵ The Governing Body has requested the Secretary and the Contracting Parties to continue promoting initiatives to support national and regional programmes in the development and transfer of information technologies for, and data analysis of, PGRFA. FAO (2015), above n. 8.

⁷⁶ Ostrom, E. (2010). "Polycentric systems for coping with collective action and global environmental change", in *Global Environmental Change*, 20(4), 550–557.

⁷⁷ See section 2.4 above.

4. Conclusions

The Treaty community has conceptualised a GLIS that can receive, store or reference and make publicly available, information on plant germplasm, including associated non confidential information such as characterization, evaluation, genomic data for utilization for research and breeding. It is an ambitious effort that cannot ignore the complexities that ABS brings forward with regard to access to and utilization of information.

In the short term, a number of measures are advisable in order to deal with such complexities. This paper has suggested building the initial GLIS infrastructure around the non-confidential information, including genomic information that Recipients of germplasm with the SMTA will share with the Multilateral System. It has also suggested deploying the DOI function to associate information to the SMTA status of the source germplasm and a neutral approach to information management whereby the provider of information would retain the legal control over the information. It has recommended creating an observatory of new national ABS legislation in order to keep users of the GLIS informed of legislative developments concerning information extracted from genetic resources.

However, a longer-term policy trajectory is also desirable for the GLIS to position itself with influence and relevance. Through the GLIS vision, the Treaty is well equipped to gradually bring more legal certainty into the domain of germplasm information and facilitate the access to and utilization of such information for food security and sustainable agriculture. But, rather than pursuing upfront comprehensive normative solutions, e.g. information sharing standards for the whole GLIS, which appear improbable in the current contrasted landscape, the Treaty community should start exploring within GLIS the relationship between normative incentives, for instance in the form of soft-law voluntary guidelines, and structural incentives, for instance the DOI infrastructure, in use cases and small pilot projects, with the idea to stimulate, through capacity building and technology transfer, bottom up solutions to the availability and use of genomic information for the benefit of all relevant stakeholders.